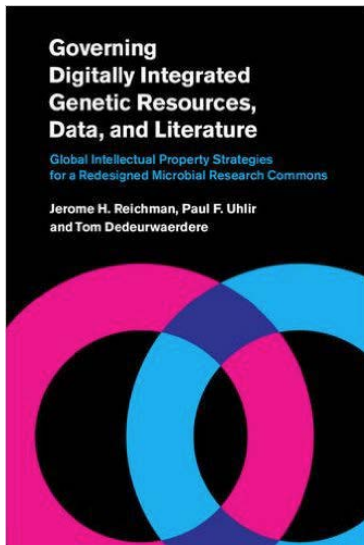


# Governing Digitally Integrated Genetic Resources, Data, and Literature



## Global Intellectual Property Strategies for a Redesigned Microbial Research Commons

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Cambridge University Press (2016)

PART ONE: INTERNATIONAL REGULATION OF GENETIC RESOURCES  
AND THE ASSULT ON SCIENTIFIC RESEARCH

World Federation for Culture Collections (WFCC)

Consultative Group on Agricultural Research  
(CGIAR)

# United Nations Declaration on Sovereignty of States on Natural Resources (1964)

# UPOV – International Treaty for the Protection of Plant Varieties (1991)

# Agreement to Establish World Trade Organization (WTO) (1994)

# TRIPS Agreement

- Agreement on Trade Related Aspects of International Property Rights (TRIPS)

# Convention on Biological Diversity (1992)

# Convention on Biological Diversity

## *Article 1. Objectives*

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.



# Convention on Biological Diversity

## ***Article 8. In-situ Conservation***

Each Contracting Party shall, as far as possible and as appropriate:

- (a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;
- (b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;
- (c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;
- (d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;
- (e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;
- (f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, *inter alia*, through the development and implementation of plans or other management strategies;
- (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

# Convention on Biological Diversity

## ***Article 8. In-situ Conservation (continued)***

- (h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;
- (i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components;
- (j) 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;
- (k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;
- (l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and
- (m) Cooperate in providing financial and other support for *in-situ* conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.

# Convention on Biological Diversity

## ***Article 15. Access to Genetic Resources***

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

# Convention on Biological Diversity

## ***Article 16. Access to and Transfer of Technology***

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.
2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.
3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

# Convention on Biological Diversity

## *Article 16. Continued*

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

# Bilateral Approach

- PIC – Prior Informal Consent
- MAT – Mutually Agreed Terms
- ABS – Access and Benefit Sharing Agreements

## TRIPS (Part II) Article 27.3

### **Article 27.3: Patentable Subject Matter**

3. Members may also exclude from patentability:
  - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
  - (b) 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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

# International Treaty on Plant Genetic Resources for Food and Agriculture – 2001 (ITPGRFA)



# ITPGRFA (2001)

## Article 1 – Objectives

1.1 The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.

1.2 These objectives will be attained by closely linking this Treaty to the Food and Agriculture Organization of the United Nations and to the Convention on Biological Diversity.

# ITPGRFA (2001)

## Article 2 - Use of terms

For the purpose of this Treaty, the following terms shall have the meanings hereunder assigned to them. These definitions are not intended to cover trade in commodities:

"In situ conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated plant species, in the surroundings where they have developed their distinctive properties.

"Ex situ conservation" means the conservation of plant genetic resources for food and agriculture outside their natural habitat.

"Plant genetic resources for food and agriculture" means any genetic material of plant origin of actual or potential value for food and agriculture.

"Genetic material" means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.

# ITPGRFA (2001)

## Article 2 – Continued

"Variety" means a plant grouping, within a single botanical taxon of the lowest known rank, defined by the reproducible expression of its distinguishing and other genetic characteristics.

"Ex situ collection" means a collection of plant genetic resources for food and agriculture maintained outside their natural habitat.

"Centre of origin" means a geographical area where a plant species, either domesticated or wild, first developed its distinctive properties.

"Centre of crop diversity" means a geographic area containing a high level of genetic diversity for crop species in in situ conditions.

# ITPGRFA (2001)

## Article 10 - Multilateral System of Access and Benefit-sharing

10.1 In their relationships with other States, the Contracting Parties recognize the sovereign rights of States over their own plant genetic resources for food and agriculture, including that the authority to determine access to those resources rests with national governments and is subject to national legislation.

10.2 In the exercise of their sovereign rights, the Contracting Parties agree to establish a multilateral system, which is efficient, effective, and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis.

# ITPGRFA (2001)

## Article 11 - Coverage of the Multilateral System

11.1 In furtherance of the objectives of conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use, as stated in Article 1, the Multilateral System shall cover the plant genetic resources for food and agriculture listed in Annex I, established according to criteria of food security and interdependence.

11.2 The Multilateral System, as identified in Article 11.1, shall include all plant genetic resources for food and agriculture listed in Annex I that are under the management and control of the Contracting Parties and in the public domain. With a view to achieving the fullest possible coverage of the Multilateral System, the Contracting Parties invite all other holders of the plant genetic resources for food and agriculture listed in Annex I to include these plant genetic resources for food and agriculture in the Multilateral System.

# ITPGRFA (2001)

## Article 11 – Continued

11.3 Contracting Parties also agree to take appropriate measures to encourage natural and legal persons within their jurisdiction who hold plant genetic resources for food and agriculture listed in Annex I to include such plant genetic resources for food and agriculture in the Multilateral System.

11.4 Within two years of the entry into force of the Treaty, the Governing Body shall assess the progress in including the plant genetic resources for food and agriculture referred to in paragraph 11.3 in the Multilateral System. Following this assessment, the Governing Body shall decide whether access shall continue to be facilitated to those natural and legal persons referred to in paragraph 11.3 that have not included these plant genetic resources for food and agriculture in the Multilateral System, or take such other measures as it deems appropriate.

# ITPGRFA (2001)

## Article 11 – Continued

11.5 The Multilateral System shall also include the plant genetic resources for food and agriculture listed in Annex I and held in the ex situ collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR), as provided in Article 15.1a, and in other international institutions, in accordance with Article 15.5.

# ITPGRFA (2001)

Article 12 - Facilitated access to plant genetic resources for food and agriculture within the Multilateral System

12.1 The Contracting Parties agree that facilitated access to plant genetic resources for food and agriculture under the Multilateral System, as defined in Article 11, shall be in accordance with the provisions of this Treaty.

12.2 The Contracting Parties agree to take the necessary legal or other appropriate measures to provide such access to other Contracting Parties through the Multilateral System. To this effect, such access shall also be provided to legal and natural persons under the jurisdiction of any Contracting Party, subject to the provisions of Article 11.4.



# ITPGRFA (2001)

## Article 12 – Continued

12.3 Such access shall be provided in accordance with the conditions below:

(a) Access shall be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses. In the case of multiple-use crops (food and non-food), their importance for food security should be the determinant for their inclusion in the Multilateral System and availability for facilitated access.

(b) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;

(c) All available passport data and, subject to applicable law, any other associated available non-confidential descriptive information, shall be made available with the plant genetic resources for food and agriculture provided;

# ITPGRFA (2001)

## Article 12 – Continued

(d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System;

(e) Access to plant genetic resources for food and agriculture under development, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development;

(f) Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;

(g) Plant genetic resources for food and agriculture accessed under the Multilateral System and conserved shall continue to be made available to the Multilateral System by the recipients of those plant genetic resources for food and agriculture, under the terms of this Treaty; and

# ITPGRFA (2001)

## Article 12 – Continued

(h) Without prejudice to the other provisions under this Article, the Contracting Parties agree that access to plant genetic resources for food and agriculture found in in situ conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body.

12.4 To this effect, facilitated access, in accordance with Articles 12.2 and 12.3 above, shall be provided pursuant to a standard material transfer agreement (MTA), which shall be adopted by the Governing Body and contain the provisions of Articles 12.3a, d and g, as well as the benefit-sharing provisions set forth in Article 13.2d(ii) and other relevant provisions of this Treaty, and the provision that the recipient of the plant genetic resources for food and agriculture shall require that the conditions of the MTA shall apply to the transfer of plant genetic resources for food and agriculture to another person or entity, as well as to any subsequent transfers of those plant genetic resources for food and agriculture.

# ITPGRFA (2001)

## Article 12 – Continued

12.5 Contracting Parties shall ensure that an opportunity to seek recourse is available, consistent with applicable jurisdictional requirements, under their legal systems, in case of contractual disputes arising under such MTAs, recognizing that obligations arising under such MTAs rest exclusively with the parties to those MTAs.

12.6 In emergency disaster situations, the Contracting Parties agree to provide facilitated access to appropriate plant genetic resources for food and agriculture in the Multilateral System for the purpose of contributing to the re-establishment of agricultural systems, in cooperation with disaster relief coordinators.

# ITPGRFA (2001)

## Article 13 - Benefit-sharing in the Multilateral System

13.1 The Contracting Parties recognize that facilitated access to plant genetic resources for food and agriculture which are included in the Multilateral System constitutes itself a major benefit of the Multilateral System and agree that benefits accruing therefrom shall be shared fairly and equitably in accordance with the provisions of this Article.

13.2 The Contracting Parties agree that benefits arising from the use, including commercial, of plant genetic resources for food and agriculture under the Multilateral System shall be shared fairly and equitably through the following mechanisms: the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization, taking into account the priority activity areas in the rolling Global Plan of Action, under the guidance of the Governing Body:

# ITPGRFA (2001)

## Article 13 – Continued

### (a) Exchange of information:

The Contracting Parties agree to make available information which shall, inter alia, encompass catalogues and inventories, information on technologies, results of technical, scientific and socio-economic research, including characterization, evaluation and utilization, regarding those plant genetic resources for food and agriculture under the Multilateral System. Such information shall be made available, where non-confidential, subject to applicable law and in accordance with national capabilities. Such information shall be made available to all Contracting Parties to this Treaty through the information system, provided for in Article 17.

# ITPGRFA (2001)

## Article 13 - Continued

### (b) Access to and transfer of technology

- (i) The Contracting Parties undertake to provide and/or facilitate access to technologies for the conservation, characterization, evaluation and use of plant genetic resources for food and agriculture which are under the Multilateral System. Recognizing that some technologies can only be transferred through genetic material, the Contracting Parties shall provide and/or facilitate access to such technologies and genetic material which is under the Multilateral System and to improved varieties and genetic material developed through the use of plant genetic resources for food and agriculture under the Multilateral System, in conformity with the provisions of Article 12. Access to these technologies, improved varieties and genetic material shall be provided and/or facilitated, while respecting applicable property rights and access laws, and in accordance with national capabilities.

# ITPGRFA (2001)

## Article 13 - Continued

(ii) Access to and transfer of technology to countries, especially to developing countries and countries with economies in transition, shall be carried out through a set of measures, such as the establishment and maintenance of, and participation in, crop-based thematic groups on utilization of plant genetic resources for food and agriculture, all types of partnership in research and development and in commercial joint ventures relating to the material received, human resource development, and effective access to research facilities.



# ITPGRFA (2001)

## Article 13 - Continued

(iii) Access to and transfer of technology as referred to in (i) and (ii) above, including that protected by intellectual property rights, to developing countries that are Contracting Parties, in particular least developed countries, and countries with economies in transition, shall be provided and/or facilitated under fair and most favourable terms, in particular in the case of technologies for use in conservation as well as technologies for the benefit of farmers in developing countries, especially in least developed countries, and countries with economies in transition, including on concessional and preferential terms where mutually agreed, inter alia, through partnerships in research and development under the Multilateral System. Such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.

# ITPGRFA (2001)

## Article 13 - Continued

### (c) Capacity-building

Taking into account the needs of developing countries and countries with economies in transition, as expressed through the priority they accord to building capacity in plant genetic resources for food and agriculture in their plans and programmes, when in place, in respect of those plant genetic resources for food and agriculture covered by the Multilateral System, the Contracting Parties agree to give priority to

- (i) establishing and/or strengthening programmes for scientific and technical education and training in conservation and sustainable use of plant genetic resources for food and agriculture,

# ITPGRFA (2001)

## Article 13 - Continued

(ii) developing and strengthening facilities for conservation and sustainable use of plant genetic resources for food and agriculture, in particular in developing countries, and countries with economies in transition, and

(iii) carrying out scientific research preferably, and where possible, in developing countries and countries with economies in transition, in cooperation with institutions of such countries, and developing capacity for such research in fields where they are needed.

(d) Sharing of monetary and other benefits of commercialization

(i) The Contracting Parties agree, under the Multilateral System, to take measures in order to achieve commercial benefit-sharing, through the involvement of the private and public sectors in activities identified under this Article, through partnerships and collaboration, including with the private sector in developing countries and countries with economies in transition, in research and technology development;

# ITPGRFA (2001)

## Article 13 - Continued

(ii) The Contracting Parties agree that the standard Material Transfer Agreement referred to in Article 12.4 shall include a requirement that a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to the mechanism referred to in Article 19.3f, an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment.

The Governing Body shall, at its first meeting, determine the level, form and manner of the payment, in line with commercial practice. The Governing Body may decide to establish different levels of payment for various categories of recipients who commercialize such products; it may also decide on the need to exempt from such payments small farmers in developing countries and in countries with economies in transition. The Governing Body may, from time to time, review the levels of payment with a view to achieving fair and equitable sharing of benefits, and it may also assess, within a period of five years from the entry into force of this Treaty, whether the mandatory payment requirement in the MTA shall apply also in cases where such commercialized products are available without restriction to others for further research and breeding.

# ITPGRFA (2001)

## Article 13 - Continued

13.3 The Contracting Parties agree that benefits arising from the use of plant genetic resources for food and agriculture that are shared under the Multilateral System should flow primarily, directly and indirectly, to farmers in all countries, especially in developing countries, and countries with economies in transition, who conserve and sustainably utilize plant genetic resources for food and agriculture.

13.4 The Governing Body shall, at its first meeting, consider relevant policy and criteria for specific assistance under the agreed funding strategy established under Article 18 for the conservation of plant genetic resources for food and agriculture in developing countries, and countries with economies in transition whose contribution to the diversity of plant genetic resources for food and agriculture in the Multilateral System is significant and/or which have special needs.

# ITPGRFA (2001)

## Article 13 - Continued

13.5 The Contracting Parties recognize that the ability to fully implement the Global Plan of Action, in particular of developing countries and countries with economies in transition, will depend largely upon the effective implementation of this Article and of the funding strategy as provided in Article 18.

13.6 The Contracting Parties shall consider modalities of a strategy of voluntary benefit-sharing contributions whereby Food Processing Industries that benefit from plant genetic resources for food and agriculture shall contribute to the Multilateral System

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 1. Objective

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 2. Use of Terms

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

- (a) “Conference of the Parties” means the Conference of the Parties to the Convention;
- (b) “Convention” means the Convention on Biological Diversity;
- (c) “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;
- (d) “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;
- (e) “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 to the Convention on Biological Diversity (2009)

## Article 3. Scope

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 to the Convention on Biological Diversity (2009)

## Article 4. Relationship with International Agreements and Instruments

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.
2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 5. Fair and Equitable Benefit-sharing

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with 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. Such sharing shall be upon mutually agreed terms.
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.
3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.
4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.
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 to the Convention on Biological Diversity (2009)

## Article 10. Global Multilateral Benefit-sharing Mechanism

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 11. Transboundary Cooperation

1. In instances where the same genetic resources are found in situ within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.
2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 13. National Focal Points and Competent National Authorities

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 13. Continued

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 14. The Access and Benefit-sharing Clearing-House and Information Sharing

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.
2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:
  - (a) Legislative, administrative and policy measures on access and benefit-sharing;
  - (b) Information on the national focal point and competent national authority or authorities; and
  - (c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.



# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 14. Continued

3. Additional information, if available and as appropriate, may include:

- (a) Relevant competent authorities of indigenous and local communities, and information as so decided;
- (b) Model contractual clauses;
- (c) Methods and tools developed to monitor genetic resources; and
- (d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 15. Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.
2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.
3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

# Nagoya Protocol to the Convention on Biological Diversity (2009)

## Article 16. Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.
2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.
3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

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## Article 18. Compliance with Mutually Agreed Terms

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:
  - (a) The jurisdiction to which they will subject any dispute resolution processes;
  - (b) The applicable law; and/or
  - (c) Options for alternative dispute resolution, such as mediation or arbitration.
2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.
3. Each Party shall take effective measures, as appropriate, regarding:
  - (a) Access to justice; and
  - (b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.
4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.