

**AIPPI considerations related to the  
ONLINE SURVEY ON INFORMATIONS SYSTEMS, REGISTERS AND DATABASES  
Prepared by The Secretariat of the World Intellectual Property Organization.**

**AIPPI** acknowledge the invitation from WIPO to participate in the Online Survey on information Systems, Registers and Databases and support the initiative to gather relevant experiences and already implemented practical solutions for the establishment, functioning and management of information systems on genetic resources (GRs)traditional knowledge (TK)and traditional cultural Expressions (TCEs)

**A.- AIPPI**

Has been monitoring, studied and advised on the development on IP/TK/GR/TCE, to the members of the National Groups, but has not specifically carry out an analysis or monitoring about Information Systems, Registers and Databases, as the Online Survey Prepared by the Secretariat of WIPO, but it can share relevant information that could be useful to implement practical solutions for the establishment of, functioning and management of information systems on (GRs), (TK) and (TCEs)

**B.-AIPPI Committee IP/TK/GRs/TCEs**

On 2021 the Committee, prepared a Questionnaire on Intersection of IP /TK/GR/TCE, which was responded by 26 countries. The questionnaire did not specifically addressed the issue of Information Systems, Registers, and Databases , but in the report ( See document attached#), countries , such as Brazil, Canada ,India, Panama, Philippines, China , Indonesia, France , Vietnam indicated that they have implemented or have some guidelines about Systems, Registers and Databases , but is not specified if there is General o Special law implemented.

It is believed that the questionnaire prepared by AIPPI, as well as the answers to the report by the National Groups, would provide useful information.

**C-. The Report is structured in three sections: 1) Traditional Knowledge (TK), 2) Genetic Resources (GRs), 3) Traditional Cultural Expressions (TCEs).**

On each section it is indicated by the national groups if the countries are members of International Conventions, have implemented National Laws to protect it. (General or Specific Legislation) If there is a positive or defensive protection in their jurisdictions, in connection to any of the three items.

**1) Traditional Knowledge (TK).**

Some countries protect (Tk) by a General Law such as Canada, India; Indonesia, Panama, and Philippines.

According to the report other jurisdictions, protects it through an Environmental Law, such as Australia, Brazil, Canada, Chile, Dominican Republic, France, India, Indonesia, Japan; Luxembourg, Mexico, Panama, Philippines and Turkey

**2) Genetic Resources (GRs)**

National members indicated if there is a legal framework. (General or Specific Law) that protects GR .In the report is mentioned that only Brazil and Panama have implemented. a national law to protect Digital Sequence Information (DSI)

Most of the jurisdictions are members of the Nagoya Protocol (NP), but not so many have implemented in National Law, or design a framework in connection to the ABS (Access and Benefit Sharing),PIC(Prior and Informed Consent) and MAT(Mutually Agreed Terms), or mechanisms provided by (NP).

Most of the answers indicated that the countries are members of the Cartagena Agreement, but Australia, Bulgaria, Canada, Chile, Haiti, Italy, Luxemburg, and Paraguay have not implemented yet.

**3) Traditional Cultural Expressions (TCEs),**

According to the report, most of the jurisdictions are members of the Convention for the Safeguarding of Intangible Cultural heritage of 2003, and the Convention on the Protection and Promotion of the Diversity of Cultural Expressions of 2005, but not so many implemented in National Law.

Some Countries have a special Laws related to (TK/TCEs), like Brazil, Bulgaria, Chile, China, Mexico; Panama, Paraguay, Philippines. Others, have provisions that protect TK/TCEs in IP Laws (Trademarks; Copyright, Geographical Indications).

In the report is indicated that in many jurisdictions in National Laws are defined the objectives of the protection afforded to Tk/TCEs. Only three countries (Colombia, Denmark and Luxembourg) mentioned that in their jurisdiction is a term of protection TK/TCE.

Regarding Positive Protection of TK/TCEs, only Brazil, Bulgaria, China, Denmark, Luxembourg and Panama, provide it. Meanwhile Australia, Bulgaria, India, Indonesia, Luxembourg, Mexico and Vietnam, provide Defensive Protection.

In the Report is indicated that in jurisdictions, such as China, Colombia, Indonesia, Italy, Mexico, Panama, Philippines and Vietnam the Beneficiaries of the protection of TK/TCEs on the national laws are the Indigenous Communities

Recommendations.

**AIPPI:**

**A).**-Supports the WIPO initiatives to continue the study, monitoring and reach consensus in connection to the protection of Tk, GRs, TCEs at the International level, through a Legal Instrument.

**B).**-Suggest to gather information in consultation with relevant stakeholders, national governments, members of International associations, such as AIPPI, Indigenous Communities etc about the legal implications , scope of protection and limitations of the Information Systems, Registers and Databases. at the national and international level.

**C).**-Considering that TK / GRs/TCEs could be located in the territory of more than one member state to determine if the Information Systems, Registers and Database shall consider Transboundary Cooperation with the involvement of Indigenous Communities

**May 9, 2023**

**Martín Michaus**

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Standing Committee on Intellectual Property and Traditional Knowledge, Genetic Resources and  
Traditional Cultural Expressions  
Working Guidelines  
Questionnaire on  
Intersection of Intellectual Property Traditional Knowledge, Genetic Resources and Traditional  
Cultural Expressions  
By

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### Introduction

The development of intercultural societies deeply communicated and the combination of tradition and modernity have increased the importance and economic value of the Traditional Knowledge (TK) related to Genetic Resources (GR) and Traditional Cultural Expressions (TCEs) in which innovation and creativity have a fundamental role so there is an important interaction with Intellectual Property.

Experts have been discussing whether and how to protect the TK/GR/TCE and if it could be recognized as a form of Intellectual Property or should be provided a special system, but there is no consensus at the international level. Nevertheless, there have been recent and important developments to be considered in the study or analysis of the subject.

The Standing Committee on Intellectual Property on Genetic Resources, Traditional Cultural Expressions and Traditional Knowledge (IP and GRTCE/TK) of AIPPI has been studying issues related to the intersection of IP with the framework that has been established around the use of Genetic Resources (GR) as it will be explained but has not been studying issues related to the Traditional Knowledge (TK) in connection with Traditional Cultural Expression (TCE).

### Previous work of AIPPI in connection with TK/GR

- 1) **Special Committee Q166** (Gothenburg 2006) (Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore) monitored, studied, and advised on the development on IP on GRTKF
- 2) **Resolution of Special Committee Q166.** Through a Questionnaire distributed in 2006, special Committee Q166 collected information and opinions concerning National legal Requirements for indicating the country of origin or the source for Genetic Resources and TK in patent applications involving Genetic Resources. The AIPPI Gothenburg Congress 2006 passed a resolution on the bases on the result from the 2006 questionnaire. The 2006 Resolution of Special Committee Q166 to this Working Guidelines as Annexure A for ease of reference.
- 3) **2010 Questionnaire.** In February 2010, special Committee (WTO/TRIP's) and Q166 jointly distributed a Questionnaire to update information collected for the 2006 Questionnaire and to collect information and practical experience with the application of any relevant laws and regulations. Thirty-four Groups responded, of which twelve reported a legal requirement in their country the source and/or country of origin of biological/resources and TK must be indicated in patent applications for inventions based on biological/genetic resources or TK.
- 4) **Resolution Q232** "The Relevance of Traditional Knowledge to Intellectual Property Law" Seoul 2012. It resolved that: Adoption of harmonized definition of TK 1) is desirable, 2) Should take into account the word of IGC relating to TK, 3) Should be compatible with definitions of IP, Genetic Resources and TCEs, 4) International and National Laws covering TK should include provisions promoting a comprehensive regime for TK that provides legal certainty for all state holders in relation to TK, and that is aligned with the principles existing IP system. Such laws make provide sui-generis treatments of TK. The 2012 Resolution as Annexure B for ease of reference.

#### **5) Standing Committees IP-GR/TK/TCE and TRIPs (October 2018).**

Questionnaire on the Requirement of Indicating the Source and/or Country of Origin of GR/TK in Patent Applications. The questionnaire was sent out in September 2016 to update information collected from the National and Regional Groups and Independent Members on provisions and existing laws and draft bills and to collect information on practical experience with the application on such laws and regulation. This study also provides definitions of TK, explain existing means of protections as well as the positive and defensive protection of TK holders' legal rights over the TK, likewise the defensively protection, to prevent third parties from obtaining or exercising illegitimate IP rights over TK, some indication of the impact of Nagoya Protocol on patent application. The questionnaire was responded by 23 National Groups. The summary report with the outcome of the responses was distributed in October 2018. The 2018 Questionnaire, as Annexure C for ease of reference.

#### **No Previous work of AIPPI in connection with TK/Traditional Cultural Expressions (TCE).**

As it was explained the IP and GRTKTCE Committee has conducted an intensive and comprehensive analysis as well as monitored and studied complex issues and discussions at the international level in connection with TK/Genetic Resources, but not in connection with TK related to Traditional Cultural Expressions (TCE), that have increasing attention, not only from governments, cultural institutions, indigenous people and local community but also from policy makers, industry (such as pharmaceutical, entertainment, cultural, fashion, tourism, etc.) an international organizations like WIPO an International Associations such as AIPPI and Intellectual Property experts.

Considering the increasing importance of the TCEs and the complaints of the indigenous communities in different jurisdictions about the use of TCEs, the IP and GRTKTCE Committee continues to study GR/TK issues but now is also concentrated on the analysis and discussion about TCE associated to TK at the international level.

#### **Definitions**

##### **Traditional Knowledge (TK)**

In the Working Guidelines of Q232 it is mentioned that TK is not static. The content of TK, as it relates at any even group develops and changes overtime. It was discussed if in the context of the legal protection of the TK it is possible or desirable to develop a definition of the term TK. In such documents provides various samples definitions but it was not possible to develop a precise one. As one of the sample definitions is stated; "Content or substance of knowledge, resulting from intellectual activity in a traditional context, including the know-how, skills, innovations, practices and learning that form part of Traditional Knowledge systems and knowledge embodying traditional lifestyles of indigenous and local communities, all contain in a codify knowledge systems passed between generations" (WIPO/GRTKF/IC/19/IMF/8).

In the Working Guidelines of Q232, is mentioned that a singular definition might not be necessary to delimit the scope of the subject matter of TK for which IP protection is sought. Definitions in many national IP systems function satisfactorily on the basis of inclusive definitions. This appreciation still valid since there is not yet accepted a definition of TK at the international level.

##### **Genetic Resources (GR)**

There are several international instruments, such as the Convention on Biological Diversity (Art. 2) 1992, that defines "Genetic Resources" as "Genetic Material of Actual or Potential Value". Decision 391 on Access to Genetic Resources of Andean Community (1996) as all biological material that contains genetic information of value or of potential value. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (2001) defines plant genetic resources as "any material of plant origin, including reproductive and vegetative propagating material and containing functional units of heredity" (WIPO Glossary of key terms related to IP and GR, TK and TCE).

##### **Traditional Cultural Expressions (TCE)**

Although there is no consensus at the international level of a definition WIPO uses the terms “Traditional Cultural Expressions” to refer tangible and intangible or mix forms in which traditional knowledge cultures are expressed communicated or manifested. Examples includes traditional music, performances, narratives, names and symbols, designs and architectural forms (WIPO Glossary of key terms related to IP and GR, TK and TCE). Are handed down from generation to generation either orally or by imitation. Reflects a community’s cultural and social identity. They normally belong to a community under customary laws and from unknown author.

There is no consensus at the international level, about the options for protection and promoting TCEs with IP. It has not been set an agreement if it can be under the framework of the IP system, or develop a sui generis protection in which TCEs could be recognized as a form of Intellectual Property. Whether it could include property rights and non-property rights and how to prevent misappropriation and misuse, as opposed to preservation and safeguarding (WIPO/AIPPI Webinar “How to Protect and Promote Traditional Cultural Expressions”).

From the perspective of the copyright principles, for some jurisdictions TCEs are in the public domain, for others they form part of the cultural heritage of the indigenous communities and the use or exploitation for commercial purposes requires either their authorization or a permit granted by a government authority. The exploitation without an authorization, are sanctioned by local law.

Examples of complaints by indigenous communities due to unauthorized use of the TCE could be mentioned:

- 1) Australia Aboriginal flag  
<https://www.managingip.com/article/b1p0mzvdx55nzy/opinion-sensitivity-crucial-as-australia-seeks-to-resolve-aboriginal-copyright-row>
- 2) Japan- Victoria & Albert Museum (V&A) in London opened "Kimono: Kyoto to Catwalk"  
<https://edition.cnn.com/style/article/kimono-fashion-history-cultural-appropriation/index.html>
- 3) Malaysia  
<https://www.therakyatpost.com/2020/08/21/the-fine-line-between-cultural-appropriation-cultural-appreciation/>
- 4) Mexico - Isabel Marant and the Mixe Huipil  
<https://www.theguardian.com/global-development-professionals-network/2015/jun/17/mexican-mixe-blouse-isabel-marant>  
  
Voladores de Papantla vs. Beer Marketing Campaign  
<https://desinformemonos.org/voladores-papantla-denuncian-la-cervecera-cuauhtemoc-moctezuma-profana-ceremonia-ritual/>
- 5) Somalia Social Media Users Accuse Zara of Culturally Appropriating Somali Baati ZARA  
<https://www.allure.com/story/zara-accused-cultural-appropriation-somali-baati>

- 6) US - United States Cherokee  
Chief of Cherokee Nation asks Jeep to stop using tribe's name

<https://edition.cnn.com/2021/02/22/business/jeep-chokeee-name-trnd/index.html>  
Chief of Cherokee Nation Says 'It's Time' for Jeep to Stop Using Name  
Chief of Cherokee Nation Says 'It's Time' for Jeep to Stop Using Name  
Chief of Cherokee Nation Says 'It's Time' for Jeep to Stop Using Name  
Chief of Cherokee Nation Says 'It's Time' for Jeep to Stop Using Name  
Chief of Cherokee Nation Says 'It's Time' for Jeep to Stop Using Name  
<https://www.caranddriver.com/news/a35568468/chokeee-nation-jeep-stop-using-name/>

## **Discussion**

The scope of this questionnaire is different from the previous work of AIPPI described above. First, it focuses not only on TK/GR, it also includes TK/TCE and its relevance to IP law. Second, it considers broader issues than those discussed in previous questionnaires and resolutions related on TK/GR. Third, it also includes specific issues in connection with TK/TCE. Considering the essential intersection between TK and GR and TCE, with IP, the questionnaire is divided in three sections, the first one, General Traditional Knowledge (TK), the second one Genetic Resources (GR) and the third one Traditional Cultural Expressions (TCE).

In connection with the first section, National Groups are invited to indicate if there are general law or specific legislation related to General Traditional Knowledge TK, such as any environmental law. Regarding the second section GR, focused on the impact and update of the implementation of the Nagoya Protocol, as well as if there is any specific regulation related to academic research or traditional medicine. In the third section TCE, should be indicated if there any specific national law that protects TCEs, or are others like trademark law, copyright law, geographical indications law that protects them, if they provide positive and/or defensive regulation or registration and who are the beneficiaries of the protection.

## **Background**

### **Previous Work of AIPPI**

#### **Outcome of the 2021 Questionnaire**

**Responses to the Questionnaire were received from 26 National Groups Australia, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Denmark, Dominican Republic, France, Haiti, Hungary, India, Indonesia, Italy, Japan, Luxembourg, Malaysia, Mexico, Panama, Paraguay, Philippines, The Netherlands, Turkey, Vietnam**

## **I.- General**

### **Traditional Knowledge/TK**

1) Is there a legal frame either general law or specific legislation in your country that protects TK including at least Genetic Resources (GR) and Traditional Cultural Expression (TCE)?

a) General law

**Australia, Canada, China, Denmark, India, Indonesia, Japan, Mexico, Panama, Phillipines, indicated that they have a general legal framework that protects TK including GR and TCE**

**Australia** - There are no specific statutes Regulating the protection of TK. Depending on the specific circumstances, TK could theoretically be protected under common law protections or through other general and intellectual Property (IP) statutes.

**Canada** – the Canadian constitution protects the title and treaty rights of Canada's indigenous peoples. Specifically, Section 35 of the Constitution Act, 1982 affirms the right of indigenous peoples (named "Aboriginal" People in the Constitution Act 1982 <https://laws.justice.gc.ca/eng/Const/page-13.html#h-53> to continue their traditional practices, and any law that seeks to deprive them of this right is inconsistent of the Constitution. To the extent that there are existing common law indigenous (aboriginal) rights in TK as used in traditional practices, Section 35 elevates those existing rights by giving them the constitutional status. The protected rights cannot be unilaterally abrogated by the government and cannot be infringed except for justifiable reasons, in the pursuit substantial and compelling public objectives. Section 35 does not protect TK itself although the Canadian constitution are arguably affirming the rights of indigenous peoples.

**India** – Does not have any separate/specific act for protection of TK but its constitution (Art 29) Protect the Cultural Rights of the citizens and therefore, the protection of TK would fall under the aegis of the said article. Art. 51 A (f) puts the onus of preservation, respecting and safeguarding the rich heritage of the Indian culture of every citizen of India as their fundamental duty. The TCEs and folklore constitute heritage as well as culture.

**Panama** – Has enacted a sui-generis legislation to protect TK and TCE Law No. 20 of June 26, 2000, establishes a special Intellectual property regime for the collective rights of indigenous communities for the protection of their cultural identities and traditional knowledge. In order to be protected the TK must be registered with the competent authority. The registration of the TK grants exclusive right to the use of the TK. The Panamanian Criminal Code penalizes the unauthorized use of a registered TK with 4-6 years of imprisonment.

**Philippines** – "The Indigenous People Rights Act" (Republic Act No. 8371-RA8371) Enacted in 1997, provides in Section 32, 34 and 35 that the Indigenous Cultural Communities (ICCs)/Indigenous Peoples (IPs) have the right to practice and revitalize their own cultural traditions and customs. The State should present, protect, and develop the past, present and future manifestations of their cultures as well as the right to the restitution of cultural, intellectual religious and spiritual property taken without their free and prior informed consent or in violation of their laws, traditions, and customs. It recognizes (Section 34) The full ownership and control end protection of their cultural and intellectual rights and provides (Sec. 35) access to Biological and Genetic Resources and to indigenous knowledge related to the conservation, utilization, and enhancement of these resources. Shall be allowed within the ancestral lands and domains of the ICCs only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community.



## Specific Law

**Brazil, Chile, China, Denmark, Dominican Republic, France, Indonesia, Italy, Japan, Mexico, Turkey, and Vietnam** have a specific law to protect, TK including GR and/or TCE. In some of them GR, TK and TCE are protected under the Intellectual Property Rights as provided by the patent, designs, trademark, unfair competitions, and copyrights acts.

**China** - TK are protected by different laws or regulations, for instance, human genetic resources are protected by “Regulation on the Management of Human Genetic Resources”, traditional arts and crafts are protected by “Regulations on the Protection of Traditional Arts and Crafts”, traditional Chinese medicine is protected by “Traditional Chinese Medicine Law” and “Regulations on the Protection of Traditional Chinese Medicine Varieties”.

**Denmark** - Danish law has relevant provisions on the sharing benefits from the utilization of Genetic Resources (lov nr. 1375 af 23 December 2012 Lov om udbyttedeling ved anvendelse af genetiske ressourcer) Art. 4 the provision that relates to the Nagoya Protocol states that “TK in Relation to GR that are in the possession of indigenous or local communities, may not be used in Denmark, if this knowledge is obtained contrary to law on the matter. Similar provision exists in Greenlandish law in “Inatsisartulov nr.3 af. 3 juni 2016 om udnyttelse af genetiske ressourcer og aktiviteter i forbindelse dermed”

**Indonesia** – Regulation of Ministry of Law and Human Right. No. 13 of 2017 on Data Communal Intellectual Property dated July 14, 2017.

**Japan** – In relation to Indigenous People, the act “Act Promoting Measures to Achieve a Society in which the Pride of Ainu People is Respected” (Law No. 16 of 2019) “Ainu Culture” consists of the Ainu language and cultural properties such as music, dance, crafts, and other cultural properties which had been inherited by the Ainu people, another cultural property developed from these.

**Mexico** – “Federal Law for the Protection of the Cultural Heritage of Indigenous and Afromexican People and Communities” (FLPCHIAPC) Published on January 17, 2022, recognizes, guarantee the protection and safeguard of the development of the Cultural Heritage (CH) and the collective Intellectual Property of the Indigenous and Afro-Mexican Peoples and Communities (IAPC). The IAPC, has the free determination and autonomy, to define, preserve, protect, control and develop the elements of their CH. The Law defines the use, enjoyment and exploitation of their CH and its use by third parties and establish a protection system and sanctions for misappropriation and unduly use, exploitation, commercialization or reproduction of the CH and TCE.

### b) Environmental law

Australia, Brazil, Canada, France, India, Indonesia, Japan, Malaysia, Mexico, Panama, Paraguay, Philippines, Turkey, Vietnam, have provisions or a specific Environmental law that protects TK and GR.

**Australia** - Each Australian State or Territory government manages access to biological resources in its jurisdiction (except Commonwealth areas under the EPBC Act).<sup>7</sup> To date, Queensland has enacted the *Biodiscovery Act 2004* (Qld), the Northern Territory has enacted the *Biological Resources Act 2006* (NT), Western Australia has enacted the *Biodiversity Conservation Act 2016* (WA) and the Australian Capital Territory has enacted the *Nature Conservation Act 2014* (ACT). The definitions of “biological resources” and “genetic resources” under these Acts are largely consistent with the EPBC Act.

**Brazil** – As for the interplay between TK and GR, there is a specific legislation (Law No. 13,123/2015) [http://www.planalto.gov.br/ccivil\\_03/\\_ato2015-2018/2015/lei/l13123.htm](http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2015/lei/l13123.htm) and (Decree No. 8.772/2016) [http://www.planalto.gov.br/ccivil\\_03/\\_ato2015-](http://www.planalto.gov.br/ccivil_03/_ato2015-)

[2018/2016/decreto/d8772.htm](https://www.legifrance.gouv.fr/eli/decree/2016/10/13/2016-1087/2016-10-13/JOUE) that provides for access to GR protection and access to TK and benefit sharing for the conservation and sustainable use of biodiversity.

**Canada** – Canadian Federal acts require the consideration of TK and there are obligations to protect confidential indigenous knowledge, such as Impact Assessment Act (IAA) sets out a federal process for assessing the impact of major projects and the prevention of significant adverse environmental effects for projects on federal lands and outside Canada. Similarly, the Canadian Federal Fisheries Act requires consideration of indigenous knowledge for habitat decisions and provides for the confidentiality of indigenous knowledge.

**France** – The French Environmental Code provide details on the conditions of access to and use of GR and the shared use of associated TK in accordance with the 1992 Convention on Biological Diversity and the Nagoya Protocol. The regime applicable to Genetic Resources has been specified within two European Regulations that have enabled the application of Nagoya Protocol in France and the implementation of benefit sharing for TKGRs: European Regulation 511/2014 of April 16, 2014, on measures concerning compliance by users in the Union with the Nagoya Protocol on ABS and its implementing regulation 2015/1866 of October 13, 2015. The Law 2016-1087 of 8 August 2016 for the reconquest of Biodiversity, Nature and Landscapes (“Biodiversity Act”) is the mechanism to implement the Nagoya Protocol in France, in particular through the deployment of the ABS Mechanism

**India** – As signatories to the Convention on Biological Diversity India has enacted the biodiversity act 2002. The objective is to provide for conservation of Biological Diversity sustainable use of its composes and fair and equitable shearing of the benefits arising out of the use of biological resources, knowledge and for maters connected therewith or incidental there to. The preamble of act also make reference to traditional knowledge. The act puts restrictions on the ability to apply for intellectual property protection related to biodiversity as any person who wants to apply for obtaining an intellectual property right (within or outside India) for an invention which is based on a biological resource from India, has to take approval from the National Biodiversity Authority for making some application. The law provides for the structure of profit to be shared with the people responsible for developing, improving and using the technology from the commercial use of TK.

**Indonesia** – Regulation of Ministry of Environment and forestry No. P.34/MENLHK/SETJEN/KUM.1/5/2017 On Recognition on Protection on Local Wisdom in the Management of Natural Resources and Life Environment dated 20 May 2017.

**Japan** - As domestic ABS measures to implement the Nagoya Protocol, the Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (hereinafter referred to as the "ABS guidelines"). They became effective on the day of entry into force of the Nagoya Protocol in Japan (20 August 2017). Subsequently, the ABS guidelines were partially revised on 28 April 2021.

The purpose of the ABS guidelines is to ensure the appropriate and smooth implementation of the Nagoya Protocol by taking measures concerning the access and benefit-sharing (ABS), and thereby to contribute to the conservation and sustainable use of biological diversity.

**Malaysia** – There is not specific law directed towards the protection of TK. However, the recent Access to Biological Resources and Benefit Sharing Act 2017, governs the access to biological resources and traditional knowledge associated with biological resources and the sharing of benefits arising from their utilization (implementation of the Convention on Biological Diversity). Prior to any access or utilization of biological resources or TK associated with a biological resource, prior informed consent from the relevant indigenous/local community must be sought, and an appropriate benefit sharing agreement with mutually agreed terms should be established.

**Mexico** - The General Biodiversity Law protects of GR associated to TK, by enforcing the Nagoya Protocol in relation to the fair and equitable distribution of benefits that come from

GR and associated TK, always agreeing to the terms of the indigenous communities that own such GR for negotiation. There are some non-sui generis laws for reference: General Law of Ecological Balance and Environmental Protection, General Law of Sustainable Forest Development, General Law of Wildlife, Law for Sustainable Rural Development, General Law of Sustainable Fisheries and Aquaculture and National Indigenous Institute Law

**Panama** - Has ratified the Convention on Biological Diversity by means of Law No. 2 of January 12, 1995 and the Nagoya Protocol by means of Law No. 57 of October 4, 2012. Executive Decree No. 19 dated March 26, 2019. The environmental law protects GR, including TK/GR, to wit. It regulates access to and control of the use of genetic and biological resources of which Panama is the country of origin, whether wild or domesticated, under ex situ or in situ conditions, their derivative products, and the GR of migratory species that, due to natural causes, are found in the territory of Panama; as well as the procedures for access to TK, innovations and practices of indigenous peoples associated with the use of genetic and/or biological resources, and the benefits derived from commercial use or other type of use of such resources, excluding human genetic resources. It also regulates the control of the use of GR and TK of Panama and of any other country that has ratified the Nagoya Protocol.

**Paraguay** - National Constitution makes reference GR and TCE. It is also regulated the trafficking of GR and their technology, protecting national interest. Authorities should safeguard and rescue the expressions of oral culture and the collective memory of the nation. The inappropriate and/or on duly use of the goods, their destructions, willful alteration the removal of their original places or alienation for export purposes are prohibited.

**Philippines** – “The Indigenous Peoples Rights Act” or Republic Act No. 8371 (“RA8371”), “The Wildlife Resources and Conservation Act (RA9147) The Traditional and Alternative Medicines Act or Republic Act No. (RA8423), are the relevant laws with respect to the country policy of protection of TK in terms of environmental law. RA9147 states policy to conserve and protect wildlife resources for sustainability. RA8423, mandates a legally workable basis for the ownership by the indigenous people of their knowledge for traditional medicine.

**Turkey** - A Biosafety Law was approved in 2010. The objective of the Law (Art. 1) is "to establish and implement a biosafety system in order to prevent the potential risks of the genetically modified organisms and products thereof obtained through modern biotechnological means within the context of scientific and technological advancements; protect human, animal and plant health; safeguard and ensure the sustainable use of the environment and biological diversity and to determine the procedures and principles governing the control, regulation and monitoring of these activities."

**Vietnam** – There is no specific provisions on protection of inventions concerning TK but the law on Biodiversity No. 20/2008/QH12 provides that by TK of GR means knowledge, experiences, and initiatives of native people on the conservation and use of GR. It provides (Art. 60) rights and obligations of organizations and individuals that are granted licenses for access to GR and also provides protection (Art. 64) on TK Copyrights on GR. The Decree No 59/2017 ND-CP on Management of access to GR and benefit sharing arising from the utilization provides for access to GR, transfer of GR and derivatives thereof to the third party and registration of Intellectual Property rights to utilization of GR, as well as the benefits from their utilization.

**Belgium** report, indicates that since there are no indigenous or local communities in Belgium and its regions there are no legal provisions (in general or in specific laws), on the subject matter of TK. This has also been declared a such by Belgium in the ABS Clearing House.

Bulgaria, Denmark, Haiti, Hungary, Italy, The Netherlands states that there is no environmental regulation that specifically regulates TK.

- c) Is there is a positive or defensive protection for TK in your jurisdiction

Brazil, Bulgaria, France, and Luxembourg have stated that there is a **positive protection** for TK in their jurisdictions.

Australia, Canada, Chile, Dominican Republic, Indonesia, Luxembourg, Mexico, Panama and Vietnam have a **defensive protection**.

The report of China, Denmark, Hungary, Indonesia, Italy, Malaysia, Paraguay, Philippines, and The Netherlands have stated that there is **no specific (positive or defensive) protection** for TK. TK is subject to the same eligibility criteria for protection as other project of IP protection.

### **Positive Protection**

**Brazil** - The protection for TK in the specific legislation is positive when allows TK holders to freely negotiate the access, including being able to deny it, and also defensive when creates rules for people outside the community to obtain the access to TK.

As for TCE, Brazil has a body called IPHAN – Instituto do Patrimônio Histórico e Artístico Nacional, which is in charge of cataloguing and protecting the country's cultural heritage. In this sense, IPHAN has established the Registry of Cultural Assets of an Intangible Nature that constitute Brazilian cultural heritage, and it created the National Program for Intangible Heritage through Decree no. 3.551/2000 (available at [http://www.planalto.gov.br/ccivil\\_03/decreto/d3551.htm](http://www.planalto.gov.br/ccivil_03/decreto/d3551.htm)).

**Bulgaria** – TK protection according to Bulgaria legislation is preliminary positive.

**France** - TK is not defined under French law and thus French law does not provide for general protection as such.

**Luxembourg** – Nagoya Convention implemented by UE regulation 511/2014 set up a positive protection. Any additional protection related to IP rights of equivalent would be of defensive nature (possibility to challenge misappropriation or unauthorize use)

### **Defensive Protection**

**Australia** –There is no specific statute or registration system for the Protection of TK TCE. Instead, elements of TKTCE remain unprotected while others can be protected by existing IP Laws (Copyright, TMK, Designs acts and ACL). They offer more **defensive** protections than positive protections.

**Canada** - Section 35 of the Constitution provides **defensive** protection for certain TK. The *IAA* and *Fisheries Act* also each impose an obligation to consider Indigenous knowledge in the development or management of natural resources. However, Canadian legislation does not directly protect TK or grant exclusive rights over TK or allow indigenous peoples to prevent the dissemination or use of TK by unauthorized users.

**Chile** - There is a **defensive** protection. The IP regulation and provisions prevent the acquisition or illegitimate maintenance of rights over GR, TK, TCE but its misuse or unauthorized use is not forbidden. Further, there is no regulation regarding access and benefit sharing.

**Dominican Republic** – The report indicates **defensive** protection of TK on “Regulation of Access to GR, associated TK and fair and equitable distribution of benefits of the Dominican Republic” (Article 7K). There are sanctions for not compliance with the regulation.

**India** - It has a **defensive** protection for TK. A TK Digital Library (TKDL) has been set up since 2001 to prevent bio-piracy (please see - [TKDL Traditional Knowledge Digital Library](#)). It contains more than 3.9 lakh formulations from the texts of traditional medicine systems of India including Ayurveda, Unani and Siddha. The database is available to only patent examiners through TKDL

Access (Non-disclosure) Agreement and so far, Access Agreements have been signed with 13 international patent offices including India.

**Mexico**- There is not a sui-generis or specific regulation for TK, but there are various laws that incorporate some provisions to some extent intellectual property law can be seen as providing positive and defensive protection for certain TK, such as associated GR or associated TCEs. The Federal Law for the Protection of the Industrial Property, recognizes and protect collective trademarks, geographical indications (GI's) that cannot be protected as appellation of origin but are GI's of a region identified for the production of art crafts or goods that can be protected as collective marks. Likewise the Federal Copyright Law regarding mediation and arbitration for negotiation with indigenous communities and the Federal Law for the protection of the Cultural Heritage of Indigenous and Afromexican People and communities.

**Vietnam** - TK protection in Vietnam is defensive since it is aimed at preventing the acquisition of intellectual property rights over TK by parties other than the local community. It has compiled a searchable database of medicinal plants that can be used as evidence of prior art by patent examiners when assessing patent applications.

### **Sui Generis Protection**

**Panama** - Has enacted a sui generis legislation to protect TK and TCE. Law No. 20 of June 26, 2000. It establishes a “special IP regime for the collective rights of indigenous communities, for the protection of their cultural identities and traditional knowledge.”

Executive Decree No. 12 of March 20, 2001,(Art 2) defines TK as “Collective knowledge of the indigenous peoples based on centuries-old and even millenary traditions that at the same time are tangible and intangible expressions that encompass their sciences, technologies, cultural manifestations, including genetic resources, medicines, seeds, knowledge about the properties of fauna and flora, the oral traditions, designs, visual and performing arts”.

In order to be protected, the TK must be registered with the competent authority. The registration of the TK grants exclusive right to the use of the TK. The Panamanian Criminal Code penalizes the unauthorized use of a registered TK with 4-6 years of imprisonment.

## 2) Is TK protected permanently or a limited time frame?

**Australia**, there is no specific status regulating the protection of TK (see answer to Question 1.a))

Brazil, Bulgaria, Denmark, Dominican Republic, Indonesia, Mexico TK is protected permanently.

**Panama** has a limited time frame.

**Italy** since there are no laws protecting TK and TCE there is no time limit of protection.

Belgium, Canada, France, Haiti, Hungary, Japan, Malaysia, Paraguay, The Netherlands, Turkey indicated that is not applicable

## 3) Is there any judicial, administrative, decision or case law protecting TK?

Judicial Decisions:

**Australia** - As indicated is not a party to the Nagoya Protocol, there is no case law or court precedent in Australian law concerning the operation of the Protocol, but in the Supreme Court of Queensland case of *Franklin v Giddins* [1978] Qd R 72 is authority for the

proposition that an equitable (general law) **obligation of confidence** can protect **genetic information trade secrets**.

**Brazil.** The Ashaninka case docket No. 2007.30.00002117-3 Class: 7100-Public Civil Action Defendance Fabio Dias-ME and others (payment of damages to the Ashaninka Community/Disentanglement of documents related to the search sponsors by Indigenous Research Center)

**Denmark.** Case law THULE Tribe. Case before the Danish Supreme Court regarding indigenous people. Thule-Tribe had been forcefully moved from their native area in the north of Greenland due to the establishment and expansion of an American Military Base in the area.

**India.** The Neem Case cancellation of a EUIPO Patent granted to a multinational agribusiness corporation in relation to a method of controlling fungi on plant comprising of contacting the fungi with a Neem Oil formulation.

Turmeric Case Revocation of a patent in 1997 the ground of lack of novelty. Turmeric is use in medicinal properties and cosmetics.

More cases:

<http://www.tkdI.res.in/tkdI/LangDefault/Common/outcomemain.asp?GL=Eng>

**Indonesia** - Cancellation of 51 patent applications on 11 different compound of traditional Indonesia medical plants or jamu, by Shiseido in the late 1990. The herb species are originated from Indonesia, and have been commonly known in the community as traditional herbs.

Ketut Deni Aryasa, traditional silver jewelry artist in Bali who was allegedly copied the design of John Hardy International Ltd., in fact the motive of the design has been known in his Community in Bali, namely Crocodile Skin

**Japan** - Although there is no specific system (*sui generis* system) that protect TK. A decision according to which the existing law (the Trademark Act) has a defensive effect in certain cases related to indigenous people:

Cancellations trademark "AINU"

On 28 March 2020, an individual filed an application with the Japan Patent Office (JPO) to register a trademark represented by "AINU" in standard letters. This application was found to be contrary to public order and morality under Article 4 (1) (vii) of the Trademark Act and refused (Trademark Application No.2020-034136). (Notice of decision of refusal was sent on 8 September 2021.) AINU in roman letters is highly likely to be interpreted as referring to the indigenous people of the northern part of the Japanese Archipelago, Hokkaido.

**Mexico** - Case law protecting the indigenous communities and their use of media and its scope regarding their indigenous identity, same that was ruled in a Supreme Court resolution on July 2, 2021 (regarding Amparo in revision 603/2019 promoted by Telecomunicaciones Indígenas Comunitarias, A.C.). This case law concludes that the indigenous communities shall be considered as vulnerable sectors, thus, legislation must be made taking into consideration its segregation and discrimination, always looking to remedy this situation.

**Vietnam** – Cancellation of word mark “BÀU ĐÁ” for alcohol product  
- “BÀU ĐÁ” is the name of a village having reputation on rice alcohol made by its own traditional process with specific materials of that locality (underground spring water of that locality of the village); The Locality filed an appeal for cancellation of such figure trademark.

## **II Genetic Resources/GR**

4) Is there a legal frame either general law or specific legislation in your country that protects Genetic Resources (GR)?

### **General Law**

Australia, Chile, Colombia, Denmark, Dominican Republic, France, Hungary, India, Mexico, Panama, Philippines, The Netherlands, Turkey, Vietnam reported either a General Law or specific legislation to protect GR

**Australia** - Australia has enacted specific Commonwealth and State or Territory based legislation governing access to and benefit-sharing of GR. The current framework covers publicly owned and managed biological materials (including GR) and is separate to any intellectual property regime in Australia. There is National Legislation, such as the Environmental Protection and Biodiversity Act 1999 (EPBC Act.) and the Environmental Protection on Biodiversity Conservation Regulations 2000 (EPBC regulations). At state or territory-based legislation, each state or territory government manages access to biological resources in its jurisdiction.

**Chile** - Law No. 17,288 of National Monuments.  
It has been used by CONADI (National Corporation of Indigenous Development) to deny access to genetic resources of indigenous communities since this law allows to declare these resources as indigenous cultural heritage in the absence of proper regulation.

**Colombia** - Andean Decision 396/96, Environmental Law and Constitutional Protection of indigenous land and how to control access to GR.

**Denmark** - Order No. 25 of January 18, 2013, on Patents and Supplementary Protection Certificates, Part I, Chapter 2, section 3(5) stipulates that *“If an invention relates to or makes use of a biological material, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant’s non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent”*.

**Dominican Republic** - Regulation of access to GR, associated to TK and fair and equitable distribution of benefits of the Dominican Republic  
<https://ambiente.gob.do/wp-content/uploads/2018/04/REGLAMENTO-ACCESO-A-RECURSOS-GENETICOS-Publicacion.pdf>

Sectorial Law on Biodiversity, No. 333-15. G. O. No. 10822 of December 17, 2015.  
<http://idard.org.do/wp-content/uploads/2017/10/Ley-Sectorial-sobre-Biodiversidad-No.-333-15.pdf>

Law 64-00 (articles 33, 17, 141, 136) and numeral 44 of page 43 for purposes of conceptualizing genetic material  
<https://ambiente.gob.do/wp-content/uploads/2016/09/Ley-No-64-00.pdf>

### **France - General law**

The regime applicable to GR has been specified within two European regulations that have enabled the application of the Nagoya Protocol in France and the implementation of benefit sharing for TKGRs:

- **European Regulation 511/2014** of 16 April 2014 on measures concerning compliance by users in the Union with the Nagoya Protocol on ABS and
- its implementing **regulation 2015/1866** of 13 October 2015.

Further, **Law 2016-1087 of 8 August 2016 for the reconquest of biodiversity**, nature and landscapes (“Biodiversity Act”) constitutes the mechanism that effectively implemented the Nagoya Protocol in France,

**Hungary** – Convention on Biological Diversity announced with Act. No. LXXXI of 1995.

**India** - Biological Diversity Act, 2002 (“BD Act”) – which was enacted to meet the meet the obligations under Convention on Biological Diversity.

Biological Diversity Rules, 2004 - Regulation of procedures and mechanisms for the implementation of the BD Act.

Numerous guidelines, rules and regulations framed under the BD Act can be found here: <http://nbaindia.org/content/18/21/1/notifications.html> including Guidelines on *Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014* and *Guidelines for International Collaboration Research Projects involving Transfer or exchange of Biological Resources or information relating thereto between institutions including Government sponsored Institutions and such institutions in other countries.*

*Key provisions of the BD Act and its corresponding Rules can be found here:* <http://nbaindia.org/uploaded/pdf/ABS%20Provisions%20of%20the%20Act.pdf>.

**Mexico** - There is no a specific national law that regulates GR but there are different legislations that set forth provisions about the respect, preservation and maintenance of GR, as it is provided in the **Biological Diversity Convention of 1992** (BDC) Such as: General Law of Climate Change, General Law of Ecological Balance and Environmental Protection, etc.

**Panama** - *Law 2 of January 12, 1995 (“CBD”), Regarding the Convention on Biological Diversity, Law 57 of October 4<sup>th</sup>, 2012 (“NP”) Approves the Nagoya Protocol for the promotion and safeguarding of “the fair and equitable sharing of benefits arising from the utilization of genetic resources”*

**Philippines** - “The Indigenous People Rights Act” (Republic Act No. 8371-RA8371) Enacted in 1997, provides in Section 32, 34 and 35 that the Indigenous Cultural Communities (ICCs)/Indigenous Peoples (IPs) have the right to practice and revitalize their own cultural traditions and customs.

**The Netherlands** - The Nagoya Protocol (and EU Regulation 511/2014) has been implemented in the Netherlands through the Nagoya Protocol (Implementation) Act (Wet Implementatie Nagoya Protocol, 30 September 2015) which entered into force on 23 April 2016. See <https://www.absfocalpoint.nl/nl/absfocalpoint.htm> for download. In addition, GR, and associated information, may be protected under general (Intellectual Property) law such as patents, breeder’s rights, copyright and trade secrets, provided that it meets the criteria for such protection.

**Turkey** - The Biosafety Law approved in 2010 and some regulations like: Regulation on the Traditional Herbal Medicinal Products, Regulation on the Collection, Protection and Use of Plant Genetic Resources, Regulation on the Protection and Sustainable Use of Fisheries Genetic Resources,

**Vietnam** – Circular 01/2007/TT-BKHCN and 23.11. Additional provisions applicable to the disclosure requirements on patent applications for inventions concerning GR or TK. Apart from the general requirements for patent applications for inventions specified at Rules 23.1 thru 23.7 of this Circular, a patent application for invention concerning genetic resource or



traditional knowledge must also contain documents explaining the origin of the genetic resource and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that genetic resource and/or traditional knowledge.

- If the inventor or the applicant cannot identify the origin of the genetic resource and/or traditional knowledge, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration.

### **Specific Law**

Belgium, Brazil, Bulgaria, Canada, China, Colombia, Denmark, Luxembourg.

**Belgium** - Protection of GR (in situ or held ex situ) is a competence of the regions. The GR which are held ex situ in federal research institutions (including the Natural History Museum, the Africa Museum and Sciensano) are a federal competence (The federal authorities had drafted and were discussing a law which was similar to the Decree in Wallonia).

**Brazil** - (Law no. 13,123/2015 and Decree no. 8,772/2016) provides access to GR, protection and access to TK, and benefit-sharing for the conservation and sustainable use of biodiversity. There are several resolutions, technical guidelines, etc. issued by CGen (Genetic Heritage Management Council) which are related to this subject and can be found in the following link: [Normas do CGen \(mma.gov.br\)](http://mma.gov.br)

**Canada** - Some laws and regulations at the federal, provincial and territorial levels cover some of the elements of ABS for various GR in Canada. Provincial ABS-like schemes govern research activities, for example, in Yukon (*Scientists and Explorers Act, 2002*) and Nunavut and the Northwest Territories (NWT)

**China** - GR are not protected by general law but by specific legislation, such as Seed Law, Animal Husbandry Law, Regulations on management of crop germplasm resources, Regulations on the Management of Human Genetic Resources etc.

**Luxembourg** - GR may be protected under patent rights. According to Article 4 of Luxembourg law of 20 July 1992, as modified, an invention relating to biological material is patentable.

5) Is there a legal frame either general law or specific legislation in your country that protects digital sequence information (DSI)\*

<https://www.cbd.int/dsi-gr/>

[https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_ipk\\_ge\\_21/wipo\\_ipk\\_ge\\_21\\_presentation\\_14\\_tshitw\\_amulomoni.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipk_ge_21/wipo_ipk_ge_21_presentation_14_tshitw_amulomoni.pdf)

Brazil and Panama reported that there is a legal frame in their jurisdictions.

**BRAZIL**- According to the definition of the Biodiversity Law no. 13,123/2015, GR is any piece of information derived from the genetic heritage (GH) which means that both material sample or digital information are considered GR.

The specific mention to *in silico* sources in Article 22 of Decree no. 8,772/2016 is the Brazilian law provision that refers to DSI.

**Panama** – Law 2 of January 12, 1995, Convention on Biological Diversity (“CBD”). Law 57 of October 4<sup>th</sup>, 2012, Nagoya Protocol (“NP”), Law No. 41 of July 1<sup>st</sup>, 1998, General Environmental Law, Executive Decree No. 19 dated March 26, 2019, access and control of the use of biological and GR.

All other reports indicated that no general law or specific legislations protects digital sequence information (DSI) in their jurisdictions.

6) The following questions relate specifically to the Nagoya Protocol.

- a) If your country has not (yet) implemented the Nagoya Protocol, please indicate this.
- b) The Nagoya protocol stipulates ABS ("access and benefit sharing"). In your country, is there any impact on intellectual property protection and/or enforcement if ABS is not satisfied?
- c) The Nagoya Protocol also stipulates PIC ("prior informed consent"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in PIC?
- d) The Nagoya Protocol also stipulates MAT ("mutually agreed terms"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in MAT?

No.	COUNTRY	IMPLEMENTATION NAGOYA PROTOCOL (NP)		ABS		PIC		MAT	
		YES	NO	YES	NO	YES	NO	YES	NO
1	Australia		X		X		X		X
2	Belgium	✓		✓		✓		✓	
3	Brazil	✓		✓		✓		✓	
4	Bulgaria	✓			X		X		X
5	Canada		X		X		X		X
6	Chile		X		X		X		X
7	China		X	✓			X		X
8	Colombia		X	✓			X		X
9	Denmark	✓		✓		✓		✓	
10	Dominican Republic	✓		✓		✓		✓	
11	France		X	✓		✓		✓	
12	Haiti		X		X		X		X
13	Hungary		X		X		X		X
14	India	✓		✓		✓		✓	
15	Indonesia	✓			X		X		X
16	Italy		X		X		X		X
17	Japan	✓			X		X		X
18	Luxembourg	✓		✓		✓		✓	
19	Malaysia	✓		✓			X		X
20	Mexico	✓			X		X		X
21	Panama	✓		✓		✓		✓	
22	Paraguay		X		X		X		X
23	Phillipines	✓		✓		✓		✓	
24	The Netherlands	✓			X		X		X
25	Turkey		X		X		X		X
26	Vietnam	✓		✓		✓		✓	

e) Has your country implemented the Cartagena Agreement?

The report of the national groups of Belgium, Brazil, China, Colombia, Denmark, Dominican Republic, France, Hungary, India, Indonesia, Japan, Malaysia, Mexico, Panama, Turkey, and Vietnam indicated that they have implemented the Cartagena Protocol.

The reports of Australia, Bulgaria, Canada, Chile, Haiti, Italy, Luxembourg, Paraguay indicated that they have not implemented yet.

7) Academic research often involves GRTK. Are there any special regulations and/or measures for academics and/or academic institutions such as universities to protect and promote the protection and development of GRTK

Report of Australia, Brazil, Bulgaria, Canada, China, Colombia, Denmark, France, India, Indonesia, Malaysia, Mexico, Panama, Philippines, Vietnam have special regulations and/or measures for academic institutions.

**Australia**- Academic research carried out in and by universities and publicly funded research must comply with an ethical framework that includes the following:

The National Health & Medical Research Council (**NHMRC**), Australian Research Council (**ARC**) & Universities Australia (**UA**) *National Statement on Ethical Conduct in Human Research*. The Australian Institute of Aboriginal and Torres Strait Islander Studies (**AIATSIS**) *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research*. The NHMRC *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*.

**Brazil** - Has special regulations provisional measures (MP 2186/2001)

**Bulgaria** – There are academic institutions that protect and promote GR (Agricultural Academy, Sofia, and Agricultural University Plovdiv)

**Canada** - There are specific institutions who have politics and policies and procedures in place (Indigenous-led non-profit organization the first nations information governates centre)

**China** – There are some regulations on the management on the GRTK protection and development in different Chinese law such as seed law, animal husbandry law.

**Colombia** – Contract with specific requirements regulated and controlled by Ministry of Environment, the regulates the access to GR and how can be used. Decree 1376/2013, Decree 1375/2013 Law 165/1994 Andean Decision 391/1996, etc.

**Denmark** – There are several laws providing access to funding of research activities within different sectors, establishing different research institutions and ensuring academic freedom.

**France** – **Regulation**; Use of GR is subject to declaration and not to authorisation Environmental Code (L.412-7, L.412-8). **Promotion** Consultative Committee on Ethics and Deontology of the Institute of Research for Development (IRD) ([Guide to good practice in research for development, 2018, IRD, p7](#))

**India** - The *Indian Council of Agricultural Research*, an autonomous organisation under the Department of Agricultural Research and Education (DARE), Ministry of Agriculture and Farmers Welfare, Government of India, has been proactive in protecting GRTK by establishing the following institutes: **Plant GR** - The ICAR - **National Bureau of Plant Genetic Resources** [Link to Institute website: <http://www.nbpgr.ernet.in/>] **Animal GR** - The

ICAR- National Bureau of Animal GR [Link to Institute website: <https://nbagr.icar.gov.in/en/home/>]

**Indonesia** - The Indonesian IP Office (Directorate General of Intellectual Property) is active in helping the institutions to record the GRTK.

**Malaysia** - Under the Access to Biological Resources and Benefit Sharing Act 2017, academic institutions would fall under the scope of a non-commercial purpose, and understandably a permit to obtain access may be easier to facilitate.

**Mexico** - For non-commercial scientific research there are two ways to obtain a permit of the General Law of Ecological Balance and Environmental Protection; (Arts. 87 and 87bis NOM 126). The most important is to transfer to recognized and established national researchers a certain part of the state responsibility for granting permits. Thus, a researcher holding a "Scientific Collector's License" can extend permits to students and her collaborators, nationals and foreigners.

**Panama** - Regulations are contained in Executive Decree No. 19 dated March 26, 2019. Executive Decree No. 19 (Art. 6) Ministry of Environment is in charge of reviewing, processing and approving or rejecting the petitions for scientific investigations to be performed by universities or by national or international research centers, including the ones related to GRTK.

**Philippines** - Under the Technology Transfer Act or Republic Act No. 10055 (enacted in 2009), all universities and research and development institutions are required to disclose any genetic or biodiversity resource for possible intellectual property protection.

**Vietnam** - Decree No. 59/2017/ND-CP (Art. 20). Requirements for Vietnamese students, doctoral students, or science and technology organizations who wish to transfer genetic resources abroad.

**Canada** – There are no federal or provincial regulations or measures governing generally the protection and development of GRTK although specific institutions may have policies and procedures in place. For example, an indigenous-led non-profit organization, the [First Nations Information Governance Centre](#) (FNIGC)

All other reports indicated that there is any special regulation and/or measures,

8) "Traditional medicine" may fall within GRTK. Information relating to traditional medicine is generally not found in the literature or in other written form in the public domain. Does your country permit patent or any other form of intellectual property protection in relation to traditional medicine? If yes, does your country have any specific legislation or examination practice for the protection of traditional medicine? Please include links to websites dealing with these practices or legislation, if appropriate.

Brazil, Colombia, India, Panama, Philippines indicated that their countries permit patent or any other form of intellectual property protection in relation to traditional medicine and they have specific legislation.

The reports of Canada, China, France, Japan and The Netherlands indicated that there are no special laws or examination practices to protect traditional medicine but in some the general patent rules apply with respect to an invention that might derive from traditional medicine.

**Brazil** - According to the Biodiversity Legislation (Law no. 13,123/2015 and Decree no. 8,772/2016), "traditional medicines" can be patented just like any other product from GR and/or TK, if they fulfill the patentability requirements. The applicant must inform CGen (Genetic Heritage Management Council) that it will patent the traditional medicine by means of a simple electronic registration. The applicant must also inform the BRPTO that the patent application is a result of an access to the GR and/or TK.

Link for Law no. 13,123/2015 in Portuguese:

[http://www.planalto.gov.br/ccivil\\_03/ato2015-2018/2015/lei/l13123.htm](http://www.planalto.gov.br/ccivil_03/ato2015-2018/2015/lei/l13123.htm)

Link for no. Decree 8,772/2016 in Portuguese:

[http://www.planalto.gov.br/ccivil\\_03/ato2015-2018/2016/decreto/d8772.htm](http://www.planalto.gov.br/ccivil_03/ato2015-2018/2016/decreto/d8772.htm)

**Colombia** - Is not part of the Nagoya Protocol, but “Traditional Medicine” has been categorized as “Alternative Medicine” and it has a particular regulation regarding which authorizations are required both for a place where this treatment can be provided, and for the particular treatment to be approved.

**India** - The Indian Patent Act, 1970 prohibits patenting an invention which in effect, is TK or which is an aggregation or duplication of known properties of traditionally known component or components. It protects traditional Indian medicinal knowledge. In 2001, it created a digital knowledge repository known as **Traditional Knowledge. Digital Library** (TKDL) to prevent misappropriation of such knowledge in Patent Offices across the world.

The TKDL contains systematically and scientifically converted and structured information as obtained from the ancient texts on Indian traditional medicinal knowledge. The access to TDKL is available to thirteen Patent Offices for the purpose of search and examination only under an Access (Non-disclosure) Agreement. Over 3.6 lakh formulations/ practices have been transcribed into the TKDL database.

[Link to TKDL:

<http://www.tkdل.res.in/tkdل/LangDefault/Common/Home.asp?GL=Eng>

[Link to TKDL Access Agreement:

<http://www.tkdل.res.in/tkdل/langdefault/common/terms.pdf>

**México** - The Traditional Medicine fall within GRTK and there is a specific legislation call Law of the National Institute of Indigenous Peoples, (Art 4-XLIII).

Links to websites dealing with these practices or legislation:

[http://www.diputados.gob.mx/LeyesBiblio/pdf/LINPI\\_041218.pdf](http://www.diputados.gob.mx/LeyesBiblio/pdf/LINPI_041218.pdf)

<https://www.gob.mx/salud/acciones-y-programas/medicina-tradicional>

INPI | Instituto Nacional de los Pueblos Indígenas | Gobierno | gob.mx

[www.gob.mx](http://www.gob.mx)

<https://www.gob.mx/impj>

<http://www.salud.gob.mx/unidades/cdi/nom/compi/ris.html>

**Panama** - Allows intellectual property collective rights in relation to traditional medicine. This IP protection is granted by Law No. 20 of June 26, 2000, regulated by Executive Decree No. 12 of March 20, 2001 and more specifically by Law No. 17 of June 27, 2016 and its Regulations (Executive Decree No. 39 of February 12, 2019).

Law No. 17 of June 27, 2016, (Art. 13) 1) “Medicinal plants and their active principles as well as preparations obtained from plants in their various forms, and the knowledge associated with these are patrimony of the indigenous peoples”. 2) Patent applications based on knowledge of indigenous traditional medicine, innovations and practices of indigenous peoples must have the express free, prior and informed consent of the indigenous congresses or authorities 3) Traditional medicine knowledge per se and the natural resource directly associated therewith cannot be the subject matter of patent applications by third parties.

Links of the statutes and regulations:

[https://utp.ac.pa/sites/default/files/documentos/2021/pdf/decreto\\_ejecutivo\\_12\\_de\\_2001.pdf](https://utp.ac.pa/sites/default/files/documentos/2021/pdf/decreto_ejecutivo_12_de_2001.pdf)

[https://www.asamblea.gob.pa/APPS/LEGISPAN/PDF\\_NORMAS/2010/2016/2016\\_625\\_173\\_1.pdf](https://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_NORMAS/2010/2016/2016_625_173_1.pdf)

[https://www.gacetaoficial.gob.pa/pdfTemp/28712\\_A/GacetaNo\\_28712a\\_20190212.pdf](https://www.gacetaoficial.gob.pa/pdfTemp/28712_A/GacetaNo_28712a_20190212.pdf)

[http://gacetas.procuraduria-admon.gob.pa/28316\\_2017.pdf](http://gacetas.procuraduria-admon.gob.pa/28316_2017.pdf)

**Philippines** - Republic Act No. 8423 (“RA8423”) or the Traditional and Alternative Medicine Act of 1997 provides a general policy framework on this matter RA aims to a) encourage scientific research on and develop traditional and alternative health care systems that have direct impact on public health care; (See b, c, d, e, f, g). The law mandates the creation of the Philippine Institute of Traditional and Alternative Healthcare, an attached agency to the Philippine Department of Health.

See link: [PITAHC | May PITAHC sa puso ng bawat Pilipino](#)

Canada, China, France, Japan and The Netherlands indicated there are no special laws but in some the general patent rules apply with respect to an invention that might derive from traditional medicine.

**Canada** - There is typically no intellectual property available for traditional medicine because it has been known and used for a long time.

**China** - China permits patent protection related to traditional Chinese medicine, but does not have any special examination standards for patents related to traditional Chinese medicine. The examination standards for patents related to traditional Chinese medicine are the same as other ordinary patents.

**France** - France does not have specific patent law provision that address the situation of traditional medicine. General patent rules apply with respect to an invention that may derive from traditional medicine.

**Japan** - There are no special laws, regulations, or examination practices to protect traditional medicine.

**The Netherlands** - In general, traditional medicine can be protected with intellectual property, including patents, to the extent it meets the requirements for protection. However, is difficult to identify existing traditional medicine as prior art since such data is frequently not collected in an electronic database

All other reports indicated that there is no specific legislation in relation to the protection the traditional medicine itself.

9) Have there been any authoritative studies in your country on the impact of the Nagoya Protocol? If yes, please provide author(s), title, and information where such studies can be found.

**Australia** – Despite is not member of the Nagoya Protocol, such treaty has been the subject of academic research and publication in Australia *The Nagoya Protocol and its impact on biotechnology* (2011) 24(2) IPLB.

**Brazil** - Study prepared by the National Confederation of Industry (CNI) a good one. The study can be found at <https://www.portaldaindustria.com.br/publicacoes/2020/10/importancia-da-ratificacao-do-protocolo-de-nagoia-para-industria-brasileira/> for download (in Portuguese).

**Bulgaria** - Studies could be found in “Practical Agriculture” magazine (vol. 1, January 2017, Velcheva, N., IPGR-Sadovo, Kaisheva, M. “People and Nature” Association. [www.praktichnozemedelie.com](http://www.praktichnozemedelie.com)

**China** - There are studies in China on the access and benefit sharing of genetic resources including the impact of Nagoya Protocol. Among them, the following one may be an authoritative study made by scholars from Ministry of Environmental Protection of China. The following is the relevant information of that book:

Title: Access and benefit sharing (ABS) on genetic resources and associated traditional knowledge: 100 highlights

Authors: Zhang Yuanyuan, Xue Dayuan

Press: Chinese Environmental Science Press Group

Publication date: 2019

Where to find the book: Chinese Public Libraries, Chinese Bookstores

**Dominican Republic** - Manuel Ruiz Muller. Access and Benefit-Sharing Policy and Legal Framework in Central America and the Dominican Republic. <https://businessdocbox.com/Forestry/72996712-Access-and-benefit-sharing-policy-and-legal-framework-in-central-america-and-the-dominican-republic-manuel-ruiz-muller.html>

**India** - There have been certain studies and reports on the implementation of the Nagoya Protocol in India. Some of these studies are listed below:

Author: Ministry of Environment, Forest & Climate Change, Government of India  
Title: Implementation of Nagoya Protocol on Access and Benefit Sharing - India's Experience  
Link: <http://nbaindia.org/uploaded/pdf/Implementation%20of%20Nagoya%20Protocol%20in%20India.pdf>

Author: A UNDP-GEF Project  
Title: 'Strengthening Human Resources, Legal Frameworks, and Institutional Capacities to Implement the Nagoya Protocol' (Global ABS Project) - Access and Benefit Sharing In India - A Handbook For Researchers  
Link: [http://nbaindia.org/uploaded/pdf/IDB\\_ABS.pdf](http://nbaindia.org/uploaded/pdf/IDB_ABS.pdf)

Author: Shloka Narayanan and Balakrishna Pisupati  
Title: Reconciling Implementation of the Nagoya Protocol in India  
Link: <http://fledgein.org/wp-content/uploads/2017/11/FLEDGE-Policy-Brief-3-2015.pdf>

Author: Deva Prasad and Suchithra Menon

Title: India: Implementing the Nagoya Protocol on Access and Benefit-Sharing: Emerging Legal Challenges

Link: <https://content.iospress.com/articles/environmental-policy-and-law/epl200241>

Author: Christian Prip and Charlotte van't Klooster

Title: The Nagoya Protocol on access to genetic resources and benefit sharing: User-country measures and implementation in India

Link: <https://www.fni.no/getfile.php/131690-1469868968/Filer/Publikasjoner/FNI-R0216.pdf>

Author: R. Selvam

Title: The Implications of Intellectual Property Rights in Protecting Animal Genetics Resources and Biodiversity: A Review

Link: <https://www.ijcmas.com/abstractview.php?ID=17982&vol=9-7-2020&SNo=16>

Author: KP Ramesha

Title: Intellectual Property Rights Regime for Livestock Agriculture in India – Present Status and Future Prospects

Link: <http://www.ask-force.org/web/IP/Ramesha-IP-Regime-Livestock-India-2011.pdf>

Author: Pushpa Kumar Lakshmanan

Title: An Inquiry into the Biological Diversity Act, 2002 in Light of the Nagoya Protocol on Access and Benefit Sharing

Link:

[https://www.researchgate.net/publication/320243388\\_An\\_Inquiry\\_into\\_the\\_Biological\\_Diversity\\_Act\\_2002\\_in\\_Light\\_of\\_the\\_Nagoya\\_Protocol\\_on\\_Access\\_and\\_Benefit\\_Sharing](https://www.researchgate.net/publication/320243388_An_Inquiry_into_the_Biological_Diversity_Act_2002_in_Light_of_the_Nagoya_Protocol_on_Access_and_Benefit_Sharing)

**Italy** - To the best of our knowledge, there is just the following study in Italy related to the impact of the Nagoya Protocol:

Author: Pavone Ilja Richard

Title: Il Protocollo di Nagoya e l'attuazione del principio di "Access and Benefit Sharing" con particolare riferimento "all'user compliance pillar" (The Nagoya Protocol and the enactment of the principle of Access and Benefit Sharing, referring in particular to the "user compliance pillar")

Periodical: BioLaw Journal - Rivista di BioDiritto, 2018, fasc. 1, pp. 23

**Japan** - (1) Hiroji ISOZAKI, "Towards Effective Implementation of International Treaty: An Obligation to Take National Measures," Global Environmental Studies, No. 10 (2014), pp. 1-26. available at

<https://digital-archives.sophia.ac.jp/repository/view/repository/00000035278>

(2) Hiroji ISOZAKI, "Nagoya Protocol Conclusion and Guidelines for Domestic Measures," *Research on Environmental Disruption*, Vol. 47, No. 3 (2018), pp. 2-8.

**Luxembourg** - 6<sup>th</sup> National Report for the Convention on Biological Diversity, published on 21 December 2018, on the CHM (<https://www.cbd.int/countries/?country=lu>).

**Mexico** – Author: Martin Michaus

Title: Acceso a Conocimientos Tradicionales, Asociados a Recursos Genéticos y Comunidades Indígenas en el Protocolo de Nagoya. Traditional Knowledge Associated to Genetic Resources and Indigenous Communities in the Nagoya Protocol.

Revista Derechos Intelectuales 24/I-ASIPI October 2019.

Link: <https://asipi.org/biblioteca/es/download/derechos-intelectuales-24-tomo-1/>

**Panama** - Study published in 2016 entitled Proyecto de Nagoya. Principales Resultados y Lecciones Aprendidas – Panamá. (Nagoya Project. Main Results and Lessons Learned - Panama). It was prepared by the Global Environment Fund, the United Nations Development Programme and the Ministry of Environment of Panama.



The link to access this study is:

[https://www.pa.undp.org/content/panama/es/home/library/environment\\_energy/sistematizacion\\_proyecto\\_nagoya.html](https://www.pa.undp.org/content/panama/es/home/library/environment_energy/sistematizacion_proyecto_nagoya.html)

**Philippines** - 2020 study/article "Revisiting the State of Philippine Biodiversity and the Legislation on Access and Benefit Sharing" by the Food and Fertilizer Technology Center for the Asian and Pacific Region – Agricultural Policy Platform, written by Princess Alma B. Ani and Monica B. Castillo. See link: [Revisiting the State of Philippine Biodiversity And The Legislation on Access and Benefit Sharing | FFTC Agricultural Policy Platform \(FFTC-AP\)](#)

**The Netherlands** - There are a few publications and reports that address the implications of the Nagoya Protocol from different perspectives and from stake holder reviews. Some of these have been peer reviewed, others are from private practice IP law firms. Furthermore, the competent authority in the Netherlands has published a report on the inspections conducted in 2019-2020.

- Schebesta, H. (2021) The Potential of Private Standards for Valorizing Compliance with Access and Benefit Sharing Obligations of Genetic Resources and Traditional Knowledge. *Agronomy* 2021, 11, 1823. <https://doi.org/10.3390/agronomy11091823> – Describing the obstacles of the ABS legislation for R&D and commercial activities, and proposing private standards to incentivize ABS obligation compliance. (Peer reviewed) See <https://www.mdpi.com/2073-4395/11/9/1823/htm> for download.

- Brink M and van Hintum T (2020) Genebank Operation in the Arena of Access and Benefit-Sharing Policies. *Front. Plant Sci.* 10:1712. doi: 10.3389/fpls.2019.01712 – Describing the consequences of the national and international ABS legislation for genebanks and hampered access to GR as a result of unclarity and complexity of the rules. (Peer reviewed) See <https://www.frontiersin.org/articles/10.3389/fpls.2019.01712/full> for download.

- van Vegchel M (June 2018) Implementation of Nagoya Protocol: A comparison between The Netherlands, Belgium and Germany. See <https://publications.vo.eu/implementation-of-nagoya-protocol/> for download.

- Van Vooren B (September 18, 2019) The Nagoya Protocol at Its 5th Anniversary: Legal Lessons Learned in the Pharmaceutical, Food and Cosmetics Sectors – Describing the negative impact of ABS regulations on R&D and business transactions in the Life Sciences. See <https://www.cov.com/-/media/files/corporate/publications/2019/09/nagoya-protocol-legal-lessons-learned.pdf>, for download

- the Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit, "NVWA") has published a report on its inspections conducted in 2019-2020. The NVWA is charged with monitoring compliance with the provisions under or pursuant to the Nagoya Protocol (Implementation) Act. The report (in Dutch) can be accessed at <https://www.nvwa.nl/onderwerpen/nagoya-protocol/jaaroverzicht-nagoya-protocol>

**Turkey** - Zeynep Kivilcim, Cartagena Protocol And Turkey's Biosafety Legislation  
Related link: <https://dergipark.org.tr/tr/download/article-file/1337>

**Vietnam** - <https://absch.cbd.int/database/NR/ABSCH-NR-VN-238745>

10) Is there any case law or court precedent that can be mentioned?

**Australia** – *Franklin v Giddins* [1978] Qd R 72 is authority for the proposition that an equitable (general law) **obligation of confidence** can protect **genetic information trade secrets**. (see answer to question I. General TK 3).

**Brazil** - The Ashaninka case docket No. 2007.30.00002117-3 Class: 7100-Public Civil Action Defendance Fabio Dias-ME and others (payment of damages to the Ashaninka Community/Disentanglement of documents related to the search sponsors by Indigenous Research Center)

**India - Divya Pharmacy vs Union Of India And Others.** However, this case sets precedent for an administrative issue i.e., the power of State Biodiversity Boards to regulate companies and collect fees from companies using biological resources. The case has also been submitted on the ABSCH platform as seen here: <https://absch.cbd.int/en/database/news/119785>

- **Indonesia** - Case on H5N1 Virus  
Indonesia sent specimen of virus H5N1 to WHO, but then the specimens were shared with pharmaceutical companies without notification of the Indonesia Government and vaccines were patented by major pharmaceutical companies, which then selling the vaccines to Indonesia with significant price.

All other reports indicates that there were not aware of any case law or court precedent.

### III- Traditional Cultural Expressions TCE

1. Is your country member or has implemented on National law the:
  - a. Convention for the Safeguarding of Intangible Cultural Heritage of 2003

Belgium, Brazil, Bulgaria, Chile, China, Colombia, Denmark, Dominican Republic, France, Hungary, India, Indonesia, Italy, Japan, Luxembourg, Malaysia, Mexico, Panama, Philippines, The Netherlands, Turkey, and Vietnam, are members or have implemented on National Law this Convention

Australia, Canada, Haiti, Paraguay are not members of it.

**Belgium** - Report stated that countries who are signatories to the convention undertake to list intangible cultural heritage in their territory and to protect it by adopting suitable measures.

**Italy** - Implemented de Convention in National Law "Code of Cultural Heritage and Landscape.

- b. Convention on the Protection and Promotion of the Diversity of Cultural Expressions of 2005

Australia, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Denmark, Dominican Republic, France, Hungary, India, Indonesia, Italy, Luxembourg, Mexico, Panama, The Netherlands, Turkey, and Vietnam, are members or have implemented on National Law this Convention

Haiti, Japan, Malaysia, Paraguay, and Philippines are no members of the Treaty.

2. Is there any special statute regulating TK/TCE in your country? If yes, please identify the statute.

Brazil, Bulgaria, China, Panama, Paraguay, Philippines reported that they have special statute.

**Brazil** – It has a body called IPHAN – Instituto do Patrimônio Histórico e Artístico Nacional, which is in charge of cataloguing and protecting the country's cultural heritage. In this sense, IPHAN has established the Registry of Cultural Assets of an Intangible Nature that constitute

Brazilian cultural heritage, and it created the National Program for Intangible Heritage through Decree no. 3.551/2000 (available at [http://www.planalto.gov.br/ccivil\\_03/decreto/d3551.htm](http://www.planalto.gov.br/ccivil_03/decreto/d3551.htm)).

Although such programs have fallen short their goals in view of lack of funding, they are still the main public policies in this field.

**Bulgaria** – The Cultural Heritage act is a general act with a specific chapter dedicated to TK/TCE. It regulates the preservation and protection of the Cultural Heritage and it encompasses intangible and tangible immovable and movable heritage as an aggregate of cultural values which Bear Historical Memory and National Identity and have their own academic of cultural value.

**China** - Intangible cultural heritage law and others.

**Panama** - Law No. 20 of June 26, 2000, is regulated by **Executive Decree No. 12 of March 20, 2001**. <https://wipolex.wipo.int/es/legislation/details/3397> . It creates a special intellectual property regime for the collective rights of indigenous peoples, for the protection and defense of their cultural identity TK and TCE  
[https://www.mici.gob.pa/uploads/media\\_ficheros/2018/08/2/digerpi-leyes-reglamentos/ley-20-2000.pdf](https://www.mici.gob.pa/uploads/media_ficheros/2018/08/2/digerpi-leyes-reglamentos/ley-20-2000.pdf)

**Paraguay** - Law No. 1328/1998 on Copyright and Related Rights Title VIII Protection of Folklore Art. 83, Art. 84.

**Philippines** – National Cultural Heritage Act or Republic Act No. 10066, adopted in 2010 it incorporates Intangible Cultural Heritage in to the law’s scope of protection, conservation and promotion.

All other reports indicated that they do not have it.

Australia indicates that there is no specific status regulating TK/TCE. However, some relevant rights and protections, are conferred through a non-TK/TCE specific IP statutes and common law

3. Are there any other laws regulating TK/TCE in your country, such as, Trademark Law, Copyright Law, Geographical Indications Law?  
If yes, please identify the laws.

Reports of Australia, Brazil, Bulgaria, Canada, Chile, China, Colombia, Denmark, Dominican Republic, France, Hungary, India, Indonesia, Japan, Luxembourg, Malaysia, Mexico, Panama, Philippines, The Netherlands, Turkey, and Vietnam, indicate that Copyright law, Trademark Law and regulations about geographical indications regulates and protect TK/TCE, to the extent that they regulate copyrighted works, registered and unregistered trademarks and geographical indications. There are some other laws concerning TK/TCE that protects traditional arts and crafts

Reports of Belgium, Haiti, Italy, Paraguay indicated that there is no law regulating TK/TCE

4. Does your law provide a definition or description for TK/TCE?  
If yes, please provide the definition or description.

**Australia** – There is no legislative definition or description. However, in IP Australia’s 2021 Indigenous Knowledge Consultation Paper (Not yet release) uses ‘Indigenous Knowledge’ or ‘IK’ as a term to cover a range of knowledge held and continually developed by

Aboriginal and Torres Strait Islander people. (It is merely indicative and does not form part of Australian law). It includes:

- *Traditional Cultural Expressions* – or ‘TCEs’ are sometimes referred to as ‘folklore’ and include languages, music, performances, songlines, stories, dance, symbols, designs, visual art, crafts, and architecture.
- *Traditional Knowledge* – or ‘TK’, refers to knowledge resulting from intellectual activity in a traditional context and includes know-how, practices, skills, and innovations. This can be in a range of contexts such as agricultural, scientific, technical, ecological, medicinal, and biodiversity-related knowledge. It includes knowledge about genetic resources.

. A ‘genetic resource’ can be any biological material, including plants, fungi, and animals. In some areas within Australia, the informed consent of the local Aboriginal or Torres Strait Islander community is a precondition for permission to collect a genetic resource for commercial purposes, which may include research.

**Brazil** - Law 13,123/2015 provides the following definitions:

“Associated Traditional Knowledge: information or practice of the indigenous population, traditional community or traditional farmer about the properties or direct or indirect uses associated with the genetic resources;”

“Associated Traditional Knowledge for Unidentifiable Origin: associated traditional knowledge in which there is no possibility of linking its origin to at least one indigenous population, traditional community, or traditional farmer;”

**Bulgaria** - There is no specific definition for TK/TCE, however the Bulgarian Cultural Heritage Act provides an exhaustive list of the objects that are considered TK/TCE as Intangible cultural heritage: 1. oral traditions and forms of expression, including language as a bearer of intangible cultural heritage; 2. artistic and performing arts; 3. social customs, rites and celebrations; 4. knowledge and customs that relate to nature and the universe; 5. knowledge and skills related to traditional crafts.

**Dominican Republic** - Article 4 of the official regulation serves as a glossary for different terms used throughout it. Said article includes a definition for TK, but not for TCE.

**h) Traditional knowledge:** Knowledge, innovations and practices of local communities associated with genetic resources, be they oral, documented or in some other way, reflecting a relevant cultural heritage for the conservation and sustainable use of biological diversity.  
<https://ambiente.gob.do/wp-content/uploads/2018/04/REGLAMENTO-ACCESO-A-RECURSOS-GENETICOS-Publicacion.pdf>

**France** - TCE is **not** defined under French law.

Cultural expressions (i.e. not necessarily traditional) are defined in Article 4 of the 2005 Paris Convention on the Protection and Promotion of the Diversity of Cultural Expressions (implemented in France by Law 2006-792 of 5 July 2006 and Decree No. 2007-376 of 20 March 2007), reciting that cultural expressions refer to, inter alia, "*expressions that result from the creativity of individuals, groups and societies, and that have a cultural content*".

TCEs may be described as; the **concrete expression** or an **embodiment**, of part of the traditional knowledge of indigenous communities.

Thus, if TK represents a set of traditions and skills, a TCE would be an expression of it.

**Italy** - Law no. 133/2020, that ratified in Italy the Faro Convention, introduced the notion of cultural heritage. The art. 2 of the Convention defines cultural heritage as «a group of resources inherited from the past which people identify, independently of ownership, as a reflection and expression of their constantly evolving values, beliefs, knowledge and traditions. It includes all aspects of the environment resulting from the interaction between people and places through time».

**Mexico** - Federal Law for the Protection of the Cultural Heritage of Indigenous and Afro-Mexican People and Communities provides a definition for “*cultural heritage*”, same that comprises TK and TCE, same that will be helpful for determining the scope of protection of such law:

*“The set of tangible and intangible goods that include languages, knowledge, objects and all the elements that constitute the cultures and territories of indigenous and Afro-Mexican people and communities that give them a sense of community with their own identity and that are perceived by others as characteristic, to which they have the full right of ownership, access, participation, practice and enjoyment in an active and creative manner.”*

**Panama** – Regulations of Law No. 20 of June 26, 2000. Executive Decree No. 12 of March 20, 2001, defines:

a) TK as “Collective knowledge of the indigenous peoples based on centuries-old and even millenary traditions that at the same time are tangible and intangible expressions that encompass their sciences, technologies, cultural manifestations, including GR, medicines, seeds, knowledge about the properties of fauna and flora, the oral traditions, designs, visual and performing arts”.

b) TCEs as Indigenous Collective Rights, “These are indigenous cultural and intellectual property rights that refer to art, music, literature, biological, medical, ecological and other aspects and expressions that have no known author or owner, or date of origin and are heritage of an entire indigenous people”.

**Philippines** - TK is not expressly defined in RA8371. However, its implementing Rules and Regulations (i.e., NCIP Administrative Rules and Regulations Order No. 01-98) defines TK, or “Community Intellectual Rights” as “rights of indigenous cultural communities/indigenous peoples (ICCs/IPs, for brevity) to own, control, develop and protect: (a) the past, present and future manifestations of their cultures, such as but not limited to, archaeological and historical sites, artifacts, designs, ceremonies, technologies, visual and performing arts and literature as well as religious and spiritual properties; (b) science and technology including, but not limited to, human and other genetic resources, seeds, medicine, health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, resource management systems, agricultural technologies, knowledge of the properties of fauna and flora, oral traditions, designs, scientific discoveries; and (c) language, script, histories, oral traditions and teaching and learning systems”.

## **Vietnam** –

Copyright folklore and folk artworks (IP Law Art. 23.1) Means a collective creation based on the traditions of a community or individuals reflecting the ambitions of such community and expressed in a form appropriate to the cultural and social characteristics, standards and values of such community which have been passed down by adaptation or by other means. Folklore and folk art works shall comprise: a) Folk tales, poems and riddles; b) Folk songs and melodies; c) Folk dances, plays, rites and games; d) Folk art products including graphics, paintings, sculptures, musical instruments, architectural models and other art genres in any material form.

Intangible cultural heritages (Law on Cultural Heritage Art. 4.1) are spiritual products of historical, cultural or scientific value, being saved in memory or in scripts, handed down orally and through professional teaching, performance and other forms of saving and handing down, including speech, scripts, literary, art or scientific works, oral philology, folk oratorio, lifestyle, way of life, rites, traditional craft know-hows, knowledge about traditional medicine and pharmacy, about gastronomic culture, about traditional costumes, and other folk knowledge.

All other reports their national laws do not provide a definition or description of TK/TCE.

### 5. What are the objectives of the protection afforded to TK/TCE in your country?

**Brazil** - The Law 13,123/2015 aims to regulate access to Brazilian GR, protect access to TK and ensure the fair sharing of benefits for the conservation and sustainable use of biodiversity.

**Bulgaria** - The objectives are to preservation and protection of the cultural heritage of Bulgaria.

**China** – Protection and development.

**Colombia** - Guarantee the survival of traditional / indigenous cultures and protecting their heritage.

**Denmark** – Protection of Danish Cultural Heritage

**France** - The main protection afforded in France relates to indications of origin, whether through AOP, AOC or PDO. The legislator's main objective is to ensure the transparency and traceability of products in order to guarantee consumer confidence.

**India** - Traditional knowledge (TK) is an integral part of the heritage and culture of India, and its preservation is a necessity.

**Luxembourg** - The protection of intangible cultural heritage is to promote the respect of cultural diversity, create a feeling of identity and continuity, respect human creativity (<http://www.iki.lu/post>).

**Mexico** – Under the General Culture and Cultural Rights Law and Federal Law for the Protection of the Cultural Heritage of Indigenous and Afro-Mexican People and Communities some of the objectives are: Recognizing cultural rights of people who reside in Mexican territory. Prevent the unauthorized appropriation, use, exploitation, or commercial exploitation of knowledge, culture, identity, and knowledge, culture and identity.

**Panama** - The objective of the protection afforded to TK/TCE by the national laws is to protect the collective intellectual property rights and traditional knowledge of indigenous peoples over their creations.

**Philippines** - “The Indigenous People Rights Act” (Republic Act No. 8371-RA8371) Enacted in 1997, provides in Section 32, 34 and 35 that the Indigenous Cultural Communities

(ICCs)/Indigenous Peoples (IPs) have the right to practice and revitalize their own cultural traditions and customs.

**Vietnam** - 1. The State (Law on Cultural Heritage Art. 9) adopts the policy of protecting and promoting the value of cultural heritages in order to raise the people's spiritual life, contributing to the socio-economic development of the country and the lawful rights and interests of owners of cultural heritages.

**All other reports** indicate, that since there is no specific system for protection TK and TCE, there are not objectives of the protection afforded to TK/TCE.

6. Is there a term of protection for TK/TCE in your country?

**Colombia** - Term will vary according to the protection granted. Perhaps the most extensive protection is for GR and Appellations of Origin.

**Denmark.** There is no singular statute on the protection of TK/TCE, the term of protection depends on the legislation on which the protection is based, such as the Danish Act on Copyright and the Danish Museum Act, in which certain artefacts are time-unlimited.

**Luxembourg** - Regarding tangible cultural heritage (Law of 18 July 1983 relating to the conservation and protection of national sites and monuments, as modified), the protection is not limited Intangible cultural heritage's protection is unlimited, until any protected intangible item is removed from the national list (which never happened until today).

**All other reports** indicate that there is no term of protection for TK/TCE. Some others mentioned that there is no specific system (sui generis system) for protection TK/TCE, there is no term of protection but TK/TCE could be protected for a prescribed term if they satisfied the requirements for protection specified by the respective acts.

7. Does your law provide a positive and/or defensive protection and/or a registration system of TK/TCE? Please explain.

**Australia** – As indicated above, there is no specific statute or registration system for the Protection of TK TCE. Instead, elements of TKTCE remain unprotected while others can be protected by existing IP Laws (Copyright, TMK, Designs acts and ACL). They offer more **defensive** protections than positive protections

**Brazil** - The protection for TK in the specific legislation is **positive** because allows TK holders to freely negotiate the access, including being able to deny it, and also **defensive** when creates rules for people outside the community to obtain the access to TK. The **registration** occurs only if there was access to GR or TK, through an electronic system called SIGGEN (National System for the Management of Genetic Resources and Associated Traditional Knowledge).

**Bulgaria** - Cultural Heritage Act provides **positive** protection, while the Bulgarian Law on Marks and GIs provides **defensive** protection of TK/TCE.

**China** - The protection on TK/TCE in Chinese laws should be deemed to be **positive**. According to the laws, the governments have the obligations to investigate and register intangible cultural heritage.

**Denmark** - Protection under the Danish Act on Copyright provides a **positive** protection with no registration system in place whereas protection under the Danish law on the protection of cultural heritage (lov nr. 332 af 4. juni 1986 om sikring af kulturværdier i Danmark) provides a **defensive** protection, with a committee in place to process any applications for the required export permit.

**India** – Has a **defensive** protection regime.

**Indonesia** – **Defensive** protection, how ever there is no registration system yet.

**Luxembourg** - The protection is **positive** with regards to national protection of tangible and intangible cultural heritage: the protection aims to protect the heritage against alteration, destruction, and exportation of moveable heritage. The protection is **defensive** for any creation covered by copyrights or other IP right if any.

**Mexico** –General Culture and Cultural Rights Law and the Federal Law for the Protection of the Cultural Heritage of Indigenous and Afro-Mexican, provides a **positive** protection system. **Defensive** protection is provided by IP Laws, to the extent the legislation in which the protection is based. There is no **registration** system per se.

**Panama** - Panamanian Law provides for the **positive** protection of TK / TCEs resulting from Law No. 20 of June 26, 2000 and Executive Decree No. 12 of March 12, 2001, which establish a **registration** system of collective rights of the indigenous peoples.

**The Netherlands** - Under national Dutch law there is no specific (positive or defensive) protection for TK/TCEs. TK/TCE is subject to the same eligibility criteria for protection as other objects of IP protection. There is no registration system of TK/TCE in an IP context. The Netherlands has established the Dutch Center for Intangible Cultural Heritage.

**Vietnam** - TCE protection in Vietnam is **defensive** since it is aimed at preventing the acquisition of intellectual property rights over TCE by parties other than the local community.

The use of TCE must be cited properly.

8. Which are the government authorities in charge of the Registry of TK/TCE?

**Brazil** - The Genetic Heritage Management Council - CGen, SISGEN (National System for the Management of Genetic Resources and Associated Traditional Knowledge).

**Bulgaria** – The Bulgarian Ministry of Culture.

**Chile** - National Institute of Intellectual Property (INAPI), National Service of Cultural Heritage through the Intellectual Rights Department, The Ministry of Cultures, Arts and Heritage through the Under-Secretariat for Heritage or the Heritage Service.

**China** - For intangible cultural heritage, the Ministry of Culture and Tourism and the local cultural authorities. For trademark and geographic indication, the Intellectual Property Administration, PRC (CNIPA).

**Denmark** – Minister of Culture and Danish Patent and Trademark office (Ministry of Industry).

**France** - Ministry of Culture (Department Regional Directorate of Cultural Affairs (DRAC)).

**Luxembourg** - Ministry in charge of cultural affairs (*Ministère de la culture*)

**Panama** - TK/TCE are registered with the Department of Collective Rights and Expressions of Folklore, which is part of the Industrial Property Office of the Ministry of Commerce and Industries of the Republic of Panama.

**Philippines** - National Commission on Indigenous Peoples (NCIP) and the National Commission on the Culture and Arts (NCAA).



**The Netherlands** - For TCE the Dutch Center for Intangible Cultural Heritage (Kenniscentrum Immaterieel Erfgoed) is in charge of coordinating, registration and inventory of the Dutch Intangible Cultural Heritage. This institute is assigned this role by the Ministry of Education, Culture and Science.

**Vietnam** - Intellectual Property Office of Vietnam and Copyright Office of Vietnam

All other reports indicated that there is no government authorities are in charge of the registry of TK/TCE.

9. Who are the beneficiaries (indigenous communities) of the TK/TCE protection under your laws?

**Brazil** - The beneficiaries of TK protection under Law 13,123/2015 are: indigenous populations, traditional farmers or traditional communities (culturally differentiated group that recognizes itself as such).

**Chile** – Indigenous Communities

**China** - The communities and the public

**Colombia** – Indigenous Communities

**India** – the Legislations which cover certain aspects of TK/TCE aim to protect, farmers, communities, tribes, forest dwellers and the like.

**Indonesia** - The Government

**Italy**- Heritage Community, (HM) term introduced by Law No. 133/2020 that ratified Faro Convention. HM «people who value specific aspects of cultural heritage which they wish, within the framework of public action, to sustain and transmit to future».

**Mexico** – Indigenous and Afro-Mexican Communities. (Art. 2 Constitution)

**Panama** - Indigenous communities collectively.

**Philippines** - Theoretically, beneficiaries must be the indigenous peoples and local communities.

**Vietnam** - The owners of certificate issued for TCE-based subject matters will directly benefit from the protection. However, the TCE holders (i.e., the communities, or the localities) will also get some benefits since the patent/certificate owners have the obligation of benefit sharing under the laws of Vietnam.

**All other reports** do not indicate specific beneficiaries due to there is no specific legislation in relation to TK/TCE. However, Australia reports indicates that any TK/TCE protection offer is by virtue of statutes which are non-specific to TK/TCE

10. How is the commercial exploitation of TK/TCE regulated by your laws? Is it required to obtain an authorization, license or a previous and inform consent from an indigenous community.

**Brazil** - According to the Law 13,123/2015, in general terms, without considering exceptions, the interested user must first obtain prior consent from the TK holder. After obtaining prior consent, the interested user must register access to TK in SISGEN. Only after registering the access to TK, the interested user can apply for IP rights. When the product is finished, the interested user must notify CGEN and present, within one year of notification of the finished product, the benefit-sharing agreement.

The benefits resulting from the economic exploitation of the finished product or reproductive material arising from access to TK will be shared, fairly and equitably, in case the associated TK component is one of the main elements of added value of the finished product, with the TK holder.

Prior informed consent shall follow the standards set forth by ILO Convention 169.

**Bulgaria** - Cultural Heritage Act provides the right of commercial exploitation of TK/TCE via concession.

**China** - The commercial exploitation of TK/TCE shall not conflict with the protection of intangible cultural heritage or the like. If the TK/TCE involves IP rights, license of the IP rights shall be obtained from the right holder.

**Colombia** - previous consent, and compensation is required in more than one scenario.

**Indonesia** - Accessor to local wisdom (TK/TCE) must inform the central government/local government the intention to have financial or non financial benefit which determined in the collective agreement from the use of Local Wisdom (TK/TCE) in a way that is correct, open, fair, balanced, sustainable, and respectful of the Indigenous Law Community or the local community.

**Malaysia** - Access to Biological Resources and Benefit Sharing Act 2017 requires for a permit to access biological resources and traditional knowledge associated with a biological resource, and requires for prior informed consent and a benefit sharing agreement to be set in place.

**Mexico** – The Federal Law for the Protection of the Cultural Heritage of Indigenous People and Afro-Mexican People and Communities and The Copyright Federal Law contemplates that an authorization from an indigenous community is needed for the use or exploitation of any type of cultural patrimony owned by indigenous communities.

**Panama** - It is imperative to sign a License Agreement, by means of which the indigenous people, as Licensor, grants to third parties, as Licensee, by written contract, a right to use a registered collective right. The Ministry of Commerce and Industry (MICI), with the express prior consent of the indigenous people's general congresses, traditional authorities, or councils, will authorize industrial reproduction, either total or partial, of registered collective rights.

**All the other reports**, indicate that there is no special regulation regarding the commercial exploitation or seek obligation to obtain an authorization from indigenous communities before using TK/TCE.

11. How are TK/TCE rights enforced in your country and what are the penalties established for infringement of those rights in your country? Could you indicate any case law or court precedent in connection with TK/TCE?

**Australia** - Remedies available are no different to those for non-TK/TCE rights. Relief available from a Court includes: injunctions (both interlocutory and permanent); declarations; damages (including additional damages for especially egregious conduct); accounts of profit; and other orders such as corrective advertising.

Case Law or court precedent *Australian Competition Consumer Commission v Birubi Art Pty Ltd* [2018]. The Federal Court order that Birubi pay \$2.3 million (plus costs) for making false or misleading representations

Other cases dealing with First Nations Australians intellectual property rights, include the following:

- *Bulun Bulun v R & T Textiles Pty Ltd* (1998) 86 FCR 244; [1998] FCA 1082 (copyright)
- *Thomas v Brown (Aboriginal Flag Case)* (1997) 37 IPR 207; [1997] FCA 215 (copyright)
- *Milpurrurru v Indofurn (Carpets Case)* (1994) 54 FCR 240; [1994] FCA 975 (copyright)
- *Yumbulul v Reserve Bank of Australia (Morning Star Pole Ten-Dollar Note Case)* (1991) 21 IPR 48; [1991] FCA 332 (copyright; misleading or deceptive conduct)

**Brazil** – Enforcement of right. Decree 8,722/2016 defines administrative infractions in Chapter VI. The fine can vary from BRL 1,000 up to 10,000,000.

**China** - TK/TCE rights mainly are civil rights, the person who infringes those rights usually should assume civil liabilities. There are some court judgments directed to dispute of copyright or trademark involving TK/TCE which are selected by the Supreme Court as typical cases, e.g. Hong Fufang et al. v. Guizhou Wufufang Food Ltd. et al. (No. Zhu Zhiminchu 17/2015), Shandong Lujin Industry Ltd. v. Zhencheng Lujin Handicraft Ltd. et al. (No. Lu Minsanzhong 34/2009).

**Colombia** - Since TK/TCE are protected under different figures, the enforcement and penalties will be according to the type of protection granted

**Denmark** - Since there is no singular legislation on the protection of TK/TCE, the enforcement of TK/TCE rights and the penalty for infringement varies depending on the statutes on which the protection is based.

Case law regarding TK/TCE is scarce, however it can be noted that regarding Trademark law the Danish Maritime and Commercial Court has rejected the registration of a closed royal crown as a trademark, as it is used by Danish authorities and the Danish royal family and the case called “Thule”-case the Indigenous *inughuit* population “Thule”-tribe.

**Luxembourg** - National courts have jurisdiction for the enforcement of IP rights and may grant damages in case of infringement

**Malaysia** - Enforcement of rights is based on any existing IP rights that could possibly be linked to TK/TCEs. To our knowledge there is no case law/court precedent in this area.

**Mexico** – Enforcement of rights (administrative infringements, civil and criminal complaints), are based on “Federal Law for the Protection of the Cultural Heritage of Indigenous and Afro-Mexican People and Communities” IP Laws, and Criminal Code. They are fines and criminal sanctions by the unauthorized exploitation of a TCE.

**Panama** - The law prohibits the importation of non-original reproductions of protected objects; the smuggling; the industrial reproduction, in whole or in part, of traditional dresses and other collective rights recognized by the law, unless authorized by the Ministry of Commerce and Industry, with the prior express consent of the respective indigenous general congresses and councils.

Infringing cases not covered by Customs law, Industrial Property laws or the Criminal Code shall be punished with fines from US\$1,000.00 to US\$5,000.00. Criminal Code penalizes unauthorized use of a registered TK/TCE. There are penalties of imprisonment (2 to 6 years) to whoever manufactures or assembles, distributes, or circulates a product protected by the Collective Law of Indigenous Peoples and their Traditional Knowledge, without the consent of the right holders.

Case Law the Guna Yala people, one of the most prominent indigenous people in Panama, has filed several criminal complaints with the IP District Attorney's Office against well-known local companies claiming that their collective right (TK/TCE) called MOLA (an artistic design that originated from the tradition of Guna Yala women painting their bodies with geometrical designs, which later on started being reproduced in textiles that made up Guna Yala women's blouses) was being infringed due to the alleged use (manufacturing and circulation) of that collective right without authorization, on their products, for example, coffee mugs, liquor bottles, toiletries bags.

**Philippines** - See answer to question 1(c) above. Nothing significant in terms of TK/TCE.

**Turkey**- TK/TCE rights are not protected by law in Turkey

**Vietnam** - TK/TCE rights are enforced in Vietnam as regular IP subject matters (patent, trademark, GI, copyright, etc.), which vary based on the type of protection pursued. Cancellation of a figure trademark for tile products; Patterns describing architectural drawing of the gate of a pagoda of a locality that are used for long time for tile products of that locality; An enterprise registered that combination as figure trademark for its tile product and got exclusive rights; When market of this product developed, other enterprises of that locality filed an appeal for cancellation of such figure trademark.

National groups are invited to comments on any additional issue or proposal concerning the relevant of TK/GR/TCE to IP Law.

Australia report indicates that in 2020 IP Australia, launched the Indigenous Knowledge (IK), Project to look at ways the IP System in Australia can better protect TK/TCE under the current IP legislative framework. It releases the Indigenous Knowledge Consultation Paper. It includes four key proposals to improve IP systems ability to recognized, protect, and provide a benefit to First Nations right holders and potential rights holders: 1. *Establishing an Indigenous Advisory Panel* – providing a formalized Indigenous voice to IP Australia. 2. *Measures for trademark or designs using Indigenous Knowledge* – changes to processes to ensure IK owners benefit from, or have consented to, the use of their IK as the basis for rights. 3. *New requirements to declare the source of Indigenous Knowledge used in new innovations* – to make it easier to determine if IK has been used in a patent or plant breeder's right and encourage conversations about access and benefit sharing. 4. *Labelling to promote authentic Indigenous Products* – exploring interest in label

NOTE:

It will be helpful and appreciated in the following points could be taken into consideration when editing the Group Report:

- Kindly follow the order of the questions and use the questions and numbers for each answer.
- If possible, type your answers in a different colour.
- Please send in a word document.
- In case images, need to be included high resolution (not less than 300dpi) is required for good quality printing.