Annex I: Regional and national TK and ABS-related Legislation

Legislation	**Thailand - 1999** **Act on protection and promotion of traditional Thai medicinal intelligence, H.E. 2542**	**Portugal - 2002** **Decree-Law No. 118/2002**	**South Africa - 2004** **National Environmental Management: Biodiversity Act (below: NEMB Act)** **South Africa - 2008** **Regulations on Bio-Prospecting, Access and Benefit-Sharing (below: Regulations BPABS)**	**Guyana - 2006** **An Act to provide for the recognition and protection of the collective rights of Amerindian Villages and Communities, the granting land to Amerindian Villages and Communities and the promotion of good governance within Amerindian Villages and Communities**
Objectives		**Article 1. Object** (1) This Decree establishes the legal regime for the registration, conservation, legal safeguarding and transfer of autochthonous plant material of current or potential interest to agrarian, agroforest and landscape activity, including the local varieties and spontaneously occurring material referred to in Article 2, as well as associated knowledge, [...]	**NEMB Act Chapter 1 Interpretation, Objectives and Application of Act** **Objectives of Act** 2. The objectives of this Act are - (a) within the framework of the National Environmental Management Act, to provide for - (i) the management and conservation of biological diversity within the Republic and of the components of such biological diversity; (ii) the use of indigenous biological resources in a sustainable manner; and (iii) the fair and equitable sharing among stakeholders of benefits arising from bioprospecting involving indigenous biological resources; **NEMB Act CHAPTER 6 Bioprospecting, access and benefit-sharing** **Purpose and application of Chapter** 80. (1) The purpose of this Chapter is - (a) to regulate bioprospecting involving indigenous biological resources; (b) to regulate the export from the Republic of indigenous biological resources for the purpose of bioprospecting or any other kind of research; and (c) to provide for a fair and equitable sharing by	

			stakeholders in benefits arising from bioprospecting involving indigenous biological resources.	
Subject Definition	"**traditional Thai medicinal Intelligence**" means the basic knowledge and capability concerned with traditional Thai medicine; **"traditional Thai medicine"** means the medicinal procedures concerned with examination. diagnosis, therapy. treatment or prevention or, or promotion and rehabilitation of the health of humans or animals, obstetrics, traditional Thai massage, and also includes the production traditional Thai drugs and the invention of medical devices, on the basis of knowledge or text that has been passed on from generation to generation;	**Article 2. Scope** (1) This Decree-Law applies to all local varieties and other spontaneously occurring autochthonous material of plant species that are of current or potential interest to agricultural, agroforest or landscape activity, regardless of their genotypical composition, with the exception of varieties protected by intellectual property rights or concerning which the grant of such protection is pending. **Article 3. TK** (1) TK comprises all intangible elements associated with the commercial or industrial utilization of local varieties and other autochthonous material developed in a non-systematic manner by local populations, either collectively or individually, which form part of the cultural and spiritual traditions of those populations. That includes, but is not limited to, knowledge of methods, processes, products and designations with applications in agriculture, food and industrial activities in general, including traditional crafts, commerce and services, informally associated with the use and preservation of local varieties and other spontaneously occurring autochthonous material covered by this Decree.	**NEMB Act Chapter 1 Interpretation, Objectives and Application of Act** 1.(1) In this Act, unless the context indicates otherwise - ‘‘stakeholder’’ means - (a) a person, an organ of state or a community contemplated in section 82(1)(a); or (b) an indigenous community contemplated in section 82(1)(b); **Regulations BPABS Interpretations and purpose of regulations** **Definitions** 1. In these Regulations, a word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates -. **"indigenous community"** means any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure and- (a) whose traditional uses of the indigenous biological resources to which an application for a permit relates, have initiated or will contribute to or form part of the proposed bioprospecting; or (b) whose knowledge of or discoveries about the indigenous biological resources to which an application for a permit relates are to be used for the proposed bioprospecting; **"traditional use or knowledge"** refers to the customary utilisation or knowledge of indigenous biological resources by an indigenous community, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised	**"Amerindian"** means any citizen of Guyana who - (a) belongs to any of the native or aboriginal peoples of Guyana; or (b) is a descendant of any person mentioned in paragraph (a);

			by them, and includes discoveries about the relevant indigenous biological resources by that community.	
Holder of Rights	**Section 17.** The Minister has the power to notify that formulas on traditional Thai drugs or text on traditional Thai medicine that is of benefit, or has special medical or public health value as the national formula on traditional Thai drug, or the national text on traditional Thai medicine, as the case may be. **Section 20.** Personal formula of traditional Thai drugs or personal text on traditional Thai medicine under section 16(3) may be registered for protection of intellectual property rights and may be promoted according to the provisions of this Act by applying for registration to the registrar.	**Article 9. Applicant for Registration** (1) An application for the registration of plant material covered by the provisions of Article 4(1) may be filed by any entity, whether public or private, individual or corporate, that fulfils the following conditions: (a) as required by paragraph (2) below, it represents the interests of the geographical area in which the local variety is most widely found or where the spontaneously occurring autochthonous material displays the greatest genetic variability; (b) it complies with the provisions of Article 10(3). (2) To satisfy the conditions mentioned in (1)(a) above, the applicant shall be recognized by the competent municipal chamber by means of a document affirming the entity's fitness to protect the interests referred to in paragraph (1).	**Regulations BPABS Interpretations and purpose of regulations** **Definitions** 1. In these Regulations, a word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates -. **"indigenous community"** means any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure	**Village Councils. 10.** (1) A Village Council is established to administer a Village (2) A Village Council is a body corporate. (3) In discharging its function the Village Council shall act collectively. **Functions of Village Councils. 13.** (1) The functions of a Village Council are to - [...] (d) hold for the benefit and the use of the Village all rights, titles and interests in and over Village lands; [...] (h) ensure that places and artefacts located within the Village lands and which hold sacred or cultural values to the Village are protected and cared for; (i) protect and preserve the Village's intellectual property and TK; [...]
Scope of Rights	**Section 34.** The right holder would have the sole ownership on the production of the drug and have sole right over the research, distribution, improvement or development of formulas on traditional Thai drugs or intellectual property rights of traditional Thai medicine under the registered text on traditional Thai medicine.	**Article 10. Rights and Obligations of the Owner of the Registration** (1) The entity owning the registration has the right to receive part of any benefits resulting from the use provided for in Articles 7(1) and (2). (2) The performance of any of the acts provided for in Article 7(1) in the case of registered plant material may only be authorized after the owner of the registration has been heard. (3) The owner of the registration shall be responsible for the maintenance in situ of the registered plant material [...]	**NEMB Act Chapter 1 Interpretation, Objectives and Application of Act** 1.(1) In this Act, unless the context indicates otherwise— **''bioprospecting''**, in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes - (a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application; (b) the utilisation for purposes of such research or development of any information regarding any	

			traditional uses of indigenous biological resources by indigenous communities; or (c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; **NEMB Act CHAPTER 6 Bioprospecting, access and benefit-sharing** **Purpose and application of Chapter** 80. (2) In this Chapter - ‘‘indigenous biological resources’’ - (b) excludes - (i) genetic material of human origin; (ii) any exotic animals, plants or other organisms, other than exotic animals, plants or other organisms referred to in paragraph (a)(iii); and (iii) indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture. **Regulations BPABS Definitions** 1. In these Regulations, a word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates -. **"any other kind of research"** means research other than bioprospecting and - (a) includes the systematic collection, study or investigation of indigenous biological resources, conducted under the auspices of a bona fide research institute or organisation to generate scientific knowledge; but (b) excludes incidental surveys and searches;	
Acknowledgement of Rights	**Section 15.** The Institute for Traditional Thai Medicine shall be responsible for compiling information on traditional Thai medical intelligence concerned with formulas of traditional Thai drugs and text on traditional Thai medicine from throughout the country, for registration.	**Article 4. Registration of Plant Material** (1) Plant material that falls within the scope of this Decree, as defined in Articles 2(1) and (2), may be registered in the RRGV, which shall be kept at the DGPC’s National Center for the Registration of Protected Varieties.	**Regulations BPABS Conditions subject to which issuing authorities may issue permits** 8. (1) The Minister may only issue a bioprospecting permit or an integrated export and bioprospecting permit, if the Minister is satisfied that - (a) the relevant stakeholders have been identified in accordance with the principles set out in	**Grants of land. 60.** (1) An Amerindian Community may apply in writing to the Minister for a grant of State lands provided - (a) it has been in existence for at least twenty-five years; (b) at the time of the application and for the immediately preceding five years, it

			section 82 of the Act;	comprised at least one hundred and fifty persons.
Publicly Available TK	**Section 18.** The Minister has the power to notify the formulas of traditional Thai drugs or text on traditional Thai medicine that have been widely used or whose intellectual property protection has expired under section 33, general formula of traditional Thai drugs or general text on traditional Thai medicine, as the case may be.	**Article 3. TK** (4) The registration of TK that until it is requested has not been used in industrial activities or is not publicly known outside the population or local community in which it originated shall afford its owners the right to: (i) object to its direct or indirect reproduction, imitation and/or use by unauthorized third parties for commercial purposes; (ii) assign, transfer or license the rights in the TK, including transfer by succession; (iii) exclude from protection any TK that may be covered by specific industrial property registrations.		
ABS Elements	**Section 19.** Whoever wishes to use the national traditional Thai drugs for registration and permission for production of drugs according to the Drug Law or wishes to use it for research on improvement or development of new drug formulas for commercial benefit, or wish to research the national text on traditional Thai Drugs for development and improvement for commercial benefit, shall forward their application to obtain benefits and pay fees and the remuneration for making use thereof to the licensing authority. **Section 46.** No person shall research or export controlled herbs or sell or transform them for commercial purposes, unless a licence has been obtained from the licensing authority.	**Article 7. Access to and Allocation of Benefits** (1) Access to the germ plasm of the plant material referred to in Articles 2(1) and (2) for the purposes of study, research, improvement or biotechnological applications shall be subject to prior authorization by CoTeRGAPA, the owner of the registration having been heard. (4) Access as defined in paragraphs (1) and (2) requires a fair allocation of the benefits resulting from such use, by prior agreement with the owner of the registration.	The Act and Regulations contain numerous ABS provisions which are not reproduced in this place	**Entry and access; 5.** (1) A person [...] who wishes to enter Village lands shall apply for and obtain the permission of the Village Council. (3) A person [...] who wishes to conduct any scientific, anthropological or archaeological research or any other research or study which relates to biological diversity, the environment or natural resources or to any use of knowledge thereof within Village lands shall apply for and obtain in advance - (a) permission of the Village Council; (b) all permits required under any other written law; and (c) the permission of the Minister. **Report; use of scientific and other research. 6.** (1) A person who wishes to make use of any material derived from research or study under this section shall - (a) apply for an obtain the permission of

				the Village Council, the Minister, the Minister with responsibility for culture, and the Environmental Protection Agency [...]; (b) in good faith negotiate and enter into a benefit sharing agreement with the Village Council.
Positive IPR Elements	**Section 14.** The intellectual property rights on traditional Thai medicine to be protected under this Act shall be the right to intellectual property over the formula of traditional Thai drugs and text on traditional Thai medicine. **Section 16.** There shall be three types of traditional Thai medicinal intellectual property rights as follows: (1) the national formula of traditional Thai drugs or the national text on traditional Thai Medicine; (2) general formula of traditional Thai drugs or general traditional Thai medicine document; and Thai medicine document; and (3) personal formula of traditional Thai drugs or personal text on traditional Thai medicine.			**Powers of Village Council to make rules. 14.** (1) Subject to the other provisions of this Act, a Village Council may, in the exercise of its functions, make rules governing - [...] (n) the certification of products made by residents using traditional methods;
Defensive IPR Elements	**Section 22.** Registration for protection of intellectual property rights on traditional Thai medicine is prohibited if the registrar is of the opinion that: (1) the drug formula belongs to the national formula on traditional Thai drugs, or national text on traditional Thai medicine, or is a general formula on traditional Thai drug, or general text on traditional Thai medicine, or (2) the drug formula is a personal formula on traditional Thai drug that has been developed on non-medical basis like the use of extracts of plants, animals	**Article 3. TK** (2) That knowledge shall be protected against reproduction or commercial or industrial use or both as long as the following conditions of protection are met: (a) the TK shall be identified, described and registered in the Register of Plant Genetic Resources (RRGV); (b) the description referred to above shall be so phrased that third parties may reproduce or utilize the TK and obtain results identical to those obtained by the owner of the		**Powers of Village Council to make rules. 14.** (1) Subject to the other provisions of this Act, a Village Council may, in the exercise of its functions, make rules governing - [...] (m) access to research into and recording and publication of intellectual property and TK which belongs to the Village;

	or microorganisms that have not be obtained from natural extracts or the transformation that is not considered rough transformation.	knowledge.		

Issues	**Andean Community 2002** **Decision 391 Common Regime on Access to Genetic Resources**	**Pacific Islands Forum - 2008** **Traditional Biological Knowledge, Innovations and Practices Act**	**African Regional Intellectual Property Organization - 2010** **Swakopmund Protocol on the Protection of TK and Expressions of Folklore**
Objectives / Purpose	**Article 2**.- The purpose of this Decision is to regulate access to the genetic resources of the Member Countries and their by-products, in order to: a) Establish the conditions for just and equitable participation in the benefits of the access; b) Lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved;	to protect the rights of owners of traditional biological knowledge, innovations, and practices	**Section 1 Purpose of Protocol** 1.1. The purpose of this Protocol is: (a) to protect TK holders against any infringement of their rights as recognized by this Protocol; and (b) to protect expressions of folklore against misappropriation, misuse and unlawful exploitation beyond their traditional context.
Subject Definition	**BIOLOGICAL RESOURCES**: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products. INTANGIBLE COMPONENT: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes. **NATIVE, AFRO-AMERICAN OR LOCAL COMMUNITY:** a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them.	**4 Definitions** **traditional biological knowledge** means knowledge whether embodied in tangible form or not, belonging to a social group [which means: family, clan, tribe, village or similar social organisation] and gained from having lived in close contact with nature, regarding: (a) living things, their spiritual significance, their constituent parts, their life cycles, behaviour and functions, and their effects on and interactions with other living things, including humans, and with their physical environment; (b) the physical environment; (c) the obtaining and utilising of living or non-living things for the purpose of maintaining, facilitating or improving human life. **traditional biological innovation** means a product, belonging to a social group, which has resulted from biological material whose usefulness has been enhanced by the application of traditional biological knowledge.	**Section 2 Definitions** **"TK"** shall refer to any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources.

		traditional biological practice means a process, method or way of doing things, belonging to a social group and gained from having lived in close contact with nature.	
Holder of Rights	**Article 5.**- The Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision. **Article 7**.- The Member Countries, in keeping with this Decision and their complementary national legislation, recognize and value the rights and the authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products.	**6 Ownership** (1) For the purposes of this Act, ownership by a social group [which is a family, clan, tribe, village or similar social organisation] over an item of knowledge or an innovation or a practice is established according to the history and traditions and customs and usages of that social group.	**Section 6 Beneficiaries of protection of TK** The owners of the rights shall be the holders of TK, namely the local and traditional communities, and recognized individuals within such communities, who create, preserve and transmit knowledge in a traditional and intergenerational context in accordance with the provisions of section 4.
Scope of Rights	**Article 3.**- This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their by-products, to their intangible components and to the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries.		**Section 4 Protection criteria for TK** Protection shall be extended to TK that is: (i) generated, preserved and transmitted in a traditional and intergenerational context; (ii) distinctively associated with a local or traditional community; and (iii) integral to the cultural identity of a local or traditional community that is recognized as holding the knowledge through a form of custodianship, guardianship or collective and cultural ownership or responsibility. Such a relationship may be established formally or informally by customary practices, laws or protocols. **Section 7 Rights conferred to holders of TK** 7.1. This Protocol shall confer on the owners of rights referred to in section 6 the exclusive right to authorize the exploitation of their TK. 7.2. In addition, owners shall have the right to prevent anyone from exploiting their TK without their prior informed consent. 7.3. For the purposes of this Protocol, the term “exploitation” with reference to TK shall refer to any of the following acts:

			(a) Where the TK is a product: [...] (b) Where the TK is a process: [...]
Acknowledgement of Rights		**4 Definitions** own in relation to knowledge, innovations and practices, includes the following: (a) own as a trustee; (b) own as a custodian; (c) own as a steward; and its meaning in any particular context is to be determined according to the history and traditions and customs and usages of the social group which claims ownership over that knowledge, innovation or practice. **10 Identity of owner and prior informed consent** (3) Any social group claiming ownership must identify itself to the [Competent National Authority] within 30 days from the date the application is publicised and satisfy the [Competent National Authority] of its claim to ownership.	**Section 4 Protection criteria for TK** Protection shall be extended to TK that is: (iii) integral to the cultural identity of a local or traditional community that is recognized as holding the knowledge through a form of custodianship, guardianship or collective and cultural ownership or responsibility. Such a relationship may be established formally or informally by customary practices, laws or protocols.
Publicly available TK		**6 Ownership** (2) The [Competent National Authority] may assert ownership over an item of knowledge or an innovation or a practice in either of the following situations: (a) where it is satisfied there is no immediately verifiable owner of that knowledge or innovation or practice. The [Competent National Authority] will be considered to be the owner for the purposes of this Act of that knowledge or innovation or practice as trustee on behalf of the eventual owner. (b) where it is satisfied, after having made extensive efforts to locate an owner of an item of knowledge or an innovation or a practice, that an owner will not be found. The [Competent National Authority] will be considered to be the owner for the purposes of this Act of that knowledge or innovation or practice as trustee on behalf of [the enacting country].	Not covered by Section 4
ABS Elements	**TITLE V ON THE ACCESS PROCEDURE** **TITLE VI ON THE ANCILLARY CONTRACTS TO THE ACCESS CONTRACT**	**10 Identity of owner and prior informed consent** (1) A prospective user wanting to use an item of knowledge, an innovation or a practice for a commercial purpose, or an activity that is likely to assist in achieving a commercial purpose, must in all	**Section 9 Equitable benefit-sharing** 9.1. The protection to be extended to TK holders shall include the fair and equitable sharing of benefits arising from the commercial or industrial use of their knowledge, to be determined by mutual agreement

	TITLE VII ON THE LIMITATIONS TO ACCESS	cases apply to the [Competent National Authority] in the form prescribed by the [Competent National Authority]. **11 Access and Benefit Sharing Agreement** (1) Where the owner gives its prior informed consent to the proposed use, an agreement between the owner and the user, to be known as an Access and Benefit-Sharing Agreement, must be negotiated under the supervision of the [Competent National Authority] setting out the terms under which use is permitted and having regard to the following matters, amongst others:	between the parties. **Section 15 Access to TK associated with genetic resources** Authorization under this Protocol to access protected TK associated with genetic resources shall not imply authorization to access the genetic resources derived from the TK.
Positive IPR Elements		**8 Economic rights** (1) In addition to any rights available under applicable intellectual property laws an owner of an item of knowledge, an innovation or a practice has the exclusive right to use or to authorise the use of its knowledge, innovation or practice: (a) for a commercial purpose, or (b) for an activity that is likely to assist in achieving a commercial purpose.	**PART II: PROTECTION OF TK**
Defensive IPR Elements	**Complementary Provisions** **SECOND.-** The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of this Decision. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents. **THIRD.-** The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained	**7 Database of traditional biological knowledge, innovations and practices** (1) The [Competent National Authority] is to establish and maintain a database of knowledge, innovations and practices and shall enter into it such information as it receives or collects pertaining to knowledge, innovations and practices. (2) An owner may enter its knowledge, innovations and practices in the database. (3) Where the owner does not specify who can access the information, access will be limited to the owner. The [Competent National Authority] may also access the information for the purpose only of seeking the identity of an owner pursuant to section 10 of this Act. **3 Application** (1) Where there is an inconsistency with intellectual property laws, this Act, is to the extent of the	**Section 5 Formalities relating to protection of TK** 5.2. In the interests of transparency, evidence and the preservation of TK, relevant national competent authorities of Contracting States and ARIPO Office may maintain registers or other records of the knowledge, where appropriate and subject to relevant policies, laws and procedures, and the needs and aspirations of the TK holders concerned. **Section 10 Recognition of knowledge holders** Any person using TK beyond its traditional context shall acknowledge its holders, indicate its source and, where possible, its origin, and use such knowledge in a manner that respects the cultural values of its holders.

	or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries. The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.	inconsistency, to prevail.	

Annex II: WHO's Standard Material Transfer Agreements

SMTA 1

Standard Material Transfer Agreement within the WHO GISRS (SMTA 1)

In furtherance of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the "Framework"), this Standard Material Transfer Agreement ("Agreement" or "SMTA 1") has been developed.

Article 1. Parties to the Agreement

1.1 Parties to SMTA 1 are limited to influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO terms of reference. In this Agreement: The Provider is the laboratory sending Materials, as herein defined, (name and address of the provider or providing institution, designation of the laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory), name of authorized official, contact information for authorized official) (hereinafter referred to as "the Provider")[311]

and

The Recipient is the laboratory receiving Materials, as herein defined, (name and address of the recipient or recipient institution, designation of the laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory), name of authorized official, contact information for authorized official) (hereinafter referred to as "the Recipient")[312]

1.2 Provider and Recipient are hereafter collectively referred to as "Parties".

Article 2. Subject Matter of the Agreement

PIP biological materials as defined in Section 4.1 of the Framework (hereinafter "Materials") transferred from the Provider to the Recipient are subject to the provisions of this Agreement.

Article 3. General Provisions

The Provider or recipient will consider support to the strengthening of the laboratory and surveillance capacity of the networks of developing countries.

Article 4. Rights and Obligations of the Provider

4.1 The Provider undertakes the following with respect to the Materials:

4.1.1. To comply with its respective WHO GISRS terms of reference.
4.1.2. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.[313]

4.2. The Provider agrees to the onward transfer and use of the Materials, to all members of the WHO GISRS, on the same terms and conditions as those provided in SMTA 1.

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[311] To be completed if signature is required pursuant to Article 11 below.
[312] To be completed if signature is required pursuant to Article 11 below.
[313] "WHO Guidance on Regulations for the Transport of Infectious Substances". Document WHO/CDS/EPR/2007.2. Geneva, World Health Organization 2007 and "WHO Guidelines for the collection of human specimens for laboratory diagnosis of avian influenza infection". See http://www.who.int/csr/resources/publications/swineflu/storage_transport/en/index.html.

4.3 The Provider consents to the onward transfer and use of the Materials to entities outside the WHO GISRS on the condition that the prospective recipient has concluded an SMTA 2.

4.4. The Provider shall inform the WHO of shipments of Materials to entities inside/outside the WHO GISRS by recording in the IVTM.

Article 5. Rights and Obligations of the Recipient

5.1 The Recipient undertakes the following with respect to the Materials:

5.1.1 To comply with its respective WHO GISRS terms of reference.
5.1.2. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.
5.1.3. To inform WHO of shipments of Materials to entities inside/outside the WHO GISRS by recording in the IVTM
5.1.4 In the event of further transfers within the WHO GISRS, to do so in accordance with SMTA 1.

5.2. The Recipient shall actively seek the participation of scientists to the fullest extent possible from originating laboratories and other authorized laboratories, especially those from developing countries, in scientific projects associated with research on clinical specimens and/or influenza virus from their countries and actively engage them in preparation of manuscripts for presentation and publication.

5.3. The Recipient shall appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza virus with pandemic potential or reagents, using existing scientific guidelines.

Article 6. Intellectual Property Rights

6.1 Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials.

6.2 The Provider and the Recipient acknowledge that any IPRs on the Materials obtained before the date of adoption of the Framework by the World Health Assembly will not be affected by SMTA 1.

6.3 The Provider under SMTA 1 may have used technology protected by IPRs for the generation and/or modification of the Materials. Any recipient of such Materials acknowledges that such IPRs shall be respected.

Article 7. Dispute resolution

7.1. In the event of a dispute under SMTA 1, Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other amicable means of their own choice. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

7.2. In the event that the dispute is not settled by the means described under paragraph 1 of this Article, one of the Parties concerned may refer the dispute to the Director-General, who may seek advice of the Advisory Group with a view to settling it. The Director-General may make recommendations to the Parties regarding its resolution and shall report to the World Health Assembly on any such matters.
7.3. The Parties also acknowledge the role of the Director-General under the Framework, in particular 7.3.4.

Article 8. Warranty

The Provider makes no warranties as to the safety of the Materials, or as to the accuracy or correctness of any data provided with them. Likewise, the provider does not make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Materials being furnished. The Provider and the Recipient assume full responsibility for complying with their respective national biosecurity and biosafety regulations and rules as to import, export or release of biological materials.

Article 9. Duration of Agreement

This contractual agreement shall remain in force until December 31, 2021 and shall be automatically renewed until December 31, 2031 unless the World Health Assembly decides otherwise.

Article 10. Acceptance and Applicability

10.1.1 Recipients or Providers in the WHO GISRS at the time of the adoption of the Framework by the World Health Assembly: Acceptance by such laboratories of their WHO terms of reference, as contained in the Framework, constitutes acceptance of SMTA 1.
10.1.2 Recipients or Providers that join the WHO GISRS after adoption of the Framework by the World Health Assembly: Acceptance of designation or recognition by WHO to become a WHO GISRS laboratory will constitute acceptance of SMTA 1.

10.2. Applicability: SMTA 1 shall cease to be applicable only upon suspension or revocation of designation or recognition by WHO or upon formal withdrawal by the laboratory of its participation in the WHO GISRS or upon mutual agreement of the WHO and the laboratory. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under SMTA 1.

Article 11. Signature

Further to Article 10 above entitled "Acceptance & Applicability", unless either party requires this Agreement to be executed by signature of a printed document, no further evidence of acceptance is required.

SMTA 2
Standard Material Transfer Agreement outside WHO GISRS (SMTA 2)

Article 1. Parties to the Agreement

WHO and Recipient.[314]

Article 2. Subject matter of the Agreement

PIP biological materials as defined in Section 4.1 of the Framework (hereinafter "Materials") transferred to the Recipient are subject to the provisions of this Agreement.

Article 2. bis Definitions

(a) As provided for in Section 4 of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits.

(b) Other terms as agreed by the parties.

Article 3. Obligations of the Provider

To be agreed by the parties.

Article 4. Obligations of the Recipient

4.1 The recipient agrees to comply with the commitments selected below, in accordance with the terms set out in the Annex to this agreement.

4.1.1 The recipient shall comply with the commitments selected on a timetable determined by the WHO in consultation with the Advisory Group established by the PIP Framework and in coordination with the recipient, based on optimal pandemic preparedness and response considerations.

A. For manufacturers of vaccines and/or antivirals, the recipient shall commit to at least two of the following options:

A1. Donate at least 10%[315] of real time pandemic vaccine production to WHO

A2. Reserve at least 10%[316] of real time pandemic vaccine production at affordable prices to WHO

A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO

A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices

A5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of

[314] Recipients are all entities that receive "PIP Biological Materials" from the WHO GISRS, such as influenza vaccine, diagnostic and pharmaceutical manufacturers, as well as biotechnology firms, research institutions and academic institutions. Each recipient shall select options based on its nature and capacities.
[315] Recognizing that flexibility is important in negotiating with all manufacturers, in a range of 5-20%.
[316] Recognizing that flexibility is important in negotiating with all manufacturers, in a range of 5–20%.

affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.

A6. Grant royalty free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.

Where Option 5 or 6 is selected, the Recipient shall regularly provide to WHO information on granted licenses and the status of implementation of the licensing agreement. WHO shall provide such information to the Advisory Group.

B. Manufacturers of products relevant to pandemic influenza preparedness and response, that are not manufacturing vaccines or antivirals, shall commit to one of the following options: A5, A6, B1, B2, B3, B4.

B1. Donate to WHO at least X[317] diagnostic kits needed for pandemics

B2. Reserve for WHO at least X[318] diagnostic kits needed for pandemics, at affordable prices

B3. Support, in coordination with WHO, the strengthening of influenza specific laboratory and surveillance capacity in developing countries

B4. Support, in coordination with WHO, transfer of technology, know-how and/or processes for pandemic influenza preparedness and response in developing countries

C. The recipient shall, in addition to the commitments selected under A or B above, consider contributing to the measures listed below, as appropriate:

• Donations of vaccines
• Donations pre-pandemic vaccines

1
2

• Donations of antivirals
• Donations of medical devices
• Donations of diagnostic kits
• Affordable pricing
• Transfer of technology and processes
• Granting of sublicenses to WHO
• Laboratory and surveillance capacity building.

4.2 The Recipient shall ensure that the PIP biological materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.

4.3 If applicable, the Recipient shall appropriately acknowledge in presentations and publications, the contributions of WHO laboratories providing the materials identified in Article 2, using existing scientific guidelines.

[317] Recognizing that flexibility is important in negotiating with all manufacturers.
[318] Recognizing that flexibility is important in negotiating with all manufacturers.

4.4 The recipient shall only further transfer the PIP biological materials if the prospective recipient has concluded an SMTA with the World Health Organization. Any such further transfer shall be reported to the World Health Organization. The Director-General may, under exceptional circumstances, allow the PIP biological materials to be transferred to a prospective recipient while requesting this aforementioned recipient to enter into an SMTA, and report to the "Advisory Group" accordingly.

4.5 The recipient may exchange PIP biological materials with any other holder of an SMTA concluded with the World Health Organization.

Article 5. Dispute Resolution

If a dispute cannot be resolved through negotiations or other non-binding means of the parties' choice, disputes shall be subject to binding arbitration on conditions that are mutually agreed by the parties.

Article 6. Liability and Indemnity
To be agreed by the parties.

Article 7. Privileges and immunity

Nothing in or relating to these clauses shall imply the obligation of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.

Article 8. Name and Emblem
To be agreed by the parties.

Article 9. Warranties
To be agreed by the parties

Article 10. Duration of Agreement
To be agreed by the parties.

Article 11. Termination
To be agreed by the parties.

Article 12. Force Majeure
To be agreed by the parties.

Article 13. Governing law
To be agreed by the parties.

Article 14. Signature and Acceptance

In WITNESS Whereof, this Agreement has been duly executed by the parties.

SIGNED for and on behalf of WHO

Signature

Name

Title

SIGNED for and on behalf of Recipient

Signature

Name

Title

****

Annex

To be agreed by the parties.

Annex III: Standard Material Transfer Agreement under the ITPGRFA

STANDARD MATERIAL TRANSFER AGREEMENT UNDER THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

PREAMBLE

WHEREAS
The International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as "the **Treaty**")[319] was adopted by the Thirty-first session of the FAO Conference on 3 November 2001 and entered into force on 29 June 2004;

The objectives of the **Treaty** are the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture** and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security;

The Contracting Parties to the **Treaty**, in the exercise of their sovereign rights over their **Plant Genetic Resources for Food and Agriculture**, have established a **Multilateral System** both to facilitate access to **Plant Genetic Resources for Food and Agriculture** and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis;

Articles 4, 11, 12.4 and 12.5 of the **Treaty** are borne in mind;

The diversity of the legal systems of the Contracting Parties with respect to their national procedural rules governing access to courts and to arbitration, and the obligations arising from international and regional conventions applicable to these procedural rules, are recognized;

Article 12.4 of the **Treaty** provides that facilitated access under the **Multilateral System** shall be provided pursuant to a Standard Material Transfer Agreement, and the **Governing Body** of the **Treaty**, in its Resolution 1/2006 of 16 June 2006, adopted the Standard Material Transfer Agreement.

[319] Note by the Treaty Secretariat: as suggested by the Legal Working Group during the Contact Group for the Drafting of the Standard Material Transfer Agreement, defined terms have, for clarity, been put in bold throughout.

ARTICLE 1 — PARTIES TO THE AGREEMENT

1.1 The present Material Transfer Agreement (hereinafter referred to as "**this Agreement**") is the Standard Material Transfer Agreement referred to in Article 12.4 of the **Treaty**.

1.2 **This Agreement** is:

> BETWEEN: (name and address of the provider or providing institution, name of authorized official, contact information for authorized official [320]) (hereinafter referred to as "the **Provider**"),
> AND: (name and address of the recipient or recipient institution, name of authorized official, contact information for authorized official[321]) (hereinafter referred to as "the **Recipient**").

1.3 The parties to **this Agreement** hereby agree as follows:

ARTICLE 2 — DEFINITIONS

In **this Agreement** the expressions set out below shall have the following meaning:

"Available without restriction": a **Product** is considered to be available without restriction to others for further research and breeding when it is available for research and breeding without any legal or contractual obligations, or technological restrictions, that would preclude using it in the manner specified in the **Treaty**.

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

"Governing Body" means the **Governing Body** of the **Treaty**.

"Multilateral System" means the **Multilateral System** established under Article 10.2 of the **Treaty**.

"Plant Genetic Resources for Food and Agriculture" means any **genetic material** of plant origin of actual or potential value for food and agriculture.

"Plant Genetic Resources for Food and Agriculture under Development" means material derived from the **Material**, and hence distinct from it, that is not yet ready for **commercialization** and which the developer intends to further develop or to transfer to another person or entity for further development. The period of development for the **Plant Genetic Resources for Food and Agriculture under Development** shall be deemed to have ceased when those resources are **commercialized** as a **Product**.

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[320] Insert as necessary. Not applicable for shrink-wrap and click-wrap Standard Material Transfer Agreements.

- A "shrink-wrap" Standard Material Transfer Agreement is where a copy of the Standard Material Transfer Agreement is included in the packaging of the **Material**, and the **Recipient's** acceptance of the **Material** constitutes acceptance of the terms and conditions of the Standard Material Transfer Agreement.
- A "click-wrap" Standard Material Transfer Agreement is where the agreement is concluded on the internet and the **Recipient** accepts the terms and conditions of the Standard Material Transfer Agreement by clicking on the appropriate icon on the website or in the electronic version of the Standard Material Transfer Agreement, as appropriate.

[321] Ibid.

"Product" means **Plant Genetic Resources for Food and Agriculture** that incorporate[322] the **Material** or any of its genetic parts or components that are ready for **commercialization**, excluding commodities and other products used for food, feed and processing.

"Sales" means the gross income resulting from the **commercialization** of a **Product** or **Products**, by the **Recipient**, its affiliates, contractors, licensees and lessees.

"**To commercialize**" means to sell a **Product** or **Products** for monetary consideration on the open market, and "**commercialization**" has a corresponding meaning. **Commercialization** shall not include any form of transfer of **Plant Genetic Resources for Food and Agriculture under Development**.

ARTICLE 3 — SUBJECT MATTER OF THE MATERIAL TRANSFER AGREEMENT

The **Plant Genetic Resources for Food and Agriculture** specified in Annex 1 to **this Agreement** (hereinafter referred to as the "**Material**") and the available related information referred to in Article 5b and in Annex 1 is hereby transferred from the **Provider** to the **Recipient** subject to the terms and conditions set out in **this Agreement**.

ARTICLE 4 — GENERAL PROVISIONS

4.1 **This Agreement** is entered into within the framework of the **Multilateral System** and shall be implemented and interpreted in accordance with the objectives and provisions of the **Treaty**.

4.2 The parties recognize that they are subject to the applicable legal measures and procedures, that have been adopted by the Contracting Parties to the **Treaty**, in conformity with the **Treaty**, in particular those taken in conformity with Articles 4, 12.2 and 12.5 of the **Treaty**.[3233]

4.3 The parties to **this Agreement** agree that (the entity designated by the **Governing Body**),[324] acting on behalf of the **Governing Body** of the **Treaty** and its **Multilateral System**, is the third party beneficiary under **this Agreement**.

4.4 The third party beneficiary has the right to request the appropriate information as required in Articles 5e, 6.5c, 8.3 and Annex, 2 paragraph 3, to **this Agreement**.

4.5 The rights granted to the (the entity designated by the **Governing Body**) above do not prevent the **Provider** and the **Recipient** from exercising their rights under **this Agreement**.

ARTICLE 5 — RIGHTS AND OBLIGATIONS OF THE PROVIDER

The **Provider** undertakes that the **Material** is transferred in accordance with the following provisions of the **Treaty**:

[322] As evidenced, for example, by pedigree or notation of gene insertion.

[323] In the case of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) and other international institutions, the Agreement between the Governing Body and the CGIAR Centres and other relevant institutions will be applicable.

[324] Note by the Treaty Secretariat: by Resolution 2/2006, the Governing Body "invite[d] the Food and Agriculture Organization of the United Nations, as the Third Party Beneficiary, to carry out the roles and responsibilities as identified and prescribed in the Standard Material Transfer Agreement, under the direction of the Governing Body, in accordance with the procedures to be established by the Governing Body at its next session". Upon acceptance by the FAO of this invitation, the term, "the entity designated by the Governing Body", will be replaced throughout the document by the term, "the Food and Agriculture Organization of the United Nations".

a) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;
b) All available passport data and, subject to applicable law, any other associated available non-confidential descriptive information, shall be made available with the **Plant Genetic Resources for Food and Agriculture** provided;
c) Access to **Plant Genetic Resources for Food and Agriculture under Development**, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development;
d) Access to **Plant Genetic Resources for Food and Agriculture** protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;
e) The **Provider** shall periodically inform the **Governing Body** about the Material Transfer Agreements entered into, according to a schedule to be established by the **Governing Body**. This information shall be made available by the **Governing Body** to the third party beneficiary.[325]

ARTICLE 6 — RIGHTS AND OBLIGATIONS OF THE RECIPIENT

6.1 The **Recipient** undertakes that the **Material** shall be used or conserved only for the purposes of research, breeding and training for food and agriculture. Such purposes shall not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

6.2 The **Recipient** shall not claim any intellectual property or other rights that limit the facilitated access to the **Material** provided under **this Agreement**, or its genetic parts or components, in the form received from the **Multilateral System**.

6.3 In the case that the **Recipient** conserves the **Material** supplied, the **Recipient** shall make the **Material**, and the related information referred to in Article 5b, available to the **Multilateral System** using the Standard Material Transfer Agreement.

6.4 In the case that the **Recipient** transfers the **Material** supplied under **this Agreement** to another person or entity (hereinafter referred to as "the **subsequent recipient**"), the **Recipient** shall

a) do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement; and
b) notify the **Governing Body**, in accordance with Article 5e.

On compliance with the above, the **Recipient** shall have no further obligations regarding the actions of the **subsequent recipient**.

6.5 In the case that the **Recipient** transfers a **Plant Genetic Resource for Food and Agriculture under Development** to another person or entity, the **Recipient** shall:

a) do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement, provided that Article 5a of the Standard Material Transfer Agreement shall not apply;

[325] Note by the Secretraiat: The Standard Material Transfer Agreement makes provision for information to be provided to the **Governing Body**, in the following Articles: 5e, 6.4b, 6.5c and 6.11h, as well as in Annex 2, paragraph 3, Annex 3, paragraph 4, and in Annex 4. Such informationshould be submitted to: The Secretary International Treaty on Plant Genetic Resources for Food and Agriculture Food and Agriculture Organization of the United Nations I-00100 Rome, Italy

b) identify, in Annex 1 to the new material transfer agreement, the **Material** received from the **Multilateral System**, and specify that the **Plant Genetic Resources for Food and Agriculture under Development** being transferred are derived from the **Material**;
c) notify the **Governing Body**, in accordance with Article 5e; and
d) have no further obligations regarding the actions of any **subsequent recipient**.

6.6 Entering into a material transfer agreement under paragraph 6.5 shall be without prejudice to the right of the parties to attach additional conditions, relating to further product development, including, as appropriate, the payment of monetary consideration.

6.7 In the case that the **Recipient commercializes** a **Product** that is a **Plant Genetic Resource for Food and Agriculture** and that incorporates **Material** as referred to in Article 3 of **this Agreement**, and where such **Product** is not **available without restriction** to others for further research and breeding, the **Recipient** shall pay a fixed percentage of the **Sales** of the **commercialized Product** into the mechanism established by the **Governing Body** for this purpose, in accordance with Annex 2 to **this Agreement**.

6.8 In the case that the **Recipient commercializes** a **Product** that is a **Plant Genetic Resource for Food and Agriculture** and that incorporates **Material** as referred to in Article 3 of **this Agreement** and where that **Product** is **available without restriction** to others for further research and breeding, the **Recipient** is encouraged to make voluntary payments into the mechanism established by the **Governing Body** for this purpose in accordance with Annex 2 to **this Agreement**.

6.9 The **Recipient** shall make available to the **Multilateral System**, through the information system provided for in Article 17 of the **Treaty**, all non-confidential information that results from research and development carried out on the **Material**, and is encouraged to share through the **Multilateral System** non-monetary benefits expressly identified in Article 13.2 of the **Treaty** that result from such research and development. After the expiry or abandonment of the protection period of an intellectual property right on a **Product** that incorporates the **Material**, the **Recipient** is encouraged to place a sample of this **Product** into a collection that is part of the **Multilateral System**, for research and breeding.

6.10 A **Recipient** who obtains intellectual property rights on any **Products** developed from the **Material** or its components, obtained from the **Multilateral System**, and assigns such intellectual property rights to a third party, shall transfer the benefit-sharing obligations of **this Agreement** to that third party.

6.11 The **Recipient** may opt as per Annex 4, as an alternative to payments under Article 6.7, for the following system of payments:

a) The **Recipient** shall make payments at a discounted rate during the period of validity of the option;
b) The period of validity of the option shall be ten years renewable in accordance with Annex 3 to **this Agreement**;
c) The payments shall be based on the **Sales** of any **Products** and of the sales of any other products that are **Plant Genetic Resources for Food and Agriculture** belonging to the same crop, as set out in Annex 1 to the **Treaty**, to which the **Material** referred to in Annex 1 to **this Agreement** belongs;
d) The payments to be made are independent of whether or not the **Product** is **available without restriction**;
e) The rates of payment and other terms and conditions applicable to this option, including the discounted rates are set out in Annex 3 to **this Agreement**;
f) The **Recipient** shall be relieved of any obligation to make payments under Article 6.7 of **this Agreement** or any previous or subsequent Standard Material Transfer Agreements entered into in respect of the same crop;

g) After the end of the period of validity of this option the **Recipient** shall make payments on any **Products** that incorporate **Material** received during the period in which this Article was in force, and where such **Products** are not **available without restriction**. These payments will be calculated at the same rate as in paragraph (a) above;
h) The **Recipient** shall notify the **Governing Body** that he has opted for this modality of payment. If no notification is provided the alternative modality of payment specified in Article 6.7 will apply.

ARTICLE 7 — APPLICABLE LAW

The applicable law shall be General Principles of Law, including the UNIDROIT Principles of International Commercial Contracts 2004, the objectives and the relevant provisions of the **Treaty**, and, when necessary for interpretation, the decisions of the **Governing Body**.

ARTICLE 8 — DISPUTE SETTLEMENT

8.1 Dispute settlement may be initiated by the **Provider** or the **Recipient** or the (the entity designated by the **Governing Body**), acting on behalf of the **Governing Body** of the **Treaty** and its **Multilateral System**.

8.2 The parties to **this Agreement** agree that the (the entity designated by the **Governing Body**), representing the **Governing Body** and the **Multilateral System**, has the right, as a third party beneficiary, to initiate dispute settlement procedures regarding rights and obligations of the **Provider** and the **Recipient** under **this Agreement**.

8.3 The third party beneficiary has the right to request that the appropriate information, including samples as necessary, be made available by the **Provider** and the **Recipient**, regarding their obligations in the context of **this Agreement**. Any information or samples so requested shall be provided by the **Provider** and the **Recipient**, as the case may be.

8.4 Any dispute arising from **this Agreement** shall be resolved in the following manner:

a) Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation.
b) Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed.
c) Arbitration: If the dispute has not been settled by negotiation or mediation, any party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. Either party to the dispute may, if it so chooses, appoint its arbitrator from such list of experts as the Governing Body may establish for this purpose; both parties, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

ARTICLE 9 — ADDITIONAL ITEMS

Warranty
9.1 The **Provider** makes no warranties as to the safety of or title to the **Material**, nor as to the accuracy or correctness of any passport or other data provided with the **Material**. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the **Material** being

furnished. The phytosanitary condition of the **Material** is warranted only as described in any attached phytosanitary certificate. The **Recipient** assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of **genetic material**.

Duration of Agreement

9.2 **This Agreement** shall remain in force so long as the **Treaty** remains in force.

ARTICLE 10 — SIGNATURE/ACCEPTANCE

The **Provider** and the **Recipient** may choose the method of acceptance unless either party requires **this Agreement** to be signed.

Option 1 –Signature*

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute **this Agreement** on behalf of the **Provider** and acknowledge my institution's responsibility and obligation to abide by the provisions of **this Agreement**, both by letter and in principle, in order to promote the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture**.

Signature..... Date.....

Name of the **Provider** ……

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute **this Agreement** on behalf of the **Recipient** and acknowledge my institution's responsibility and obligation to abide by the provisions of **this Agreement**, both by letter and in principle, in order to promote the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture**.

Signature..... Date.....

Name of the **Recipient**……

Option 2 – Shrink-wrap Standard Material Transfer Agreements*

The **Material** is provided conditional on acceptance of the terms of **this Agreement**. The provision of the **Material** by the **Provider** and the **Recipient's** acceptance and use of the **Material** constitutes acceptance of the terms of **this Agreement**.

Option 3 – Click-wrap Standard Material Transfer Agreement[326]

□ I hereby agree to the above conditions.

[326] Where the **Provider** chooses signature, only the wording in Option 1 will appear in the Standard Material Transfer Agreement. Similarly where the **Provider** chooses either shrink-wrap or click-wrap, only the wording in Option 2 or Option 3, as appropriate, will appear in the Standard Material Transfer Agreement. Where the "click-wrap" form is chosen, the **Material** should also be accompanied by a written copy of the Standard Material Transfer Agreement.

Annex 1

LIST OF MATERIALS PROVIDED

This Annex contains a list of the **Material** provided under **this Agreement**, including the associated information referred to in Article 5b.

This information is either provided below or can be obtained at the following website: (URL).

The following information is included for each **Material** listed: all available passport data and, subject to applicable law, any other associated, available, non-confidential descriptive information.

(List)

Annex 2

RATE AND MODALITIES OF PAYMENT UNDER ARTICLE 6.7 OF THIS AGREEMENT

1. If a **Recipient**, its affiliates, contractors, licensees, and lessees, **commercializes** a **Product** or **Products**, then the **Recipient** shall pay one point-one percent (1.1 %) of the **Sales** of the **Product** or **Products** less thirty percent (30%); except that no payment shall be due on any **Product** or **Products** that:

(a) are **available without restriction** to others for further research and breeding in accordance with Article 2 of **this Agreement**;
(b) have been purchased or otherwise obtained from another person or entity who either has already made payment on the **Product** or **Products** or is exempt from the obligation to make payment pursuant to subparagraph (a) above;
(c) are sold or traded as a commodity.

2. Where a **Product** contains a **Plant Genetic Resource for Food and Agriculture** accessed from the **Multilateral System** under two or more material transfer agreements based on the Standard Material Transfer Agreement only one payment shall be required under paragraph 1 above.

3. The **Recipient** shall submit to the **Governing Body**, within sixty (60) days after each calendar year ending December 31st, an annual report setting forth:

(a) the **Sales** of the **Product** or **Products** by the **Recipient**, its affiliates, contractors, licensees and lessees, for the twelve (12) month period ending on December 31st;
(b) the amount of the payment due; and
(c) information that allows for the identification of any restrictions that have given rise to the benefit-sharing payment.

4. Payment shall be due and payable upon submission of each annual report. All payments due to the **Governing Body** shall be payable in United States dollars (US$)[327] for the following account established by the **Governing Body** in accordance with Article 19.3f of the **Treaty**[328]:

FAO Trust Fund (USD) GINC/INT/031/MUL,
IT-PGRFA (Benefit-sharing),
HSBC New York, 452 Fifth Ave., New York, NY, USA, 10018,
Swift/BIC: MRMDUS33, ABA/Bank Code: 021001088,
Account No. 000156426

[327] Note by the Treaty Secretariat: The Governing Body has not yet considered the question of currency of payment. Until it does so, Standard Material Transfer Agreements should specify United States dollars (US$).
[328] Note by the Treaty Secretariat: This is the Trust Account provided for in Article 6.3 of the Financial Rules, as approved by the Governing Body at its First Session (Appendix E to IT/GB-1/06/Report).

Annex 3

TERMS AND CONDITIONS OF THE ALTERNATIVE PAYMENTS SCHEME UNDER ARTICLE 6.11 OF THIS AGREEMENT

The discounted rate for payments made under Article 6.11 shall be zero point five percent (0.5 %) of the **Sales** of any **Products** and of the sales of any other products that are **Plant Genetic Resources for Food and Agriculture** belonging to the same crop, as set out in Annex 1 to the **Treaty**, to which the **Material** referred to in Annex 1 to **this Agreement** belong.

Payment shall be made in accordance with the banking instructions set out in paragraph 4 of Annex 2 to **this Agreement**.

When the **Recipient** transfers **Plant Genetic Resources for Food and Agriculture under Development**, the transfer shall be made on the condition that the **subsequent recipient** shall pay into the mechanism established by the **Governing Body** under Article 19.3f of the **Treaty** zero point five percent (0.5 %) of the **Sales** of any **Product** derived from such **Plant Genetic Resources for Food and Agriculture under Development**, whether the **Product** is **available or not without restriction**. At least six months before the expiry of a period of ten years counted from the date of signature of **this Agreement** and, thereafter, six months before the expiry of subsequent periods of five years, the **Recipient** may notify the **Governing Body** of his decision to opt out from the application of this Article as of the end of any of those periods. In the case the **Recipient** has entered into other Standard Material Transfer Agreements, the ten years period will commence on the date of signature of the first Standard Material Transfer Agreement where an option for this Article has been made.

Where the **Recipient** has entered or enters in the future into other Standard Material Transfer Agreements in relation to material belonging to the same crop[s], the **Recipient** shall only pay into the referred mechanism the percentage of sales as determined in accordance with this Article or the same Article of any other Standard Material Transfer Agreement. No cumulative payments will be required.

Annex 4

OPTION FOR CROP-BASED PAYMENTS UNDER THE ALTERNATIVE PAYMENTS SCHEME UNDER ARTICLE 6.11 OF THIS AGREEMENT

I (full name of **Recipient** or **Recipient's** authorised official) declare to opt for payment in accordance with Article 6.11 of **this Agreement**.

Signature..... Date..... [8]

[8] In accordance with Article 6.11h of the Standard Material Transfer Agreement, the option for this modality of payment will become operative only once notification has been provided by the **Recipient** to the **Governing Body**. The signed declaration opting for this modality of payment must be sent by the **Recipient** to the **Governing Body** at the following address, whichever method of acceptance of **this Agreement** (signature, shrink-wrap or click-wrap) has been chosen by the parties to **this Agreement**, and whether or not the **Recipient** has already indicated his acceptance of this option in accepting **this Agreement** itself:

The Secretary,
International Treaty on Plant Genetic Resources for Food and Agriculture
Food and Agriculture Organization of the United Nations
I-00100 Rome, Italy

The signed declaration must be accompanied by the following:

- The date on which **this Agreement** was entered into;
- The name and address of the **Recipient** and of the **Provider**;
- A copy of Annex 1 to **this Agreement**.

Annex IV: Programme

United Nations Conference on Trade and Development

Ad Hoc Expert Group Meeting on the Development Dimensions of Intellectual Property: Biological Diversity and Access and Benefit Sharing (ABS)

Programme

16-17 April 2013
Room IX, Palais des Nations
Geneva, Switzerland

Day 1, Tuesday, 16 April 2013

10:00 **Welcome Remarks**
Kiyoshi Adachi
Chief, Intellectual Property Unit
Division on Investment and Enterprise, UNCTAD

10:15 **Making Investments in R&D Using Genetic Resources – the Role of ABS**
1) The Convention on Biological Diversity and the Nagoya Protocol
Beatriz Gomez
Associate Programme Officer, Social, Economic and Legal Matters
Secretariat of the Convention on Biological Diversity, UNEP

2) Vaccine Research and the WHO Standard Material Transfer Agreements
Steven Solomon
Principal Legal Officer, WHO
Anne Huvos
Team Leader
PIP Framework Secretariat, Pandemic and Epidemic Diseases Department, WHO

11:15 Coffee Break

11:30 *3) Perspectives of the Pharmaceutical, Health Products and Cosmetics Industries*
Andrew Jenner
Director, Innovation, Intellectual Property and Trade
International Federation of Pharmaceutical Manufacturers' Associations

Maria Julia Oliva
Senior Advisor on ABS
Union for Ethical Biotrade

Discussion

12:30 Lunch Break

14:30 **Trends in Genetic Resources R&D, IP and ABS**
1) Open Science and the Freedom to Operate
Padmashree Gehl Sampath
Chief, Science and Technology Section

Division on Technology and Logistics, UNCTAD

2) Patenting the Fruits of University Research
Yumiko Hamano
Senior Program Officer
WIPO University Initiative Program, WIPO

15:30 Coffee Break

3) Misappropriation and its Prevention
Johanna von Braun (via Skype)
Natural Justice

Discussion

17:00 Close of Day 1

Day 2, Wednesday, 17 April 2013
Peer Review: Handbook on the interface between Global ABS Rules and IP

09:30 *Presentation of the Handbook*
Kiyoshi Adachi
Chief, Intellectual Property Unit
Division on Investment and Enterprise, UNCTAD

David Vivas-Eugui
Vivas Consulting

Hartmut Meyer
Independent Consultant

10:15 *Participants' and Tutors' Perspective*
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10:45 Coffee Break

11:00 *Peer Reviewers' Comments and Free Discussion*[329]
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Jayashree Watal

[329] Written comments also provided by Ms. Katrin Antonow, Lawyer and GIZ Consultant.

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Discussion

12:40 **Concluding Remarks**

12:45 *End*