

Recognising and Protecting Indigenous Knowledge Associated with Natural Resource Management



Part 3: A detailed review of the regional agreements relevant to this project

Regional instruments

In this part of the report regional instruments adopted by particular country groups are identified and their provisions compared with our Nagoya Protocol obligations and the WIPO draft articles.

1. Pacific community

Secretariat of the Pacific Community (SPC): Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture, 2002

The Pacific Regional Framework was developed to assist Pacific Island countries and territories wishing to legally protect their Traditional Knowledge and Expressions of Culture. It was developed in response to calls from the region arising from increasing exploitation and inappropriate commercialization of their traditional knowledge and expressions of culture. It provides a model law to address these issues. The approach taken in the model law is to create new rights in traditional knowledge and expressions of culture which previously might have been regarded, for the purposes of intellectual property law, as part of the public domain. The rights created by the model law fall into two categories: traditional cultural rights and moral rights. The existence of these rights does not depend upon registration or other formalities. The policy objective of the model law is to protect the rights of traditional owners in their traditional knowledge and expressions of culture and permit tradition-based creativity and innovation, including commercialisation thereof, subject to prior and informed consent and benefit-sharing. The model law also reflects the policy that it should complement and not undermine intellectual property rights.

MODEL LAW FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE AND EXPRESSIONS OF CULTURE

PART 1 – PRELIMINARY

1 Short title

This Act may be cited as the Protection of Traditional Knowledge and Expressions of Culture Act [Enacting country to insert year of enactment].

2 Commencement

This Act commences on [Enacting country to complete].

3 Application

- (1) This Act applies to traditional knowledge and expressions of culture that:
- (a) were in existence before the commencement of this Act; or
 - (b) are created on or after that commencement.

(2) This Act does not affect or apply to rights that exist immediately before the commencement of this Act, including intellectual property rights.

(3) This Act does not affect or apply to contracts, licences or other agreements entered into by traditional owners before the commencement of this Act in relation to the use of traditional knowledge or expressions of culture.

4 Definitions

In this Act, unless the contrary intention appears:

authorised user agreement means a written agreement entered into under Division 3 or 4 of Part 4.

customary use means the use of traditional knowledge or expressions of culture in accordance with the customary laws and practices of the traditional owners.

derivative work means any intellectual creation or innovation based upon or derived from traditional knowledge or expressions of culture.

derogatory treatment, in relation to traditional knowledge or expressions of culture, includes any act or omission that results in a material distortion, mutilation or alteration of the traditional knowledge or expressions of culture that is prejudicial to the honour or reputation of the traditional owners, or the integrity of the traditional knowledge or expressions of culture.

expressions of culture mean any way in which traditional knowledge appears or is manifested, irrespective of content, quality or purpose, whether tangible or intangible, and, without limiting the preceding words, includes:

- (a) names, stories, chants, riddles, histories and songs in oral narratives; and
- (b) art and craft, musical instruments, sculpture, painting, carving, pottery, terra-cotta, mosaic, woodwork, metalware, painting, jewellery, weaving, needlework, shell work, rugs, costumes and textiles; and
- (c) music, dances, theatre, literature, ceremonies, ritual performances and cultural practices; and
- (d) the delineated forms, parts and details of designs and visual compositions; and
- (e) architectural forms.

Minister means the Minister responsible for this Act.

moral rights are the rights mentioned in section 13.

prescribed means prescribed by the regulations made under this Act.

sacred-secret means any traditional knowledge or expressions of culture that have a secret or sacred significance according to the customary law and practices of the traditional owners concerned.

traditional cultural rights are the rights mentioned in sections 7(2) and (3).

traditional knowledge includes any knowledge that generally:

- (a) is or has been created, acquired or inspired for traditional economic, spiritual, ritual, narrative, decorative or recreational purposes; and
- (b) is or has been transmitted from generation to generation; and
- (c) is regarded as pertaining to a particular traditional group, clan or community of people in [Enacting country]; and
- (d) is collectively originated and held.

traditional owners of traditional knowledge or expressions of culture means:

- (a) the group, clan or community of people; or
- (b) the individual who is recognized by a group, clan or community of people as the individual; in whom the custody or protection of the traditional knowledge or expressions of culture are entrusted in accordance with the customary law and practices of that group, clan or community.

5 Customary use

The customary use of traditional knowledge or expressions of culture does not give rise to any criminal or civil liability under this Act.

PART 2 – TRADITIONAL CULTURAL RIGHTS

6 Holders of traditional cultural rights

The traditional owners of traditional knowledge or expressions of culture are the holders of the traditional cultural rights in the traditional knowledge or expressions of culture.

7 Meaning of traditional cultural rights

(1) Traditional cultural rights are the rights set out in subsections (2) and (3).

(2) The following uses of traditional knowledge or expressions of culture require the prior and informed consent of the traditional owners in accordance with section 23(1) or 25(5):

- (a) to reproduce the traditional knowledge or expressions of culture;
- (b) to publish the traditional knowledge or expressions of culture;
- (c) to perform or display the traditional knowledge or expressions of culture in public;
- (d) to broadcast the traditional knowledge or expressions of culture to the public by radio, television, satellite, cable or any other means of communication;
- (e) to translate, adapt, arrange, transform or modify the traditional knowledge or expressions of culture;
- (f) to fixate the traditional knowledge or expressions of culture through any process such as making a photograph, film or sound recording;
- (g) to make available online or electronically transmit to the public (whether over a path or a combination of paths, or both) traditional knowledge or expressions of culture;
- (h) to create derivative works;
- (i) to make, use, offer for sale, sell, import or export traditional knowledge or expressions of culture or products derived therefrom;
- (j) to use the traditional knowledge or expressions of culture in any other material form; if such use is a non-customary use (whether or not of a commercial nature).

(3) To avoid doubt, the traditional owners are entitled to use traditional knowledge or expressions of culture in the ways mentioned in subsection (2) in the exercise of their traditional cultural rights.

(4) Subsection (2) does not apply to the use of traditional knowledge or expressions of culture for any of the following:

- (a) face to face teaching;
- (b) criticism or review;
- (c) reporting news or current events;
- (d) judicial proceedings;
- (e) incidental use.

(5) A user of traditional knowledge or expressions of culture mentioned in paragraphs (4)(a) to (d) must make sufficient acknowledgement of the traditional owners by mentioning them and/or the geographical place from which the traditional knowledge or expressions of culture originated.

8 Material form not required

Traditional cultural rights exist in traditional knowledge and expressions of culture whether or not that traditional knowledge or those expressions of culture are in material form.

9 Duration

Traditional cultural rights continue in force in perpetuity.

10 Traditional cultural rights inalienable

Traditional cultural rights are inalienable.

11 Additional rights

The traditional cultural rights in traditional knowledge or expressions of culture are in addition to, and do not affect, any rights that may subsist under any law relating to copyright, trademarks, patents, designs or other intellectual property.

12 Derivative works

(1) Any copyright, trademark, patent, design or other intellectual property right that exists in relation to a derivative work vests in the creator of the work or as otherwise provided by the relevant intellectual property law.

(2) If a derivative work, traditional knowledge or expressions of culture are to be used for a commercial purpose, the authorised user agreement must:

- (a) contain a benefit sharing arrangement providing for equitable monetary or non-monetary compensation to the traditional owners; and
- (b) provide for identification of the traditional knowledge or expressions of culture on which the derivative work is based in an appropriate manner in connection with the exploitation of the derivative work by mentioning the traditional owners and/or the geographical place from which it originated; and

(c) provide that the traditional knowledge or expressions of culture in the derived work will not be subject to derogatory treatment.

PART 3 – MORAL RIGHTS

13 Meaning of moral rights

(1) The traditional owners of traditional knowledge or expressions of culture are the holders of the moral rights in the traditional knowledge or expressions of culture.

(2) The moral rights of the traditional owners of traditional knowledge and expressions of culture are:

(a) the right of attribution of ownership in relation to their traditional knowledge and expressions of culture; and

(b) the right not to have ownership of traditional knowledge or expressions of culture falsely attributed to them; and

(c) the right not to have their traditional knowledge and expressions of culture subject to derogatory treatment.

(3) The moral rights of traditional owners in their traditional knowledge and expressions of culture exist independently of their traditional cultural rights.

(4) Moral rights continue in force in perpetuity and are inalienable, and cannot be waived or transferred.

PART 4 – OBTAINING PRIOR AND INFORMED CONSENT FROM TRADITIONAL OWNERS

Division 1 – General

14 Overview

This Part sets out the procedure for obtaining the prior and informed consent of the traditional owners to use their traditional knowledge or expressions of culture for a non-customary use (whether or not of a commercial nature).

Division 2 – Applications for use and identifying traditional owners

15 Application

(1) A prospective user of traditional knowledge or expression of culture for a non-customary use (whether or not of a commercial nature) may apply to the Cultural Authority to obtain the prior and informed consent of the traditional owners to use the traditional knowledge or expressions of culture.

(2) The application must:

(a) be in the prescribed form; and

(b) specify the way in which the applicant proposes to use the traditional knowledge or expressions of culture; and

(c) state clearly the purpose for which that use is intended; and

(d) be accompanied by the prescribed fee.

(3) The Cultural Authority must finalise the application in accordance with this Part within [Enacting country to insert time period].

(4) If the Cultural Authority does not finalise the application within the period mentioned in subsection (3), the traditional owners are deemed not to have consented to the proposed use.

16 Public notification

(1) The Cultural Authority must:

- (a) give a copy of the application to those persons (if any) who it is satisfied are the traditional owners of the traditional knowledge or expressions of culture to which the application relates; and
- (b) publish a copy of the application in a newspaper having national circulation stating how interested persons may obtain a copy of the application; and
- (c) if appropriate, broadcast details of the application on radio or television stating how interested persons may obtain a copy of the application.

(2) Any person who claims to be a traditional owner of the traditional knowledge or expressions of culture to which the application relates must advise the Cultural Authority within 28 days after the application is published or broadcasted (whichever is the later). The advice may be given orally or in writing.

(3) The Cultural Authority must record in writing the details of any oral or written advice given under subsection (2).

17 Identification of traditional owners

(1) If the Cultural Authority is satisfied that it has identified all of the traditional owners it must make a written determination containing such details as to identify the traditional owners.

(2) The Cultural Authority must:

- (a) publish a copy of the determination in a newspaper having national circulation; and
- (b) if appropriate, broadcast details of the determination on radio or television.

18 Uncertainty or dispute about ownership

(1) If the Cultural Authority is not satisfied that it has identified all of the traditional owners or that there is a dispute about ownership, the Cultural Authority must refer the matter to the persons concerned to be resolved according to customary law and practice or such other means as are agreed to by the parties.

(2) When all of the traditional owners have been identified in accordance with customary law and practice or such means as have been agreed to, the traditional owners must advise the Cultural Authority, and the Cultural Authority must make a written determination containing such details as to identify the traditional owners.

(3) The Cultural Authority must:

- (a) publish a copy of the determination in a newspaper having national circulation; and
- (b) if appropriate, broadcast details of the determination on radio or television.

19 No traditional owners or no agreement about ownership

(1) If the Cultural Authority is satisfied that:

(a) no traditional owners can be identified; or

(b) no agreement has been reached on ownership within the period mentioned in section 15(3) after the application was made;

the Cultural Authority may, after consultation with the Minister, make a determination that the Cultural Authority is the traditional owner of the traditional knowledge or expressions of culture concerned for the purposes of this Act.

(2) If the Cultural Authority enters into an authorised user agreement, any monetary or non-monetary benefits arising under the agreement must be used for traditional cultural development purposes.

Division 3 – Authorised user agreements

20 Application to be rejected or negotiations for agreement

(1) The traditional owners must decide whether:

(a) to reject the application; or

(b) to accept the application and to enter into negotiations for a written authorised user agreement in relation to the application.

(2) The traditional owners must advise the Cultural Authority of their decision. The advice may be given orally or in writing.

(3) The Cultural Authority must advise the applicant in writing of the traditional owners' decision.

21 Proposed agreement to be referred to Cultural Authority

(1) Before entering into an authorised user agreement, the traditional owners must refer the proposed agreement to the Cultural Authority for its comments on the proposed terms and conditions of the agreement.

(2) The Cultural Authority may request the applicant and the traditional owners to meet with it to discuss the proposed agreement if the Cultural Authority is, after reviewing the proposed agreement, satisfied that:

(a) the traditional owners do not have sufficient information to make a full and informed decision about the proposed terms and conditions of the agreement; or

(b) the proposed terms and conditions of the agreement do not adequately protect the traditional knowledge or expressions of culture of the traditional owners.

(3) The traditional owners may accept, reject or modify any comments made by the Cultural Authority in relation to the proposed agreement.

22 Terms and conditions

An authorised user agreement should include terms and conditions about the following:

- (a) sharing of financial and other benefits arising from the use of the traditional knowledge or expressions of culture;
- (b) compensation, fees, royalties or other payments for the use;
- (c) whether the use will be exclusive or non-exclusive;
- (d) duration of the use to be allowed and rights of renewal;
- (e) disclosure requirements in relation to the use;
- (f) the possible sharing by the traditional owners of any intellectual property rights arising from the use of the traditional knowledge or expressions of culture;
- (g) access arrangements for the traditional owners;
- (h) education and training requirements for the applicant;
- (i) controls on publication;
- (j) specify whether the rights arising under the agreement can be assigned;
- (k) choice of law in relation to disputes under the agreement;
- (l) respect for moral rights of the traditional owners.

23 Authorised user agreement and prior and informed consent

- (1) If a prospective user and the traditional owners enter into an authorised user agreement, the traditional owners are deemed to have given their prior and informed consent to the proposed use.
- (2) The traditional owners must advise the Cultural Authority and forward to it a copy of the final agreement.
- (3) The Cultural Authority is to keep a register of authorised user agreements. The register is to be in such form and contain such information as the Cultural Authority determines.

24 No authorised user agreement reached

- (1) If the traditional owners and the applicant cannot agree on the terms and conditions of an agreement in relation to the application, the traditional owners must advise the Cultural Authority. The advice may be given orally or in writing.
- (2) The Cultural Authority must advise the applicant in writing that the traditional owners have rejected the proposed authorised user agreement.
- (3) The Cultural Authority must record in writing the details of any oral or written advice given under subsection (1).

Division 4 – Applications not made under this Part

25 Procedure for applications

- (1) Nothing prevents a prospective user of traditional knowledge or expressions of culture from obtaining the prior and informed consent of the traditional owners without applying to the Cultural Authority under section 15.
- (2) The prospective user must advise the Cultural Authority that the prospective user has sought the prior and informed consent of the traditional owners.
- (3) The prospective user must provide the Cultural Authority with a copy of the proposed authorised user agreement between the prospective user and the traditional owners for comment, and advice about other prospective traditional owners.

(4) The prospective user must provide a copy of the signed authorised user agreement to the Cultural Authority to be entered in the register (refer subsection 23(3)) within 28 days after the agreement comes into force.

(5) If a prospective user and the traditional owners enter into an authorised user agreement, the traditional owners are deemed to have given their prior and informed consent to the proposed use.

(6) The prospective user cannot contract out of the obligation under subsection (3). If a copy is not provided under subsection (3), the authorised user agreement is null and void.

PART 5 – ENFORCEMENT

Division 1 – Offences

26 Offence in relation to traditional cultural rights

If:

- (a) a person makes a non-customary use of traditional knowledge or an expressions of culture (whether or not such use is of a commercial nature); and
- (b) the traditional owners have not given their prior and informed consent to that use;

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

27 Offence in relation to moral rights

If:

- (a) a person does an act or makes an omission in relation to traditional knowledge or an expression of culture that is inconsistent with the moral rights of the traditional owners of that traditional knowledge or expression of culture; and
- (b) the traditional owners have not given their prior and informed consent to the act or omission;

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

28 Offence in relation to sacred-secret material

If a person uses sacred–secret traditional knowledge or an expression of culture other than in accordance with a customary use, the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

29 Offences in relation to importation and exportation

(1) If:

- (a) a person imports an article or other thing into [Enacting country] that relates to traditional knowledge or expressions of culture of that country; and

(b) the person knew, or ought reasonably to have known, that the article or thing would have contravened the traditional cultural rights or the moral rights of the traditional owners had it been created in [Enacting country];

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

(2) If:

(a) a person exports traditional knowledge or an expression of culture and the export is a non-customary use (whether or not such use is of a commercial nature); and

(b) the traditional owners have not given their prior and informed consent to the export of the traditional knowledge or expressions of culture;

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

Division 2 – Civil actions

30 Civil claims

(1) If:

(a) a person makes a non-customary use of traditional knowledge or an expression of culture (whether or not such use is of a commercial nature); and

(b) the traditional owners have not given their prior and informed consent to that use;

the traditional owners may institute proceedings against the person in the [] Court seeking all or any of the relief set out in section 31.

(2) If:

(a) a person does an act or makes an omission in relation to traditional knowledge or an expression of culture that is inconsistent with the moral rights of the traditional owners of that traditional knowledge or expression of culture; and

(b) the traditional owners have not given their prior and informed consent to the act or omission;

the traditional owner may institute proceedings against the person in the [] Court seeking all or any of the relief set out in section 31.

31 Remedies

(1) The [] Court may grant all or any of the following in relation to proceeding instituted under section 30:

(a) an injunction;

(b) damages for loss resulting from the unauthorised use;

(c) a declaration that the traditional cultural rights of the traditional owners have been contravened;

(d) an order that the defendant make a public apology for the contravention;

(e) an order that any false attribution of ownership, or derogatory treatment, of the traditional knowledge or expression of culture cease or be reversed;

- (f) an order for an account for profits;
- (g) an order for the seizure of any object made, imported or exported contrary to this Act;
- (h) such other orders as the Court considers appropriate in the circumstances.

(2) The [] Court in deciding what relief is to be granted may take into account all or any of the following:

- (a) whether the defendant was aware or ought reasonably to have been aware of the traditional cultural rights and moral rights of the traditional owners;
- (b) the effect on the honour or reputation of the traditional owners resulting from the unauthorised use;
- (c) any thing done by the defendant to mitigate the effects of the unauthorised use;
- (d) any cost or difficulty that may have been associated with identifying the traditional owners;
- (e) any cost or difficulty in ceasing or reversing any false attribution of ownership, or derogatory treatment, of the traditional knowledge or expression of culture;
- (f) whether the parties have undertaken any other action to resolve the dispute.

Division 3 – Defences and other matters

32 Defences

It is a defence to an offence against section 26 or 27, or an action under subsection 30(1) or (2), if a determination has been published under section 17 and the traditional owners specified in that determination have given their prior and informed consent to the use in question.

33 Other mechanisms to resolve disputes

Nothing in this Part prevents the traditional owner or the other person concerned from attempting to resolve a dispute using all or any of the following:

- (a) mediation;
- (b) alternative dispute resolution procedures;
- (c) customary law and practices.

34 Other rights of action and remedies

This Part does not affect any rights of action or other remedies, whether civil or criminal, provided for under other Acts or laws.

PART 6 –TRANSITIONAL ARRANGEMENTS

35 Procedure for transitional arrangements

(1) Subject to subsections 3(2) and (3), this section applies to a person if, immediately before the commencement of this Act, the person was making a non-customary use of traditional knowledge or an expression of culture.

(2) The provisions of this Act do not apply to the person during the period of 60 days (“the application period”) starting on the commencement of this Act.

(3) During the application period, the person must apply under Part 4 to the Cultural Authority to obtain prior and informed consent from the traditional owners to continue to use the traditional knowledge or expression of culture.

(4) If the person does not apply to the Cultural Authority in accordance with subsection (3), the Act applies to the person on and after the end of the application period.

(5) If a person has applied to the Cultural Authority in accordance with subsection (3), the Act continues not to apply to the person until the traditional owners reject the application or enter into an authorised user agreement with the person, whichever first occurs.

PART 7 – CULTURAL AUTHORITY

36 Designation of Cultural Authority

The Minister may designate an existing [or new] body to perform the functions of the Cultural Authority in section 37.

37 Functions of the Cultural Authority

The functions of the Cultural Authority may include the following:

- (a) to receive and process applications under Part 4;
- (b) to monitor compliance with authorised user agreements and to advise traditional owners of any breaches of such agreements;
- (c) to develop standard terms and conditions for authorised user agreements;
- (d) to provide training and education programs for traditional owners and users of traditional knowledge or expressions of culture;
- (e) to develop a Code of Ethics in relation to use of traditional knowledge and expressions of culture;
- (f) to issue advisory guidelines for the purposes of this Act;
- (g) to liaise with regional bodies in relation to matters under this Act;
- (h) to maintain a record of traditional owners and/or knowledge and expressions of culture;
- (i) if requested to do so to provide guidance on the meaning of customary use in specific cases;
- (j) such other functions as are conferred on it by this Act.

PART 8 – MISCELLANEOUS

38 Regulations

The Minister may make regulations prescribing all matters:

- (a) required or permitted by this Act to be prescribed; or
- (b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

39 Recognition of other laws

In accordance with reciprocal arrangements, this Act may provide the same protection to traditional knowledge and expressions of culture originating in other countries or territories as is provided to traditional knowledge and expressions of culture originating in the [Enacting country].

Comparison of Pacific Rim Model Law with common provisions of the Nagoya Protocol and WIPO agreements discussed in chapter 2

As the following table shows, the model law is focussed on traditional knowledge and cultural expressions *per se* and omits some of the matters Australian law needs to embrace.

Common provision	Provision in this Instrument	Comments
1. subject matter of protection- traditional knowledge, traditional cultural expressions, genetic resources	No express objective is included	
2. definition of terms- key terms	<p>4 Definitions</p> <p>In this Act, unless the contrary intention appears:</p> <p>authorised user agreement means a written agreement entered into under Division 3 or 4 of Part 4.</p> <p>customary use means the use of traditional knowledge or expressions of culture in accordance with the customary laws and practices of the traditional owners.</p> <p>derivative work means any intellectual creation or innovation based upon or derived from traditional knowledge or expressions of culture.</p> <p>derogatory treatment, in relation to traditional knowledge or expressions of culture, includes any act or omission that results in a material distortion, mutilation or alteration of the traditional knowledge or expressions of culture that is prejudicial to the honour or reputation of the traditional owners, or the integrity of the traditional knowledge or expressions of culture.</p> <p>expressions of culture mean any way in which traditional knowledge appears or is manifested, irrespective of content, quality or purpose, whether tangible or intangible, and, without limiting the preceding words, includes:</p> <p>(a) names, stories, chants, riddles, histories and songs in oral narratives; and</p> <p>(b) art and craft, musical instruments, sculpture, painting, carving, pottery, terracotta, mosaic, woodwork, metalware, painting, jewellery, weaving, needlework, shell work, rugs, costumes and textiles; and</p> <p>(c) music, dances, theatre, literature, ceremonies, ritual performances and cultural practices; and</p> <p>(d) the delineated forms, parts and details of designs and visual compositions; and</p> <p>(e) architectural forms.</p> <p>Minister means the Minister responsible for this Act.</p> <p>moral rights are the rights mentioned in section 13.</p> <p>prescribed means prescribed by the regulations made under this Act.</p> <p>sacred-secret means any traditional knowledge or expressions of culture that have a secret or sacred significance according to the customary law and practices of the traditional owners concerned.</p> <p>traditional cultural rights are the rights mentioned in sections 7(2) and (3).</p> <p>traditional knowledge includes any knowledge that generally:</p> <p>(a) is or has been created, acquired or inspired for traditional economic, spiritual, ritual, narrative, decorative or recreational purposes; and</p> <p>(b) is or has been transmitted from generation to generation; and</p> <p>(c) is regarded as pertaining to a particular traditional group, clan or community of people in [Enacting country]; and</p> <p>(d) is collectively originated and held.</p> <p>traditional owners of traditional knowledge or expressions of culture means:</p> <p>(a) the group, clan or community of people; or</p> <p>(b) the individual who is recognized by a group, clan or community of people as the individual;</p> <p>in whom the custody or protection of the traditional knowledge or expressions of culture are entrusted in accordance with the customary law and practices of that group, clan or community.</p>	These definitions relate to the purpose and execution of the Pacific Rim model law

<p>3. scope- what is covered, respect for traditional ownership, respect for sovereignty over genetic resources, moral rights</p>	<p>3 Application (1) This Act applies to traditional knowledge and expressions of culture that: (a) were in existence before the commencement of this Act; or (b) are created on or after that commencement. (2) This Act does not affect or apply to rights that exist immediately before the commencement of this Act, including intellectual property rights. (3) This Act does not affect or apply to contracts, licences or other agreements entered into by traditional owners before the commencement of this Act in relation to the use of traditional knowledge or expressions of culture.</p>	<p>Deals with transitional arrangements, moral rights addressed elsewhere, does not deal with genetic resources, traditional owners addressed elsewhere</p>
<p>4. beneficiaries- who should benefit</p>		<p>In part addressed under access provisions</p>
<p>5. access - who speaks for country, process for granting or refusing access including 5a. prior informed consent - ensuring traditional owners are aware of their rights and significance of agreements made 5b. mutually agreed terms- ensuring the bargaining process is fair and equitable</p>	<p>PART 2 – TRADITIONAL CULTURAL RIGHTS 6 Holders of traditional cultural rights The traditional owners of traditional knowledge or expressions of culture are the holders of the traditional cultural rights in the traditional knowledge or expressions of culture. 7 Meaning of traditional cultural rights (1) Traditional cultural rights are the rights set out in subsections (2) and (3). (2) The following uses of traditional knowledge or expressions of culture require the prior and informed consent of the traditional owners in accordance with section 23(1) or 25(5): (a) to reproduce the traditional knowledge or expressions of culture; (b) to publish the traditional knowledge or expressions of culture; (c) to perform or display the traditional knowledge or expressions of culture in public; (d) to broadcast the traditional knowledge or expressions of culture to the public by radio, television, satellite, cable or any other means of communication; (e) to translate, adapt, arrange, transform or modify the traditional knowledge or expressions of culture; (f) to fixate the traditional knowledge or expressions of culture through any process such as making a photograph, film or sound recording; (g) to make available online or electronically transmit to the public (whether over a path or a combination of paths, or both) traditional knowledge or expressions of culture; (h) to create derivative works; (i) to make, use, offer for sale, sell, import or export traditional knowledge or expressions of culture or products derived therefrom; (j) to use the traditional knowledge or expressions of culture in any other material form; if such use is a non-customary use (whether or not of a commercial nature). (3) To avoid doubt, the traditional owners are entitled to use traditional knowledge or expressions of culture in the ways mentioned in subsection (2) in the exercise of their traditional cultural rights. (4) Subsection (2) does not apply to the use of traditional knowledge or expressions of culture for any of the following: (a) face to face teaching; (b) criticism or review; (c) reporting news or current events; (d) judicial proceedings; (e) incidental use. (5) A user of traditional knowledge or expressions of culture mentioned in paragraphs (4)(a) to (d) must make sufficient acknowledgement of the traditional owners by mentioning them and/or the geographical place from which the traditional knowledge or expressions of culture originated. 8 Material form not required Traditional cultural rights exist in traditional knowledge and expressions of culture whether or not that traditional knowledge or those expressions of culture are in material form. 9 Duration Traditional cultural rights continue in force in perpetuity. 10 Traditional cultural rights inalienable</p>	<p>Does not deal with genetic resources</p>

	<p>Traditional cultural rights are inalienable.</p> <p>11 Additional rights The traditional cultural rights in traditional knowledge or expressions of culture are in addition to, and do not affect, any rights that may subsist under any law relating to copyright, trademarks, patents, designs or other intellectual property.</p> <p>12 Derivative works (1) Any copyright, trademark, patent, design or other intellectual property right that exists in relation to a derivative work vests in the creator of the work or as otherwise provided by the relevant intellectual property law. (2) If a derivative work, traditional knowledge or expressions of culture are to be used for a commercial purpose, the authorised user agreement must: (a) contain a benefit sharing arrangement providing for equitable monetary or non-monetary compensation to the traditional owners; and (b) provide for identification of the traditional knowledge or expressions of culture on which the derivative work is based in an appropriate manner in connection with the exploitation of the derivative work by mentioning the traditional owners and/or the geographical place from which it originated; and (c) provide that the traditional knowledge or expressions of culture in the derived work will not be subject to derogatory treatment.</p> <p>PART 3 – MORAL RIGHTS 13 Meaning of moral rights (1) The traditional owners of traditional knowledge or expressions of culture are the holders of the moral rights in the traditional knowledge or expressions of culture. (2) The moral rights of the traditional owners of traditional knowledge and expressions of culture are: (a) the right of attribution of ownership in relation to their traditional knowledge and expressions of culture; and (b) the right not to have ownership of traditional knowledge or expressions of culture falsely attributed to them; and (c) the right not to have their traditional knowledge and expressions of culture subject to derogatory treatment. (3) The moral rights of traditional owners in their traditional knowledge and expressions of culture exist independently of their traditional cultural rights. (4) Moral rights continue in force in perpetuity and are inalienable, and cannot be waived or transferred.</p> <p>PART 4 – OBTAINING PRIOR AND INFORMED CONSENT FROM TRADITIONAL OWNERS Division 1 – General 14 Overview This Part sets out the procedure for obtaining the prior and informed consent of the traditional owners to use their traditional knowledge or expressions of culture for a non-customary use (whether or not of a commercial nature).</p> <p>15 Application (1) A prospective user of traditional knowledge or expression of culture for a non-customary use (whether or not of a commercial nature) may apply to the Cultural Authority to obtain the prior and informed consent of the traditional owners to use the traditional knowledge or expressions of culture. (2) The application must: (a) be in the prescribed form; and (b) specify the way in which the applicant proposes to use the traditional knowledge or expressions of culture; and (c) state clearly the purpose for which that use is intended; and (d) be accompanied by the prescribed fee. (3) The Cultural Authority must finalise the application in accordance with this Part within [Enacting country to insert time period]. (4) If the Cultural Authority does not finalise the application within the period mentioned in subsection (3), the traditional owners are deemed not to have consented to the proposed use.</p> <p>Division 2 – Applications for use and identifying traditional owners 16 Public notification</p>	
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	<p>(1) The Cultural Authority must:</p> <p>(a) give a copy of the application to those persons (if any) who it is satisfied are the traditional owners of the traditional knowledge or expressions of culture to which the application relates; and</p> <p>(b) publish a copy of the application in a newspaper having national circulation stating how interested persons may obtain a copy of the application; and</p> <p>(c) if appropriate, broadcast details of the application on radio or television stating how interested persons may obtain a copy of the application.</p> <p>(2) Any person who claims to be a traditional owner of the traditional knowledge or expressions of culture to which the application relates must advise the Cultural Authority within 28 days after the application is published or broadcasted (whichever is the later). The advice may be given orally or in writing.</p> <p>(3) The Cultural Authority must record in writing the details of any oral or written advice given under subsection (2).</p> <p>17 Identification of traditional owners</p> <p>(1) If the Cultural Authority is satisfied that it has identified all of the traditional owners it must make a written determination containing such details as to identify the traditional owners.</p> <p>(2) The Cultural Authority must:</p> <p>(a) publish a copy of the determination in a newspaper having national circulation; and</p> <p>(b) if appropriate, broadcast details of the determination on radio or television.</p> <p>18 Uncertainty or dispute about ownership</p> <p>(1) If the Cultural Authority is not satisfied that it has identified all of the traditional owners or that there is a dispute about ownership, the Cultural Authority must refer the matter to the persons concerned to be resolved according to customary law and practice or such other means as are agreed to by the parties.</p> <p>(2) When all of the traditional owners have been identified in accordance with customary law and practice or such means as have been agreed to, the traditional owners must advise the Cultural Authority, and the Cultural Authority must make a written determination containing such details as to identify the traditional owners.</p> <p>(3) The Cultural Authority must:</p> <p>(a) publish a copy of the determination in a newspaper having national circulation; and</p> <p>(b) if appropriate, broadcast details of the determination on radio or television.</p> <p>Division 3 – Authorised user agreements</p> <p>20 Application to be rejected or negotiations for agreement</p> <p>(1) The traditional owners must decide whether:</p> <p>(a) to reject the application; or</p> <p>(b) to accept the application and to enter into negotiations for a written authorised user agreement in relation to the application.</p> <p>(2) The traditional owners must advise the Cultural Authority of their decision. The advice may be given orally or in writing.</p> <p>(3) The Cultural Authority must advise the applicant in writing of the traditional owners' decision.</p> <p>21 Proposed agreement to be referred to Cultural Authority</p> <p>(1) Before entering into an authorised user agreement, the traditional owners must refer the proposed agreement to the Cultural Authority for its comments on the proposed terms and conditions of the agreement.</p> <p>(2) The Cultural Authority may request the applicant and the traditional owners to meet with it to discuss the proposed agreement if the Cultural Authority is, after reviewing the proposed agreement, satisfied that:</p> <p>(a) the traditional owners do not have sufficient information to make a full and informed decision about the proposed terms and conditions of the agreement; or</p> <p>(b) the proposed terms and conditions of the agreement do not adequately protect the traditional knowledge or expressions of culture of the traditional owners.</p> <p>(3) The traditional owners may accept, reject or modify any comments made by the Cultural Authority in relation to the proposed agreement.</p> <p>23 Authorised user agreement and prior and informed consent</p> <p>(1) If a prospective user and the traditional owners enter into an authorised user agreement, the traditional owners are deemed to have given their prior and informed</p>	
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	<p>consent to the proposed use.</p> <p>(2) The traditional owners must advise the Cultural Authority and forward to it a copy of the final agreement.</p> <p>(3) The Cultural Authority is to keep a register of authorised user agreements. The register is to be in such form and contain such information as the Cultural Authority determines.</p> <p>24 No authorised user agreement reached</p> <p>(1) If the traditional owners and the applicant cannot agree on the terms and conditions of an agreement in relation to the application, the traditional owners must advise the Cultural Authority. The advice may be given orally or in writing.</p> <p>(2) The Cultural Authority must advise the applicant in writing that the traditional owners have rejected the proposed authorised user agreement.</p> <p>(3) The Cultural Authority must record in writing the details of any oral or written advice given under subsection (1).</p> <p>Division 4 – Applications not made under this Part</p> <p>25 Procedure for applications</p> <p>(1) Nothing prevents a prospective user of traditional knowledge or expressions of culture from obtaining the prior and informed consent of the traditional owners without applying to the Cultural Authority under section 15.</p> <p>(2) The prospective user must advise the Cultural Authority that the prospective user has sought the prior and informed consent of the traditional owners.</p> <p>(3) The prospective user must provide the Cultural Authority with a copy of the proposed authorised user agreement between the prospective user and the traditional owners for comment, and advice about other prospective traditional owners.</p> <p>(4) The prospective user must provide a copy of the signed authorised user agreement to the Cultural Authority to be entered in the register (refer subsection 23(3)) within 28 days after the agreement comes into force.</p> <p>(5) If a prospective user and the traditional owners enter into an authorised user agreement, the traditional owners are deemed to have given their prior and informed consent to the proposed use.</p> <p>(6) The prospective user cannot contract out of the obligation under subsection (3). If a copy is not provided under subsection (3), the authorised user agreement is null and void.</p> <p>CHAPTER IV: ON THE EXECUTION OF THE ACCESS</p> <p>Article 38.- Once the contract has been adopted and signed, the corresponding Resolution shall be issued in a joint act. This resolution shall then be published together with an extract of the contract, in the Official Newspaper or a newspaper with wide national circulation. As of that moment, the access shall be considered to have been granted.</p> <p>Article 39.- Such contracts as are signed in violation of the provisions of this regime shall be null and void. The nullification procedure shall be subject to the national provisions of the Member Country in which it is invoked.</p> <p>Article 40.- The rescission or resolution of the contract shall be motive for the official cancellation of the registration by the Competent National Authority.</p>	
<p>6. benefit sharing- how are benefits shared, what types of benefit, dealing with technology transfer, capacity building</p>	<p>PART 4 – OBTAINING PRIOR AND INFORMED CONSENT FROM TRADITIONAL OWNERS</p> <p>Division 3 – Authorised user agreements</p> <p>22 Terms and conditions</p> <p>An authorised user agreement should include terms and conditions about the following:</p> <p>(a) sharing of financial and other benefits arising from the use of the traditional knowledge or expressions of culture;</p> <p>(b) compensation, fees, royalties or other payments for the use;</p> <p>(c) whether the use will be exclusive or non-exclusive;</p> <p>(d) duration of the use to be allowed and rights of renewal;</p> <p>(e) disclosure requirements in relation to the use;</p> <p>(f) the possible sharing by the traditional owners of any intellectual property rights arising from the use of the traditional knowledge or expressions of culture;</p> <p>(g) access arrangements for the traditional owners;</p> <p>(h) education and training requirements for the applicant;</p>	<p>Does not deal with genetic resources</p>

	<p>(i) controls on publication; (j) specify whether the rights arising under the agreement can be assigned; (k) choice of law in relation to disputes under the agreement; (l) respect for moral rights of the traditional owners.</p>	
<p>7. Sanctions and remedies- dealing with breaches</p>	<p>PART 5 – ENFORCEMENT Division 1 – Offences 26 Offence in relation to traditional cultural rights If: (a) a person makes a non-customary use of traditional knowledge or an expressions of culture (whether or not such use is of a commercial nature); and (b) the traditional owners have not given their prior and informed consent to that use; the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.</p> <p>27 Offence in relation to moral rights If: (a) a person does an act or makes an omission in relation to traditional knowledge or an expression of culture that is inconsistent with the moral rights of the traditional owners of that traditional knowledge or expression of culture; and (b) the traditional owners have not given their prior and informed consented to the act or omission; the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.</p> <p>28 Offence in relation to sacred-secret material If a person uses sacred–secret traditional knowledge or an expression of culture other than in accordance with a customary use, the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.</p> <p>29 Offences in relation to importation and exportation (1) If: (a) a person imports an article or other thing into [Enacting country] that relates to traditional knowledge or expressions of culture of that country; and (b) the person knew, or ought reasonably to have known, that the article or thing would have contravened the traditional cultural rights or the moral rights of the traditional owners had it been created in [Enacting country]; the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both. (2) If: (a) a person exports traditional knowledge or an expression of culture and the export is a non-customary use (whether or not such use is of a commercial nature); and (b) the traditional owners have not given their prior and informed consent to the export of the traditional knowledge or expressions of culture; the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.</p> <p>Division 2 – Civil actions 30 Civil claims (1) If: (a) a person makes a non-customary use of traditional knowledge or an expression of culture (whether or not such use is of a commercial nature); and (b) the traditional owners have not given their prior and informed consent to that use; the traditional owners may institute proceedings against the person in the [] Court seeking all or any of the relief set out in section 31. (2) If: (a) a person does an act or makes an omission in relation to traditional knowledge or an expression of culture that is inconsistent with the moral rights of the traditional</p>	

	<p>owners of that traditional knowledge or expression of culture; and (b) the traditional owners have not given their prior and informed consent to the act or omission; the traditional owner may institute proceedings against the person in the [] Court seeking all or any of the relief set out in section 31.</p> <p>31 Remedies (1) The [] Court may grant all or any of the following in relation to proceeding instituted under section 30: (a) an injunction; (b) damages for loss resulting from the unauthorised use; (c) a declaration that the traditional cultural rights of the traditional owners have been contravened; (d) an order that the defendant make a public apology for the contravention; (e) an order that any false attribution of ownership, or derogatory treatment, of the traditional knowledge or expression of culture cease or be reversed; (f) an order for an account for profits; (g) an order for the seizure of any object made, imported or exported contrary to this Act; (h) such other orders as the Court considers appropriate in the circumstances. (2) The [] Court in deciding what relief is to be granted may take into account all or any of the following: (a) whether the defendant was aware or ought reasonably to have been aware of the traditional cultural rights and moral rights of the traditional owners; (b) the effect on the honour or reputation of the traditional owners resulting from the unauthorised use; (c) any thing done by the defendant to mitigate the effects of the unauthorised use; (d) any cost or difficulty that may have been associated with identifying the traditional owners; (e) any cost or difficulty in ceasing or reversing any false attribution of ownership, or derogatory treatment, of the traditional knowledge or expression of culture; (f) whether the parties have undertaken any other action to resolve the dispute.</p> <p>Division 3 – Defences and other matters 32 Defences It is a defence to an offence against section 26 or 27, or an action under subsection 30(1) or (2), if a determination has been published under section 17 and the traditional owners specified in that determination have given their prior and informed consent to the use in question.</p> <p>33 Other mechanisms to resolve disputes Nothing in this Part prevents the traditional owner or the other person concerned from attempting to resolve a dispute using all or any of the following: (a) mediation; (b) alternative dispute resolution procedures; (c) customary law and practices.</p> <p>34 Other rights of action and remedies This Part does not affect any rights of action or other remedies, whether civil or criminal, provided for under other Acts or laws.</p>	
<p>8. competent authority- establishment of a body to administer the legislation, deal with education, model clauses, codes of conduct, databases</p>	<p>PART 7 – CULTURAL AUTHORITY</p> <p>36 Designation of Cultural Authority The Minister may designate an existing [or new] body to perform the functions of the Cultural Authority in section 37.</p> <p>37 Functions of the Cultural Authority The functions of the Cultural Authority may include the following: (a) to receive and process applications under Part 4; (b) to monitor compliance with authorised user agreements and to advise traditional owners of any breaches of such agreements; (c) to develop standard terms and conditions for authorised user agreements; (d) to provide training and education programs for traditional owners and users of traditional knowledge or expressions of culture; (e) to develop a Code of Ethics in relation to use of traditional knowledge and expressions of culture; (f) to issue advisory guidelines for the purposes of this Act;</p>	

	<p>(g) to liaise with regional bodies in relation to matters under this Act;</p> <p>(h) to maintain a record of traditional owners and/or knowledge and expressions of culture;</p> <p>(i) if requested to do so to provide guidance on the meaning of customary use in specific cases;</p> <p>(j) such other functions as are conferred on it by this Act.</p>	
9. no single owner-addressing situations where traditional knowledge, cultural expressions, genetic resources are common to more than one group	<p>19 No traditional owners or no agreement about ownership</p> <p>(1) If the Cultural Authority is satisfied that:</p> <p>(a) no traditional owners can be identified; or</p> <p>(b) no agreement has been reached on ownership within the period mentioned in section 15(3) after the application was made;</p> <p>the Cultural Authority may, after consultation with the Minister, make a determination that the Cultural Authority is the traditional owner of the traditional knowledge or expressions of culture concerned for the purposes of this Act.</p> <p>(2) If the Cultural Authority enters into an authorised user agreement, any monetary or non-monetary benefits arising under the agreement must be used for traditional cultural development purposes</p>	No actual transboundary provisions
10. exceptions – emergencies, traditional use, conservation	<p>5 Customary use</p> <p>The customary use of traditional knowledge or expressions of culture does not give rise to any criminal or civil liability under this Act.</p>	Does not deal with emergencies or conservation
11. disclosure-permits, databases, disclosure in intellectual property applications		Not addressed
12. interaction with existing laws-avoiding conflict with other laws		Not addressed
13. recognition of requirements of other nations- mutual recognition of rights and ensuring they are complied with	<p>39 Recognition of other laws</p> <p>In accordance with reciprocal arrangements, this Act may provide the same protection to traditional knowledge and expressions of culture originating in other countries or territories as is provided to traditional knowledge and expressions of culture originating in the [Enacting country].</p>	
14. transitional provisions- existing uses		Not addressed

2. Andean Community Decision 391 Common Regime on Access to Genetic Resources

Decision 391 of the Andean Community recognises:

- national sovereignty over genetic resources
- the right of indigenous, Afro-American, and local communities to decision-making authority over their TK
- the importance of regional cooperation among Andean countries
- the precautionary principle
- access regulations apply to genetic resources, their by-products, their intangible compounds (TK, innovations and practices) and the genetic resources of migratory species found within the national territory for natural reasons
- access procedure includes an application, a contract, an official resolution and registration in a public list
- When accessing TK, innovations and practices the contract for access must include an annex on the equitable sharing of benefits between the provider of the knowledge and the user.

Applications and contracts may include elements such as the following:

- Participation of local people in research activities;
- Support for research inside the country;
- Transfer of environmentally-friendly technology and knowledge (including biotechnology);
- Supplying information about antecedents, state of the science about resources and products;
- Capacity-building measures;
- Depositing collected materials in national institutions;
- Mention of the country of origin in publications;
- Communicating results of the research to national authorities;
- Conditions of transfer of accessed material to third parties.

Intellectual property rights as a tracking mechanism:

- National patent offices ask the applicants to submit the access contract when the product or process they want to protect might have been developed from genetic resources or by-products thereof. Intellectual property rights already granted will be void when the access has not observed the legal provisions

Text of the Decision

THE COMMISSION OF THE CARTAGENA AGREEMENT,

HAVING SEEN: The Third Temporary Provision of Commission Decision 345 and Board Proposal 284/Rev. 1;

WHEREAS:

The Member Countries have sovereignty over the use and development of their resources, a principle that has also been ratified by the Agreement on Biological Diversity, signed in Rio de Janeiro in June 1992 and legalized by the five Member Countries;

The Member Countries possess a sizeable biological and genetic heritage that should be preserved and developed on a sustainable basis;

The Andean countries are characterized by their multi-ethnic and pluricultural nature;

The biological diversity, the genetic resources, their endemism and rarity, as well as the know-how, innovations and practices of the native, Afro-American and local communities associated with them, have a strategic value in the international context;

It is necessary to recognize the historic contribution made by the native, Afro-American, and local communities to the biological diversity, its conservation and development and the sustained use of its components, as well as to the benefits generated by that contribution;

A close interdependence exists between the native, Afro-American and local communities and the biological resources that should be reinforced, in keeping with the conservation of the biological diversity and the economic and social development of those communities and of the Member Countries;

It is necessary to strengthen integration and scientific, technical and cultural cooperation, while moving ahead with the harmonious and comprehensive development of the Member Countries;

Genetic resources have an enormous economic value as a primary source of products and processes for industry;

DECIDES:

To approve the following:

COMMON REGIME ON ACCESS TO GENETIC RESOURCES

TITLE I: ON THE DEFINITIONS

Article 1.- The following definitions shall apply for purposes of this Decision:

ACCESS: the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.

ACCESS CONTRACT: agreement between the Competent National Authority in representation of the State, and a person that establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component.

ACCESS RESOLUTION: an administrative order issued by the Competent National Authority that executes the access to genetic resources or their by-products, after having fulfilled all requirements or conditions stipulated in the access procedure.

BIOLOGICAL DIVERSITY: the variability of living organisms of any source whatsoever, including, among others, land and ocean ecosystems and other aquatic ecosystems, as well as the ecological complexes of which they are a part. Covers the diversity that exists within each species and between species and within ecosystems as a result of natural and cultural processes.

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.

BIOTECHNOLOGY: any technological application that utilizes biological systems or live organisms, parts of them or their by-products, to create or modify products or processes for specific uses.

BY-PRODUCT: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings.

COMPETENT NATIONAL AUTHORITY: State entity or public institution appointed by each Member Country, authorized to supply the genetic resource or its by-products and therefore to sign or supervise the access contracts, to take the actions provided for in this common regime and to ensure their performance.

COUNTRY OF ORIGIN OF THE GENETIC RESOURCE: country that possesses genetic resources in in situ conditions, including those which, having been in in situ conditions, are now in ex situ conditions.

ECOSYSTEM: a dynamic complex of communities of human beings, plants, animals and micro-organisms and their non-living medium that interact as a functional unit.

EX SITU CONDITIONS: those in which the genetic resources are not found in in situ conditions.

EX SITU CONSERVATION CENTER: a person or institution recognized by the Competent National Authority that conserves and collects genetic resources or their by-products outside their in situ conditions.

GENETIC DIVERSITY: variation of genes and genotypes between and within species. Sum total of the genetic information contained in biological organisms.

GENETIC EROSION: the loss of or decrease in genetic diversity.

GENETIC RESOURCES: all biological material that contains genetic information of value or of real or potential use.

IN SITU CONDITIONS: those in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties.

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.

NATIONAL SUPPORT INSTITUTION: national institution devoted to biological research of a scientific or technical nature that accompanies the applicant and participates jointly with it in the access activities.

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.

PROGRAM FOR THE LIBERALIZATION OF GOODS AND SERVICES: a program whose purpose is to eliminate levies and restrictions of all kinds on the importation of goods originating in the territory of any Member Country, pursuant to the provisions of the pertinent chapter of the Cartagena Agreement and all other applicable rules and regulations of its body of law.

SUPPLIER OF THE BIOLOGICAL RESOURCE: a person empowered by this Decision and complementary national legislation to supply the biological resource that contains the genetic resource or its by-products.

SUPPLIER OF THE INTANGIBLE COMPONENT: a person that, through an access contract and pursuant to this Decision and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products.

SUSTAINABLE USE: use of the components of biological diversity in a way and at a rate that does not cause their reduction in the long term and that enables them to maintain their possibilities for satisfying the needs and the aspirations of existing and future generations.

SYNTHESIZED PRODUCT: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis).

TITLE II: ON THE PURPOSE AND AIMS

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;
- c) Promote conservation of the biological diversity and the sustainable use of the biological resources that contain genetic resources;
- d) Promote the consolidation and development of scientific, technological and technical capacities at the local, national and subregional levels; and
- e) Strengthen the negotiating capacity of the Member Countries.

TITLE III: ON THE SCOPE

Article 3.- This Decision is applicable to genetic resources for which 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.

Article 4.- The following are excluded from the scope of this Decision:

- a) Human genetic resources and their by-products; and
- b) The exchange of genetic resources, their by-products, the biological resources containing them, or

their associated intangible components among native, Afro-American and local communities of the Member Countries for their own consumption, based on their customary practices.

TITLE IV: ON THE PRINCIPLES

CHAPTER I: ON THE SOVEREIGNTY OVER GENETIC RESOURCES AND THEIR BY-PRODUCTS

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.

The conservation and sustainable use of the genetic resources and their by-products are regulated by each Member Country in keeping with the principles and provisions of the Biological Diversity Agreement and of this Decision.

Article 6.- The genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.

Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures, without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component.

CHAPTER II: ON THE RECOGNITION OF KNOW-HOW, INNOVATIONS AND TRADITIONAL PRACTICES

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.

CHAPTER III: ON TRAINING, RESEARCH, DEVELOPMENT AND THE TRANSFER OF TECHNOLOGY

Article 8.- The Member Countries favor the establishment of scientific and technical training programs, as well as the execution of research projects that promote the identification, registration, characterization, conservation and sustainable use of the biological diversity and of the by-products of genetic resources that help to satisfy local and Subregional needs.

Article 9.- The Member Countries, recognizing that technology, including biotechnology, and both the access to it and its transfer are essential to the attainment of the objectives of this Decision, shall ensure and facilitate, through the corresponding contracts, the access to technologies that utilize genetic resources and their by-products, that are appropriate for the conservation and sustainable use of the biological diversity and that do not cause damage to the environment.

CHAPTER IV: ON SUBREGIONAL COOPERATION

Article 10.- The Member Countries shall define mechanisms for cooperation on matters of common interest concerning the conservation and sustainable use of genetic resources and their by-products and the associated intangible components.

They shall also establish Subregional technical and scientific training programs on the information, follow-up, control and evaluation of activities connected with those genetic resources and their by-products and for the performance of joint research.

CHAPTER V: ON NATIONAL TREATMENT AND RECIPROCITY

Article 11.- The Member Countries grant each other national, and not discriminatory, treatment in matters relating to access to genetic resources.

Article 12.- The Member Countries may grant national and non-discriminatory treatment to third countries that give them equal treatment.

CHAPTER VI: ON PRECAUTION

Article 13.- The Member Countries may adopt measures aimed to impeding genetic erosion or the degradation of the environment and of the natural resources. If the danger of serious and irreversible damage exists, the lack of scientific certainty should not be seized upon as a reason for postponing the adoption of effective measures.

The principle of precaution should be applied in keeping with the provisions in the Chapter on the Liberalization Program of the Cartagena Agreement and the other applicable rules and regulations of the body of law of this Agreement.

CHAPTER VII: ON FREE SUBREGIONAL TRAFFIC IN BIOLOGICAL RESOURCES

Article 14.- Provided that there is no access to the genetic resources contained in the biological resources referred to in this Decision, the provisions of this regime shall not hinder the use of and free movement of in those biological resources, nor the fulfillment of the provisions of the CITES Convention on health, food security, biosecurity and the obligations stemming from the Program of Liberalization of goods and services among Member Countries.

CHAPTER VIII: ON THE JURIDICAL SECURITY AND TRANSPARENCY

Article 15.- Provisions, procedures and acts of government authorities of the Member Countries with regard to access, shall be clear, effective, well-grounded and lawful.

The actions performed and information provided by individuals shall likewise be lawful, complete and truthful.

TITLE V: ON THE ACCESS PROCEDURE

CHAPTER I: ON THE GENERAL ASPECTS

Article 16.- All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.

Article 17.- The applications for access and access contracts and, if appropriate, accessory contracts shall include conditions like the following:

a) The participation of Subregional nationals in the research on genetic resources and their by-products and on the associated intangible component;

- b) Support for research within the jurisdiction of the Member Country of origin of the genetic resource or in any other Subregional Member Country that contributes to the conservation and sustainable use of the biological diversity;
- c) The strengthening of mechanisms for the transfer of know-how and technology, including biotechnology, that is culturally, socially and environmentally healthy and safe;
- d) The supply of information about the background and status of the science and about other matters that would contribute to a better knowledge of the situation regarding the genetic resource that originated in the Member Country, its by-product or synthesized product and its associated intangible component;
- e) The strengthening and development of the institutional capacity of the country or the Subregion in regard to genetic resources and their by-products;
- f) The strengthening and development of the capacities of the native, Afro-American and local communities with relation to the associated intangible components, the genetic resources and their by-products;
- g) The compulsory deposit of duplicates of all material collected, at institutions designated by the Competent National Authority;
- h) The obligation to inform the Competent National Authority about the results of the research carried out; and
- i) The terms for the transfer of the material to which third parties are given access.

Article 18.- The documents connected with the access procedure shall appear in a public file that the Competent National Authority shall keep.

That file shall consist of the following, at least: the application; the identification of the applicant, the resource supplier, and the national support person or institution; the site or area to which the access applies; the access methodology; the project proposal; the parts of the access contract that are not subject to confidentiality; the opinion about and registry of visits; and, if applicable, the evaluation studies of the economic, social and environmental impact or of the environmental permits.

Also included in the file are the Resolution executing the access, the reports supplied by the national support person or institution, and the follow-up and supervisory reports provided by the Competent National Authority or the entity delegated to perform that task. That file is open to consultation by any person.

Article 19.- The Competent National Authority may give confidential treatment to data and information supplied to it in the course of the access procedure or the contract performance, and not previously disclosed, which could be put to unfair commercial use by third parties, unless the knowledge of this data and information by the public is necessary to protect the social interest or the environment.

Accordingly, the applicant should state the grounds for its petition, accompanied by a non-confidential summary that will become a part of the public file.

The information or documents referred to in the second paragraph of Article 18 of this Decision cannot be made confidential.

The confidential aspects shall be covered in a separate file, in the custody of the Competent National Authority, and may not be disclosed to third parties, unless that is judicially ordered.

Article 20.- If the petition for confidential treatment fails to comply with the requirements established in the previous article, the Competent National Authority shall deny it as a matter of right.

Article 21.- The Competent National Authority shall keep a public registry where the following information shall be entered, among other data: the Resolution that may possibly deny the petition, the access contract signing, amendment, suspension and termination dates, the date and number of the Resolution executing or canceling it, the date and number of the Resolution, award or sentence determining the nullity or imposing penalties, with an indication of their kind and the parties, and accessory contract signing, amendment, suspension, termination and nullification dates.

That registry shall be of a declaratory nature.

Article 22.- As stipulated in Article 15, the execution of the access is dependent upon the provision of full and reliable information by the applicant, as called for by law.

In this connection, the applicant should present the Competent National Authority with all of the information about the genetic resource and its by-products that it knows or is in a position to know at the moment the application is presented. That information shall include the present and potential uses of the resource, by-product or intangible component, their sustainability and the risks that could result from the access.

The statements made by the applicant in the application and in the contract, including their respective annexes, shall be in the nature of a sworn statement.

Article 23.- The permits, authorizations and other documents that support the investigation, obtaining, provision, transfer, etc., of biological resources, shall not determine, qualify or presume the authorization of the access.

Article 24.- It is forbidden to use genetic resources and their by-products in biological weapons or for practices that are harmful to the environment or to human health.

Article 25.- The transfer of technology shall be carried out in accordance with the provisions contained in the body of law of the Cartagena Agreement, complementary national provisions and such rules and regulations on biosecurity and the environment as the Member Countries may approve.

Article 26.- The access to and transfer of technology subject to patents or other intellectual property rights, shall be accomplished in keeping with the Subregional and complementary national provisions regulating that area.

CHAPTER II: ON THE APPLICATION FOR ACCESS

Article 26.- The procedure starts with the presentation to the Competent National Authority of an application for access which should contain:

- a) Identification of the applicant and, if pertinent, documents that accredit its legal capacity to make a contract;
- b) Identification of the supplier of the genetic and biological resources and their by-products or of the associated intangible component;
- c) Identification of the national support person or institution;
- d) Identification and curriculum vitae of the person responsible for the project and of his working group;
- e) The access activity applied for; and
- f) The location or area where the access is to be carried out, with an indication of its geographical coordinates.

The application shall be accompanied by the project proposal, considering the referential model the Board approves through a Resolution.

Article 27.- If the application with its accompanying project proposal is complete, the Competent National Authority shall accept it, assign it a presentation or filing date, record it in the report and enter it with a declarative intent in the public registry it shall keep for that purpose and open the corresponding file.

Were the application to be incomplete, the Competent National Authority would return it without delay, indicating the information that is missing, so that it might be completed.

Article 28.- Within five working days following the date of entry of the application in the public registry referred to in the previous article, an extract of that application shall be published in a newspaper with broad national circulation and in another medium of the place where the access is to be effected, so that those that wish to might supply information to the Competent National Authority.

Article 29.- Within thirty working days after its registration, the Competent National Authority shall evaluate the application, make the visits it deems necessary and issue a technical and legal opinion about its propriety or invalidity. That period may be extended to up to sixty working days if the Competent National Authority considers it desirable.

Article 30.- When the time limit stipulated in the previous article expires, or before that, if appropriate, the Competent National Authority shall accept or deny the application, based on the results of the opinion, the records of visits, the information supplied by third parties, and the fulfillment of the conditions established in this Decision.

The applicant shall be advised about the acceptance of the application and project proposal within five working days after this occurs. The access contract shall then be immediately drawn up and negotiated.

In the event that the application and project proposal are denied, this shall be communicated through a justified Resolution and the matter shall be considered finished. This does not, however, preclude the filing of such objections as are in order, according to the procedures established in the national legislation of Member Countries.

Article 31.- If required by the national law of the Member Country or if the Competent National Authority deems it necessary, the applicant shall comply with environmental provisions in effect.

The procedures that should be followed in that event shall be independent from those stipulated in this Decision and may be started beforehand. Nonetheless, they must be concluded before the expiration of the time limit stipulated in Article 29 and must be considered by the Competent National Authority in making its evaluation.

Were the Competent National Authority to require such studies, it could grant the applicant a supplementary period set exclusively in accordance with the time needed to complete and submit them for its consideration.

CHAPTER III: ON THE ACCESS CONTRACT

Article 32.- The parties to the access contract are:

- a) The State, represented by the Competent National Authority; and
- b) The applicant requesting the access.

The applicant must be legally empowered to make a contract in the Member Country in which it requests the access.

Article 33.- The terms of the access contract must be in keeping with the provisions of this Decision and Member Country national legislation.

Article 34.- The access contract shall bear in mind the rights and interests of the suppliers of genetic resources and their by-products, the biological resources that contain them and the intangible component as applicable, in accordance with the corresponding contracts.

Article 35.- When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component.

The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the Competent National Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the Competent National Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision.

Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.

Article 36.- The Competent National Authority may enter into access contracts with universities, research centers or well-known researchers to support the execution of several projects, as provided for in this Decision and in keeping with the national legislation of each Member Country.

Article 37.- The ex-situ conservation centers or other institutions that perform activities involving access to genetic resources or their by-products and, if appropriate, the associated intangible component, should enter into access contracts with the Competent National Authority, pursuant to this Decision.

That Authority may likewise sign access contracts with third parties in regard to genetic resources of which the Member Country is the country of origin and which have been deposited at those centers, bearing in mind the rights and interests referred to in Article 34.

CHAPTER IV: ON THE EXECUTION OF THE ACCESS

Article 38.- Once the contract has been adopted and signed, the corresponding Resolution shall be issued in a joint act. This resolution shall then be published together with an extract of the contract, in the Official Newspaper or a newspaper with wide national circulation. As of that moment, the access shall be considered to have been granted.

Article 39.- Such contracts as are signed in violation of the provisions of this regime shall be null and void. The nullification procedure shall be subject to the national provisions of the Member Country in which it is invoked.

Article 40.- The rescission or resolution of the contract shall be motive for the official cancellation of the registration by the Competent National Authority.

TITLE VI: ON THE ANCILLARY CONTRACTS TO THE ACCESS CONTRACT

Article 41.- Ancillary contracts are those that are signed in order to carry out activities connected with the genetic resource or its by-products, between the applicant and:

- a) The owner, possessor or manager of the land where the biological resource containing the genetic resource is located;
- b) The ex situ conservation center;
- c) The owner, possessor or manager of the biological resource containing the genetic resource; or
- d) The national support institution, with regard to activities that it should perform and that are not a part of the access contract.

Making an ancillary contract does not authorize access to the genetic resource or its by-product, and its contents are subject to the stipulations of the access contract as provided for in this Decision.

The national support institution must be accepted by the Competent National Authority.

Article 42.- Such ancillary contracts as are signed shall include a condition that subjects their execution to that of the access contract.

As of that moment, they shall become effective and binding and shall be governed by the mutually agreed terms, the provisions of this Decision and applicable Subregional and national legislation. The responsibility for their execution and compliance lies only with the parties to the contract.

Article 43.- Without detriment to what has been agreed upon in the accessory contract and independently of it, the national support institution shall be obliged to collaborate with the Competent National Authority in the follow-up and supervision of the genetic resources, by-products or synthesized products and associated intangible components, and to submit reports about the activities for which it is responsible, in the way or with the frequency that the Authority stipulates, according to the access activity.

Article 44.- The nullity of the access contract produces the nullity of the ancillary contract.

The Competent National Authority may also terminate the access contract when the nullity of the ancillary contract is declared, if the latter is essential for the access.

Its amendment, suspension, rescission or resolution may likewise produce the amendment, suspension, rescission or resolution of the access contract by the Competent National Authority if it substantially affects the conditions of the latter contract.

TITLE VII: ON THE LIMITATIONS TO ACCESS

Article 45.- Member Countries may establish, through an express legal rule, partial or total limitations on access to genetic resources or their by-products in the following cases:

- a) Endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;
- b) Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access activities;
- c) Adverse effects of access activities on human health or on elements essential to the cultural identity of nations;
- d) Undesirable or not easily controlled environmental effects of access activities on the ecosystems;
- e) Danger of genetic erosion caused by access activities;
- f) Regulations on biosecurity; or
- g) Genetic resources or geographic areas rated as strategic.

TITLE VIII: ON VIOLATIONS AND SANCTIONS

Article 46.- Any person performing access activities without the respective authorization shall be liable for punishment.

Also to be sanctioned is any person carrying out transactions with regard to by-products or synthesized products of such genetic resources or the associated intangible component, that is not protected by the corresponding contracts, signed in keeping with the provisions of this Decision.

Article 47.- The Competent National Authority, pursuant to the procedure provided for in its own national legislation, may apply administrative sanctions, such as fines, preventive or definitive confiscation, temporary or definitive closing-down of establishments and disqualification of the violator from applying for new accesses in cases of violation of this regime.

Those sanctions shall be applied without detriment to the suspension, cancellation or nullification of the access, the payment of compensation for such damages and losses as are incurred, including those caused to the biological diversity, and the civil and criminal sanctions that may possibly be in order.

TITLE IX: ON THE NOTIFICATIONS BETWEEN MEMBER COUNTRIES

Article 48.- The Member Countries shall notify each other immediately through the Board, of all applications for access and access resolutions and authorizations, as well as of the suspension and termination of such contracts as are signed.

They shall also advise each other about the signing of any bilateral or multilateral agreement on the subject, which must be in keeping with the provisions of this Decision.

Article 49.- Without prejudice to the stipulations of the previous article, the Member Countries shall immediately inform each other through the Board of all provisions, decisions, regulations, judgments, resolutions and other rules and acts adopted nationally that have to do with the provisions of this Decision.

TITLE X: ON THE COMPETENT NATIONAL AUTHORITY

Article 50.- The Competent National Authority shall perform all of the functions conferred on it in this Decision and in Member Country national legislation. In this connection, it shall be empowered to:

- a) Issue the necessary internal administrative provisions to comply with this Decision and, until the appropriate Community rules and regulations are enacted, stipulate how the genetic resources and their by-products shall be identified and packed;
- b) Receive, evaluate, accept or deny applications for access;
- c) Negotiate, sign and authorize access contracts and issue the corresponding access resolutions;
- d) Ensure the rights of suppliers of biological resources that contain genetic resources and of the intangible component;
- e) Keep the technical files and the Public Registry of Access to Genetic Resources and their by-products;

- f) Keep a directory of persons or institutions pre-qualified to perform scientific or cultural support tasks;
- g) Amend, suspend, nullify or terminate access contracts and arrange their cancellation, as the case may be, in keeping with the terms of those contracts, this Decision and Member Country legislation;
- h) Oppose the suitability of the national support institution proposed by the applicant and demand its replacement by another, suitable one;
- i) Supervise and control compliance with the contractual conditions and the provisions of this Decision and accordingly establish such monitoring and evaluation mechanisms as it deems advisable;
- j) Review, in keeping with this Decision, contracts involving access already signed with other institutions or persons and carry out the corresponding actions for repossession;
- k) Delegate supervisory activities to other institutions, while keeping the responsibility and direction over that supervision, in conformity with national legislation;
- l) Supervise the state of conservation of the biological resources containing the genetic resources;
- m) Coordinate continuously with its respective liaison institutions all matters having to do with fulfillment of the provisions of this Decision;
- n) Keep the national inventory of genetic resources and their by-products;
- o) Keep in continuous contact with the competent national offices for industrial property and set up appropriate information systems with them; and
- p) All such other functions as the domestic legislation of the Member Country itself may assign it.

TITLE XI: ON THE ANDEAN COMMITTEE ON GENETIC RESOURCES

Article 51.- The Andean Committee on Genetic Resources is hereby created, such to be comprised of the Directors of the Competent National Authorities on matters of Access to Genetic Resources or their representatives, their advisors and such representatives of other interested sectors as each Member Country may designate.

The Committee shall be responsible for:

- a) Issuing national and Subregional recommendations for the best possible fulfillment of this Decision;
- b) Issuing technical recommendations on such matters as the Member Countries may submit for its consideration;
- c) Recommending the mechanisms for establishing an Andean information network on applications for access and access contracts in the Subregion;

- d) Recommending and promoting joint actions to strengthen Member Country capacity in research, management and transfer of technology connected with genetic resources and their by-products;
- e) Recommending to the Board for adoption through Resolutions, common documentation models, particularly those that will make it possible to easily verify the coding and identification of genetic resources and their by-products, as well as the legality of the access;
- f) Promoting management, surveillance, control and supervision of access authorizations relating to genetic resources and their by-products that exist in two or more Member Countries;
- g) Recommending and promoting joint emergency plans and warning mechanisms to prevent or resolve problems relating to access to genetic resources or their by-products;
- h) Taking cooperative actions with regard to genetic resources or their by-products;
- i) Drawing up their own internal regulations;
- j) Writing an explanatory manual of this Decision; and
- k) Such other functions as the Member Countries may assign to them.

COMPLEMENTARY PROVISIONS

FIRST.- The Member Countries shall, in keeping with their national legislation, set up or reinforce funds or other types of financial mechanisms financed by the profits from the access and resources from other sources to promote compliance with the aims of this Decision, under the direction of the Competent National Authority.

Through the Andean Committee on Genetic Resources, the Member Countries shall design and implement joint programs for the conservation of genetic resources and shall study the viability and desirability of creating an Andean Fund for their conservation.

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 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.

FOURTH.- Such health certificates supporting the export of biological resources as are issued in accordance with Commission Decision 328, its amendments or addenda, shall incorporate the following statement at the end of the format: "Use of this product as a genetic resource is not authorized."

FIFTH.- The Competent National Authority may enter into, with the institutions referred to in Article 36, contracts for the deposit of genetic resources or their by-products or of the biological resources containing them, exclusively for purposes of their care, keeping those resources under its jurisdiction and control.

Likewise, it may make contracts that do not involve access, such as intermediation or administration contracts, in relation to genetic resources or their by-products or synthesized products, in keeping with the provisions of this Regime.

SIXTH.- When requesting access to genetic resources from protected areas or their by-products, the applicant must fulfill, in addition to the stipulations of this Decision, also the special national legislation on the subject.

FINAL PROVISIONS

FIRST.- Any disputes that may arise among Member Countries shall be settled as stipulated in the Andean body of law.

Any disputes that arise with third countries must be settled according to the provisions of this Decision. If a dispute arises with a third country party to the Agreement on Biological Diversity, signed in Rio de Janeiro on June 5, 1992, the solution adopted must also abide by the principles established in that Agreement.

SECOND.- In negotiating the terms of access contracts to genetic resources that originated in more than one Member Country or to their by-products and in carrying out activities connected with that access, the Competent National Authority shall bear in mind the interests of the other Member Countries, which may present their viewpoints and such information as they deem advisable.

THIRD.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, may execute or adjust the procedure stipulated in Title V, Chapters I and II of this Decision.

FOURTH.- This Decision shall become effective on the date of its publication in the Official Newspaper of the Cartagena Agreement.

TEMPORARY PROVISIONS

FIRST.- On the date this Decision enters into force, those which possess, for purposes of access, genetic resources originated in the Member Countries, their by-products or associated intangible components, shall negotiate that access with the Competent National Authority pursuant to the provisions of this Decision. Accordingly, the Competent National Authorities shall set the time limits, which cannot exceed twenty-four months as of the date this Decision becomes effective.

Until this requirement is fulfilled, the Member Countries may disqualify such persons, as well as the institutions they represent or on whose account they act, from applying for new accesses to genetic resources or their by-products in the Subregion. This does not preclude the application of such sanctions as are in order once the time limit referred to in the previous paragraph expires.

SECOND.- Contracts or agreements signed by Member Countries or their public or State institutions with third parties in regard to genetic resources, their by-products, the biological resources containing them or associated intangible components, that are not in conformity with this Decision, may be renegotiated or may fail to be renewed, as applicable.

The renegotiation of such contracts or agreements, as well as the signing of new ones, shall be accomplished by common agreement among the Member Countries. To this end, the Andean Committee on Genetic Resources shall establish the common criteria.

THIRD.- The Member Countries may take such legal action as they deem advisable for the repossession of genetic resources of which they are the countries of origin, their by-products and the associated intangible components and for the collection of any damages and compensation to which they are entitled.

Only the State has the legal entitlement to the action for repossession of those genetic resources and their by-products.

FOURTH.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, shall establish the necessary systems for the identification and packing of the genetic resources and, if applicable, their by-products.

FIFTH.- Within a period of no more than 30 working days after this Decision enters into force, the Member Countries shall designate the Competent National Authority on access to genetic resources and shall accredit it before the Board.

SIXTH.- The Member Countries, within a period of no more than 30 working days after this Decision enters into force, shall accredit before the Board their representatives to the Andean Committee on Genetic Resources.

SEVENTH.- The Member Countries shall adopt a common regime on biosecurity within the framework of the Agreement on Diversity. To that end, the Member Countries, in coordination with the Board, shall start the respective studies, particularly with regard to the cross-border movement of modified live organisms produced by biotechnology.

EIGHTH.- The Board shall draw up, within a period of three months after the Member Countries present their national studies, a proposal to establish a special regime or a harmonization regulation, as applicable, aimed at reinforcing the protection of know-how, innovations and traditional practices of native, Afro-American and local communities, in keeping with the provision of Article 7 of this Decision, ILO Convention 169 and the Agreement on Biological Diversity.

To that end, the Member Countries should present their respective national studies during the year after this Decision enters into effect.

NINTH.- The Member Countries shall design a training program to strength the capacity of the native, Afro-American and local communities to negotiate the intangible component within the context of access to genetic resources.

TENTH.- The Board, through a Resolution, shall adopt the reference models for the application for access to genetic resources and the access contract, within a period of no more than fifteen days after this Decision comes into effect.

Signed in the city of Caracas, Venezuela on the second of July of nineteen ninety-six.

Comparison of Andean Decision 391 with common provisions of the Nagoya Protocol and WIPO agreements discussed in chapter 2

This Decision predates the Nagoya Protocol. There is very little coverage of traditional knowledge and benefit sharing contained in it.

Common provisions	Provision in this Instrument	Comments
1. subject matter of protection- traditional knowledge, traditional cultural expressions, genetic resources	<p><u>TITLE II: ON THE PURPOSE AND AIMS</u></p> <p><u>Article 2.</u>- The purpose of this Decision is to regulate access to the genetic resources of the Member Countries and their by-products, in order to:</p> <p>a) Establish the conditions for just and equitable participation in the benefits of the access;</p> <p>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;</p> <p>c) Promote conservation of the biological diversity and the sustainable use of the biological resources that contain genetic resources;</p> <p>d) Promote the consolidation and development of scientific, technological and technical capacities at the local, national and subregional levels; and</p> <p>e) Strengthen the negotiating capacity of the Member Countries.</p>	The Andean Decision does not deal with traditional knowledge
2. definition of terms- key terms used in the draft	<p><u>TITLE I: ON THE DEFINITIONS</u></p> <p><u>Article 1.</u>- The following definitions shall apply for purposes of this Decision:</p> <p>ACCESS: the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.</p> <p>ACCESS CONTRACT: agreement between the Competent National Authority in representation of the State, and a person that establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component.</p> <p>ACCESS RESOLUTION: an administrative order issued by the Competent National Authority that executes the access to genetic resources or their by-products, after having fulfilled all requirements or conditions stipulated in the access procedure.</p> <p>BIOLOGICAL DIVERSITY: the variability of living organisms of any source whatsoever, including, among others, land and ocean ecosystems and other aquatic ecosystems, as well as the ecological complexes of which they are a part. Covers the diversity that exists within each species and between species and within ecosystems as a result of natural and cultural processes.</p> <p>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.</p> <p>BIOTECHNOLOGY: any technological application that utilizes biological systems or live organisms, parts of them or their by-products, to create or modify products or processes for specific uses.</p> <p>BY-PRODUCT: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings.</p> <p>COMPETENT NATIONAL AUTHORITY: State entity or public institution appointed by each Member Country, authorized to supply the genetic resource or its by-products and therefore to sign or supervise the access contracts, to take the actions provided</p>	

	<p>for in this common regime and to ensure their performance.</p> <p>COUNTRY OF ORIGIN OF THE GENETIC RESOURCE: country that possesses genetic resources in in situ conditions, including those which, having been in in situ conditions, are now in ex situ conditions.</p> <p>ECOSYSTEM: a dynamic complex of communities of human beings, plants, animals and micro-organisms and their non-living medium that interact as a functional unit.</p> <p>EX SITU CONDITIONS: those in which the genetic resources are not found in in situ conditions.</p> <p>EX SITU CONSERVATION CENTER: a person or institution recognized by the Competent National Authority that conserves and collects genetic resources or their by-products outside their in situ conditions.</p> <p>GENETIC DIVERSITY: variation of genes and genotypes between and within species. Sum total of the genetic information contained in biological organisms.</p> <p>GENETIC EROSION: the loss of or decrease in genetic diversity.</p> <p>GENETIC RESOURCES: all biological material that contains genetic information of value or of real or potential use.</p> <p>IN SITU CONDITIONS: those in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties.</p> <p>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.</p> <p>NATIONAL SUPPORT INSTITUTION: national institution devoted to biological research of a scientific or technical nature that accompanies the applicant and participates jointly with it in the access activities.</p> <p>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.</p> <p>PROGRAM FOR THE LIBERALIZATION OF GOODS AND SERVICES: a program whose purpose is to eliminate levies and restrictions of all kinds on the importation of goods originating in the territory of any Member Country, pursuant to the provisions of the pertinent chapter of the Cartagena Agreement and all other applicable rules and regulations of its body of law.</p> <p>SUPPLIER OF THE BIOLOGICAL RESOURCE: a person empowered by this Decision and complementary national legislation to supply the biological resource that contains the genetic resource or its by-products.</p> <p>SUPPLIER OF THE INTANGIBLE COMPONENT: a person that, through an access contract and pursuant to this Decision and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products.</p> <p>SUSTAINABLE USE: use of the components of biological diversity in a way and at a rate that does not cause their reduction in the long term and that enables them to maintain their possibilities for satisfying the needs and the aspirations of existing and future generations.</p> <p>SYNTHESIZED PRODUCT: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis).</p>	
<p>3. scope- what is covered, respect for traditional ownership, respect for sovereignty over genetic resources, moral rights</p>	<p>TITLE III: ON THE SCOPE</p> <p>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.</p> <p>Article 4.- The following are excluded from the scope of this Decision:</p> <ol style="list-style-type: none"> Human genetic resources and their by-products; and The exchange of genetic resources, their by-products, the biological resources containing them, or their associated intangible components among native, Afro-American and local communities of the Member Countries for their own consumption, based on their customary practices. <p>TITLE IV: ON THE PRINCIPLES</p> <p>CHAPTER I: ON THE SOVEREIGNTY OVER GENETIC RESOURCES AND THEIR BY-PRODUCTS</p> <p>Article 5.- The Member Countries exercise sovereignty over their genetic resources</p>	<p>Traditional knowledge not directly addressed- reference to intangible components also know how innovations and traditional practice</p>

	<p>and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision. The conservation and sustainable use of the genetic resources and their by-products are regulated by each Member Country in keeping with the principles and provisions of the Biological Diversity Agreement and of this Decision.</p> <p>Article 6.- The genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.</p> <p>Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures, without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component.</p> <p>CHAPTER II: ON THE RECOGNITION OF KNOW-HOW, INNOVATIONS AND TRADITIONAL PRACTICES</p> <p>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.</p> <p>FINAL PROVISIONS</p> <p>FOURTH.- This Decision shall become effective on the date of its publication in the Official Newspaper of the Cartagena Agreement.</p>	
<p>4. beneficiaries- who should benefit</p>		
<p>5. access - who speaks for country, process for granting or refusing access including 5a. prior informed consent - ensuring traditional owners are aware of their rights and significance of agreements made 5b. mutually agreed terms- ensuring the bargaining process is fair and equitable</p>	<p>CHAPTER II: ON THE APPLICATION FOR ACCESS</p> <p>Article 26.- The procedure starts with the presentation to the Competent National Authority of an application for access which should contain:</p> <ol style="list-style-type: none"> Identification of the applicant and, if pertinent, documents that accredit its legal capacity to make a contract; Identification of the supplier of the genetic and biological resources and their by-products or of the associated intangible component; Identification of the national support person or institution; Identification and curriculum vitae of the person responsible for the project and of his working group; The access activity applied for; and The location or area where the access is to be carried out, with an indication of its geographical coordinates. <p>The application shall be accompanied by the project proposal, considering the referential model the Board approves through a Resolution.</p> <p>Article 27.- If the application with its accompanying project proposal is complete, the Competent National Authority shall accept it, assign it a presentation or filing date, record it in the report and enter it with a declarative intent in the public registry it shall keep for that purpose and open the corresponding file.</p> <p>Article 28.- Within five working days following the date of entry of the application in the public registry referred to in the previous article, an extract of that application shall be published in a newspaper with broad national circulation and in another medium of the place where the access is to be effected, so that those that wish to might supply information to the Competent National Authority.</p> <p>Article 29.- Within thirty working days after its registration, the Competent National Authority shall evaluate the application, make the visits it deems necessary and issue a technical and legal opinion about its propriety or invalidity. That period may be extended to up to sixty working days if the Competent National Authority considers it desirable.</p> <p>Article 30.- When the time limit stipulated in the previous article expires, or before</p>	

	<p>that, if appropriate, the Competent National Authority shall accept or deny the application, based on the results of the opinion, the records of visits, the information supplied by third parties, and the fulfillment of the conditions established in this Decision.</p> <p>The applicant shall be advised about the acceptance of the application and project proposal within five working days after this occurs. The access contract shall then be immediately drawn up and negotiated.</p> <p>In the event that the application and project proposal are denied, this shall be communicated through a justified Resolution and the matter shall be considered finished. This does not, however, preclude the filing of such objections as are in order, according to the procedures established in the national legislation of Member Countries.</p> <p>Article 31.- If required by the national law of the Member Country or if the Competent National Authority deems it necessary, the applicant shall comply with environmental provisions in effect.</p> <p>The procedures that should be followed in that event shall be independent from those stipulated in this Decision and may be started beforehand. Nonetheless, they must be concluded before the expiration of the time limit stipulated in Article 29 and must be considered by the Competent National Authority in making its evaluation.</p> <p>Were the Competent National Authority to require such studies, it could grant the applicant a supplementary period set exclusively in accordance with the time needed to complete and submit them for its consideration.</p> <p>CHAPTER IV: ON THE EXECUTION OF THE ACCESS</p> <p>Article 38.- Once the contract has been adopted and signed, the corresponding Resolution shall be issued in a joint act. This resolution shall then be published together with an extract of the contract, in the Official Newspaper or a newspaper with wide national circulation. As of that moment, the access shall be considered to have been granted.</p> <p>Article 39.- Such contracts as are signed in violation of the provisions of this regime shall be null and void. The nullification procedure shall be subject to the national provisions of the Member Country in which it is invoked.</p> <p>Article 40.- The rescission or resolution of the contract shall be motive for the official cancellation of the registration by the Competent National Authority.</p> <p>COMPLEMENTARY PROVISIONS</p> <p>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.</p> <p>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.</p> <p>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 or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.</p> <p>The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the</p>	
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	<p>authorized access contracts and intellectual property rights granted.</p> <p>FOURTH.- Such health certificates supporting the export of biological resources as are issued in accordance with Commission Decision 328, its amendments or addenda, shall incorporate the following statement at the end of the format: "Use of this product as a genetic resource is not authorized."</p> <p>SIXTH.- When requesting access to genetic resources from protected areas or their by-products, the applicant must fulfill, in addition to the stipulations of this Decision, also the special national legislation on the subject.</p> <p>FINAL PROVISIONS THIRD.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, may execute or adjust the procedure stipulated in Title V, Chapters I and II of this Decision.</p>	
<p>6. benefit sharing- how are benefits shared, what types of benefit, dealing with technology transfer, capacity building</p>	<p>CHAPTER III: ON TRAINING, RESEARCH, DEVELOPMENT AND THE TRANSFER OF TECHNOLOGY Article 8.- The Member Countries favor the establishment of scientific and technical training programs, as well as the execution of research projects that promote the identification, registration, characterization, conservation and sustainable use of the biological diversity and of the by-products of genetic resources that help to satisfy local and Subregional needs. Article 9.- The Member Countries, recognizing that technology, including biotechnology, and both the access to it and its transfer are essential to the attainment of the objectives of this Decision, shall ensure and facilitate, through the corresponding contracts, the access to technologies that utilize genetic resources and their by-products, that are appropriate for the conservation and sustainable use of the biological diversity and that do not cause damage to the environment.</p> <p>CHAPTER IV: ON SUBREGIONAL COOPERATION Article 10.- The Member Countries shall define mechanisms for cooperation on matters of common interest concerning the conservation and sustainable use of genetic resources and their by-products and the associated intangible components.</p> <p>They shall also establish Subregional technical and scientific training programs on the information, follow-up, control and evaluation of activities connected with those genetic resources and their by-products and for the performance of joint research.</p>	
<p>7. Sanctions and remedies- dealing with breaches</p>	<p>TITLE VIII: ON VIOLATIONS AND SANCTIONS Article 46.- Any person performing access activities without the respective authorization shall be liable for punishment.</p> <p>Also to be sanctioned is any person carrying out transactions with regard to by-products or synthesized products of such genetic resources or the associated intangible component, that is not protected by the corresponding contracts, signed in keeping with the provisions of this Decision.</p> <p>Article 47.- The Competent National Authority, pursuant to the procedure provided for in its own national legislation, may apply administrative sanctions, such as fines, preventive or definitive confiscation, temporary or definitive closing-down of establishments and disqualification of the violator from applying for new accesses in cases of violation of this regime.</p> <p>Those sanctions shall be applied without detriment to the suspension, cancellation of nullification of the access, the payment of compensation for such damages and losses as are incurred, including those caused to the biological diversity, and the civil and criminal sanctions that may possibly be in order.</p> <p>FINAL PROVISIONS FIRST.- Any disputes that may arise among Member Countries shall be settled as</p>	

	<p>stipulated in the Andean body of law.</p> <p>Any disputes that arise with third countries must be settled according to the provisions of this Decision. If a dispute arises with a third country party to the Agreement on Biological Diversity, signed in Rio de Janeiro on June 5, 1992, the solution adopted must also abide by the principles established in that Agreement.</p>	
<p>8. competent authority-establishment of a body to administer the legislation, deal with education, model clauses, codes of conduct, databases</p>	<p>Article 17.- The applications for access and access contracts and, if appropriate, accessory contracts shall include conditions like the following:</p> <ul style="list-style-type: none"> a) The participation of Subregional nationals in the research on genetic resources and their by-products and on the associated intangible component; b) Support for research within the jurisdiction of the Member Country of origin of the genetic resource or in any other Subregional Member Country that contributes to the conservation and sustainable use of the biological diversity; c) The strengthening of mechanisms for the transfer of know-how and technology, including biotechnology, that is culturally, socially and environmentally healthy and safe; d) The supply of information about the background and status of the science and about other matters that would contribute to a better knowledge of the situation regarding the genetic resource that originated in the Member Country, its by-product or synthesized product and its associated intangible component; e) The strengthening and development of the institutional capacity of the country or the Subregion in regard to genetic resources and their by-products; f) The strengthening and development of the capacities of the native, Afro-American and local communities with relation to the associated intangible components, the genetic resources and their by-products; g) The compulsory deposit of duplicates of all material collected, at institutions designated by the Competent National Authority; h) The obligation to inform the Competent National Authority about the results of the research carried out; and i) The terms for the transfer of the material to which third parties are given access. <p>Article 18.- The documents connected with the access procedure shall appear in a public file that the Competent National Authority shall keep.</p> <p>That file shall consist of the following, at least: the application; the identification of the applicant, the resource supplier, and the national support person or institution; the site or area to which the access applies; the access methodology; the project proposal; the parts of the access contract that are not subject to confidentiality; the opinion about and registry of visits; and, if applicable, the evaluation studies of the economic, social and environmental impact or of the environmental permits.</p> <p>Also included in the file are the Resolution executing the access, the reports supplied by the national support person or institution, and the follow-up and supervisory reports provided by the Competent National Authority or the entity delegated to perform that task. That file is open to consultation by any person.</p> <p>Article 19.- The Competent National Authority may give confidential treatment to data and information supplied to it in the course of the access procedure or the contract performance, and not previously disclosed, which could be put to unfair commercial use by third parties, unless the knowledge of this data and information by the public is necessary to protect the social interest or the environment.</p> <p>Accordingly, the applicant should state the grounds for its petition, accompanied by a non-confidential summary that will become a part of the public file.</p> <p>The information or documents referred to in the second paragraph of Article 18 of this Decision cannot be made confidential.</p> <p>The confidential aspects shall be covered in a separate file, in the custody of the Competent National Authority, and may not be disclosed to third parties, unless that is judicially ordered.</p> <p>Article 20.- If the petition for confidential treatment fails to comply with the requirements established in the previous article, the Competent National Authority</p>	

	<p>shall deny it as a matter of right.</p> <p>Article 21.- The Competent National Authority shall keep a public registry where the following information shall be entered, among other data: the Resolution that may possibly deny the petition, the access contract signing, amendment, suspension and termination dates, the date and number of the Resolution executing or canceling it, the date and number of the Resolution, award or sentence determining the nullity or imposing penalties, with an indication of their kind and the parties, and accessory contract signing, amendment, suspension, termination and nullification dates.</p> <p>That registry shall be of a declaratory nature.</p> <p>Article 22.- As stipulated in Article 15, the execution of the access is dependent upon the provision of full and reliable information by the applicant, as called for by law.</p> <p>In this connection, the applicant should present the Competent National Authority with all of the information about the genetic resource and its by-products that it knows or is in a position to know at the moment the application is presented. That information shall include the present and potential uses of the resource, by-product or intangible component, their sustainability and the risks that could result from the access.</p> <p>The statements made by the applicant in the application and in the contract, including their respective annexes, shall be in the nature of a sworn statement.</p> <p>Article 23.- The permits, authorizations and other documents that support the investigation, obtaining, provision, transfer, etc., of biological resources, shall not determine, qualify or presume the authorization of the access.</p> <p>CHAPTER III: ON THE ACCESS CONTRACT</p> <p>Article 32.- The parties to the access contract are: a) The State, represented by the Competent National Authority; and b) The applicant requesting the access. The applicant must be legally empowered to make a contract in the Member Country in which it requests the access.</p> <p>Article 33.- The terms of the access contract must be in keeping with the provisions of this Decision and Member Country national legislation.</p> <p>Article 34.- The access contract shall bear in mind the rights and interests of the suppliers of genetic resources and their by-products, the biological resources that contain them and the intangible component as applicable, in accordance with the corresponding contracts.</p> <p>Article 35.- When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component. The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the Competent National Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the Competent National Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision. Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.</p> <p>Article 36.- The Competent National Authority may enter into access contracts with universities, research centers or well-known researchers to support the execution of several projects, as provided for in this Decision and in keeping with the national legislation of each Member Country.</p> <p>Article 37.- The ex-situ conservation centers or other institutions that perform activities involving access to genetic resources or their by-products and, if</p>	
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	<p>appropriate, the associated intangible component, should enter into access contracts with the Competent National Authority, pursuant to this Decision. That Authority may likewise sign access contracts with third parties in regard to genetic resources of which the Member Country is the country of origin and which have been deposited at those centers, bearing in mind the rights and interests referred to in Article 34.</p> <p>CHAPTER IV: ON THE EXECUTION OF THE ACCESS</p> <p>Article 38.- Once the contract has been adopted and signed, the corresponding Resolution shall be issued in a joint act. This resolution shall then be published together with an extract of the contract, in the Official Newspaper or a newspaper with wide national circulation. As of that moment, the access shall be considered to have been granted.</p> <p>Article 39.- Such contracts as are signed in violation of the provisions of this regime shall be null and void. The nullification procedure shall be subject to the national provisions of the Member Country in which it is invoked.</p> <p>Article 40.- The rescission or resolution of the contract shall be motive for the official cancellation of the registration by the Competent National Authority.</p> <p>TITLE VI: ON THE ANCILLARY CONTRACTS TO THE ACCESS CONTRACT</p> <p>Article 41.- Ancillary contracts are those that are signed in order to carry out activities connected with the genetic resource or its by-products, between the applicant and:</p> <ul style="list-style-type: none"> a) The owner, possessor or manager of the land where the biological resource containing the genetic resource is located; b) The ex situ conservation center; c) The owner, possessor or manager of the biological resource containing the genetic resource; or d) The national support institution, with regard to activities that it should perform and that are not a part of the access contract. <p>Making an ancillary contract does not authorize access to the genetic resource or its by-product, and its contents are subject to the stipulations of the access contract as provided for in this Decision.</p> <p>The national support institution must be accepted by the Competent National Authority.</p> <p>Article 42.- Such ancillary contracts as are signed shall include a condition that subjects their execution to that of the access contract.</p> <p>As of that moment, they shall become effective and binding and shall be governed by the mutually agreed terms, the provisions of this Decision and applicable Subregional and national legislation. The responsibility for their execution and compliance lies only with the parties to the contract.</p> <p>Article 43.- Without detriment to what has been agreed upon in the accessory contract and independently of it, the national support institution shall be obliged to collaborate with the Competent National Authority in the follow-up and supervision of the genetic resources, by-products or synthesized products and associated intangible components, and to submit reports about the activities for which it is responsible, in the way or with the frequency that the Authority stipulates, according to the access activity.</p> <p>Article 44.- The nullity of the access contract produces the nullity of the ancillary contract.</p> <p>The Competent National Authority may also terminate the access contract when the nullity of the ancillary contract is declared, if the latter is essential for the access.</p> <p>Its amendment, suspension, rescission or resolution may likewise produce the amendment, suspension, rescission or resolution of the access contract by the</p>	
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	<p>Competent National Authority if it substantially affects the conditions of the latter contract.</p> <p><u>TITLE X: ON THE COMPETENT NATIONAL AUTHORITY</u></p> <p><u>Article 50.-</u> The Competent National Authority shall perform all of the functions conferred on it in this Decision and in Member Country national legislation. In this connection, it shall be empowered to:</p> <ul style="list-style-type: none"> a) Issue the necessary internal administrative provisions to comply with this Decision and, until the appropriate Community rules and regulations are enacted, stipulate how the genetic resources and their by-products shall be identified and packed; b) Receive, evaluate, accept or deny applications for access; c) Negotiate, sign and authorize access contracts and issue the corresponding access resolutions; d) Ensure the rights of suppliers of biological resources that contain genetic resources and of the intangible component; e) Keep the technical files and the Public Registry of Access to Genetic Resources and their by-products; f) Keep a directory of persons or institutions pre-qualified to perform scientific or cultural support tasks; g) Amend, suspend, nullify or terminate access contracts and arrange their cancellation, as the case may be, in keeping with the terms of those contracts, this Decision and Member Country legislation; h) Oppose the suitability of the national support institution proposed by the applicant and demand its replacement by another, suitable one; i) Supervise and control compliance with the contractual conditions and the provisions of this Decision and accordingly establish such monitoring and evaluation mechanisms as it deems advisable; j) Review, in keeping with this Decision, contracts involving access already signed with other institutions or persons and carry out the corresponding actions for repossession; k) Delegate supervisory activities to other institutions, while keeping the responsibility and direction over that supervision, in conformity with national legislation; l) Supervise the state of conservation of the biological resources containing the genetic resources; m) Coordinate continuously with its respective liaison institutions all matters having to do with fulfillment of the provisions of this Decision; n) Keep the national inventory of genetic resources and their by-products; o) Keep in continuous contact with the competent national offices for industrial property and set up appropriate information systems with them; and p) All such other functions as the domestic legislation of the Member Country itself may assign it. <p><u>TITLE XI: ON THE ANDEAN COMMITTEE ON GENETIC RESOURCES</u></p> <p><u>Article 51.-</u> The Andean Committee on Genetic Resources is hereby created, such to be comprised of the Directors of the Competent National Authorities on matters of Access to Genetic Resources or their representatives, their advisors and such representatives of other interested sectors as each Member Country may designate.</p> <p>The Committee shall be responsible for:</p> <ul style="list-style-type: none"> a) Issuing national and Subregional recommendations for the best possible fulfillment of this Decision; b) Issuing technical recommendations on such matters as the Member Countries may submit for its consideration; c) Recommending the mechanisms for establishing an Andean information network on applications for access and access contracts in the Subregion; d) Recommending and promoting joint actions to strengthen Member Country capacity in research, management and transfer of technology connected with genetic resources and their by-products; e) Recommending to the Board for adoption through Resolutions, common documentation models, particularly those that will make it possible to easily verify the coding and identification of genetic resources and their by-products, as well as the legality of the access; f) Promoting management, surveillance, control and supervision of access authorizations relating to genetic resources and their by-products that exist in two or more Member Countries; g) Recommending and promoting joint emergency plans and warning mechanisms to 	
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	<p>prevent or resolve problems relating to access to genetic resources or their by-products; h) Taking cooperative actions with regard to genetic resources or their by-products; i) Drawing up their own internal regulations; j) Writing an explanatory manual of this Decision; and k) Such other functions as the Member Countries may assign to them.</p> <p>COMPLEMENTARY PROVISIONS FIFTH.- The Competent National Authority may enter into, with the institutions referred to in Article 36, contracts for the deposit of genetic resources or their by-products or of the biological resources containing them, exclusively for purposes of their care, keeping those resources under its jurisdiction and control.</p> <p>Likewise, it may make contracts that do not involve access, such as intermediation or administration contracts, in relation to genetic resources or their by-products or synthesized products, in keeping with the provisions of this Regime.</p>	
<p>9. no single owner-addressing situations where traditional knowledge, cultural expressions, genetic resources are common to more than one group</p>	<p>FINAL PROVISIONS SECOND.- In negotiating the terms of access contracts to genetic resources that originated in more than one Member Country or to their by-products and in carrying out activities connected with that access, the Competent National Authority shall bear in mind the interests of the other Member Countries, which may present their viewpoints and such information as they deem advisable.</p>	
<p>10. exceptions – emergencies, traditional use, conservation</p>	<p>CHAPTER VI: ON PRECAUTION Article 13.- The Member Countries may adopt measures aimed to impeding genetic erosion or the degradation of the environment and of the natural resources. If the danger of serious and irreversible damage exists, the lack of scientific certainty should not be seized upon as a reason for postponing the adoption of effective measures.</p> <p>The principle of precaution should be applied in keeping with the provisions in the Chapter on the Liberalization Program of the Cartagena Agreement and the other applicable rules and regulations of the body of law of this Agreement.</p> <p>CHAPTER VII: ON FREE SUBREGIONAL TRAFFIC IN BIOLOGICAL RESOURCES Article 14.- Provided that there is no access to the genetic resources contained in the biological resources referred to in this Decision, the provisions of this regime shall not hinder the use of and free movement of in those biological resources, nor the fulfillment of the provisions of the CITES Convention on health, food security, biosecurity and the obligations stemming from the Program of Liberalization of goods and services among Member Countries.</p> <p>CHAPTER VIII: ON THE JURIDICAL SECURITY AND TRANSPARENCY Article 15.- Provisions, procedures and acts of government authorities of the Member Countries with regard to access, shall be clear, effective, well-grounded and lawful. The actions performed and information provided by individuals shall likewise be lawful, complete and truthful.</p> <p>TITLE V: ON THE ACCESS PROCEDURE CHAPTER I: ON THE GENERAL ASPECTS Article 16.- All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.</p> <p>Article 24.- It is forbidden to use genetic resources and their by-products in biological weapons or for practices that are harmful to the environment or to human health.</p> <p>Article 25.- The transfer of technology shall be carried out in accordance with the provisions contained in the body of law of the Cartagena Agreement, complementary national provisions and such rules and regulations on biosecurity and the environment as the Member Countries may approve.</p> <p>TITLE VII: ON THE LIMITATIONS TO ACCESS Article 45.- Member Countries may establish, through an express legal rule, partial or</p>	

	<p>total limitations on access to genetic resources or their by-products in the following cases:</p> <p>a) Endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;</p> <p>b) Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access activities;</p> <p>c) Adverse effects of access activities on human health or on elements essential to the cultural identity of nations;</p> <p>d) Undesirable or not easily controlled environmental effects of access activities on the ecosystems;</p> <p>e) Danger of genetic erosion caused by access activities;</p> <p>f) Regulations on biosecurity; or</p> <p>g) Genetic resources or geographic areas rated as strategic.</p> <p><u>COMPLEMENTARY PROVISIONS</u></p> <p><u>FIRST.</u>- The Member Countries shall, in keeping with their national legislation, set up or reinforce funds or other types of financial mechanisms financed by the profits from the access and resources from other sources to promote compliance with the aims of this Decision, under the direction of the Competent National Authority.</p> <p>Through the Andean Committee on Genetic Resources, the Member Countries shall design and implement joint programs for the conservation of genetic resources and shall study the viability and desirability of creating an Andean Fund for their conservation.</p>	
11. disclosure- permits, databases, disclosure in intellectual property applications	<p><u>TITLE IX: ON THE NOTIFICATIONS BETWEEN MEMBER COUNTRIES</u></p> <p><u>Article 48.</u>- The Member Countries shall notify each other immediately through the Board, of all applications for access and access resolutions and authorizations, as well as of the suspension and termination of such contracts as are signed.</p> <p>They shall also advise each other about the signing of any bilateral or multilateral agreement on the subject, which must be in keeping with the provisions of this Decision.</p> <p><u>Article 49.</u>- Without prejudice to the stipulations of the previous article, the Member Countries shall immediately inform each other through the Board of all provisions, decisions, regulations, judgments, resolutions and other rules and acts adopted nationally that have to do with the provisions of this Decision.</p>	
12. interaction with existing laws- avoiding conflict with other laws		
13. recognition of requirements of other nations- mutual recognition of rights and ensuring they are complied with	<p><u>Article 26.</u>- The access to and transfer of technology subject to patents or other intellectual property rights, shall be accomplished in keeping with the Subregional and complementary national provisions regulating that area.</p> <p><u>CHAPTER V: ON NATIONAL TREATMENT AND RECIPROCITY</u></p> <p><u>Article 11.</u>- The Member Countries grant each other national, and not discriminatory, treatment in matters relating to access to genetic resources.</p> <p><u>Article 12.</u>- The Member Countries may grant national and non-discriminatory treatment to third countries that give them equal treatment.</p>	These provisions deal with reciprocity rather than continuity
14. transitional provisions- existing uses	<p><u>TEMPORARY PROVISIONS</u></p> <p><u>FIRST.</u>- On the date this Decision enters into force, those which possess, for purposes of access, genetic resources originated in the Member Countries, their by-products or associated intangible components, shall negotiate that access with the Competent National Authority pursuant to the provisions of this Decision. Accordingly, the Competent National Authorities shall set the time limits, which cannot exceed twenty-four months as of the date this Decision becomes effective.</p> <p>Until this requirement is fulfilled, the Member Countries may disqualify such persons, as well as the institutions they represent or on whose account they act, from applying for new accesses to genetic resources or their by-products in the Subregion. This does</p>	

	<p>not preclude the application of such sanctions as are in order once the time limit referred to in the previous paragraph expires.</p> <p>SECOND.- Contracts or agreements signed by Member Countries or their public or State institutions with third parties in regard to genetic resources, their by-products, the biological resources containing them or associated intangible components, that are not in conformity with this Decision, may be renegotiated or may fail to be renewed, as applicable.</p> <p>The renegotiation of such contracts or agreements, as well as the signing of new ones, shall be accomplished by common agreement among the Member Countries. To this end, the Andean Committee on Genetic Resources shall establish the common criteria.</p> <p>THIRD.- The Member Countries may take such legal action as they deem advisable for the repossession of genetic resources of which they are the countries of origin, their by-products and the associated intangible components and for the collection of any damages and compensation to which they are entitled.</p> <p>Only the State has the legal entitlement to the action for repossession of those genetic resources and their by-products.</p> <p>FOURTH.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, shall establish the necessary systems for the identification and packing of the genetic resources and, if applicable, their by-products.</p> <p>TEMPORARY PROVISIONS</p> <p>FIFTH.- Within a period of no more than 30 working days after this Decision enters into force, the Member Countries shall designate the Competent National Authority on access to genetic resources and shall accredit it before the Board.</p> <p>SIXTH.- The Member Countries, within a period of no more than 30 working days after this Decision enters into force, shall accredit before the Board their representatives to the Andean Committee on Genetic Resources.</p> <p>TEMPORARY PROVISIONS</p> <p>SEVENTH.- The Member Countries shall adopt a common regime on biosecurity within the framework of the Agreement on Diversity. To that end, the Member Countries, in coordination with the Board, shall start the respective studies, particularly with regard to the cross-border movement of modified live organisms produced by biotechnology.</p> <p>TEMPORARY PROVISIONS</p> <p>EIGHTH.- The Board shall draw up, within a period of three months after the Member Countries present their national studies, a proposal to establish a special regime or a harmonization regulation, as applicable, aimed at reinforcing the protection of know-how, innovations and traditional practices of native, Afro-American and local communities, in keeping with the provision of Article 7 of this Decision, ILO Convention 169 and the Agreement on Biological Diversity.</p> <p>To that end, the Member Countries should present their respective national studies during the year after this Decision enters into effect.</p> <p>TEMPORARY PROVISIONS</p> <p>NINTH.- The Member Countries shall design a training program to strength the capacity of the native, Afro-American and local communities to negotiate the intangible component within the context of access to genetic resources.</p> <p>TENTH.- The Board, through a Resolution, shall adopt the reference models for the application for access to genetic resources and the access contract, within a period of no more than fifteen days after this Decision comes into effect.</p>	
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3. AFRICAN MODEL LEGISLATION FOR THE PROTECTION OF THE RIGHTS OF LOCAL COMMUNITIES, FARMERS AND BREEDERS, AND FOR THE REGULATION OF ACCESS TO BIOLOGICAL RESOURCES

Whereas, the State and its people exercise sovereign and inalienable rights over their biological resources;

Whereas, the rights of local communities over their biological resources, knowledge and technologies that represent the very nature of their livelihood systems and that have evolved over generations of human history, are of a collective nature and, therefore, are *a priori* rights which take precedence over rights based on private interests;

Whereas, the vital role that women play in the generation, conservation, and sustainable use of biological diversity and associated knowledge and technologies is self evident, and it thus becomes essential to make it possible for their full participation at all levels of policy-making and implementation in relation to biological diversity, and associated knowledge and technologies;

Whereas, it is necessary to protect and encourage cultural diversity, giving due value to the knowledge, technologies, innovations and practices of local communities with respect to the conservation, management and use of biological resources;

Whereas, it is the duty of the State and its people to regulate access to biological resources and to community knowledge and technologies;

Whereas, the State recognizes the necessity of providing adequate mechanisms for guaranteeing the just, equitable and effective participation of its citizens in the protection of their collective and individual rights and in making decisions which affect its biological and intellectual resources as well as the activities and benefits derived from their utilization;

Whereas, there is the need to promote and support traditional and indigenous technologies for in the conservation and sustainable use of biological resources and to complement them by appropriately developed modern technologies;

Whereas, there is the need to implement the relevant provisions of the Convention on Biological Diversity, in particular Article 15 on access to genetic resources, and Article 8(j) on the preservation and maintenance of knowledge, innovations and practices of indigenous and local communities;

Whereas, all forms of life are the basis for human survival, and, therefore, the patenting of life, or the exclusive appropriation of any life form or part or derivative thereof violates the fundamental human right to life;

Now, therefore, it is hereby legislated as follows:

PART I

OBJECTIVES

The main aim of this legislation shall be to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, and knowledge and technologies in order to maintain and improve their diversity as a means of sustaining all life support systems.

The specific objectives of this legislation shall be to:

- a) recognize, protect and support the inalienable rights of local communities including farming communities over their biological resources, knowledge and technologies;
- b) recognize and protect the rights of breeders;
- c) provide an appropriate system of access to biological resources, community knowledge and technologies subject to the prior informed consent of the State and the concerned local communities;
- d) promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, knowledge and technologies;
- e) ensure the effective participation of concerned communities, with a particular focus on women, in making decisions as regards the distribution of benefits which may derive from the use of their biological resources, knowledge and technologies;
- f) promote and encourage the building of national and grassroots scientific and technological capacity relevant to the conservation and sustainable use of biological resources;
- g) provide appropriate institutional mechanisms for the effective implementation and enforcement of the rights of local communities, including farming communities and breeders, and the conditions of access to biological resources, community knowledge and technologies;
- h) promote the conservation, evaluation and sustainable utilisation of biological resources with a particular focus on the major role women play;
- i) promote improvements in the productivity, profitability, stability and sustainability of major production systems through yield enhancement and maintenance of biological diversity;
- j) promote the supply of good quality seed/planting material to farmers; and
- k) ensure that biological resources are utilised in an effective and equitable manner in order to strengthen the food security of the nation.

PART II

DEFINITIONS AND SCOPE

Definitions 1.

The use of the following terms shall take the meanings in this legislation, as defined below:

Access is the acquisition of biological resources, their derivatives, community knowledge, innovations, technologies or practices as authorised by the National Competent Authority.

Benefit Sharing is the sharing of whatever accrues from the utilisation of biological resources, community knowledge, technologies, innovations or practices.

Biological resource includes genetic resources, organisms or parts thereof, populations, or any other component of ecosystems, including ecosystems themselves, with actual or potential use or value for humanity.

Collector is any natural or legal person, entity or agent obtaining access to biological resources, local practices, innovations, knowledge or technologies under authority given by the National Competent Authority.

Community Rights are those rights held by local communities over their biological resources or parts or derivatives thereof, and over their practices, innovations, knowledge and technologies.

Community Knowledge or indigenous knowledge is the accumulated knowledge that is vital for conservation and sustainable use of biological resources and/or which is of socio-economic value, and which has been developed over the years in indigenous/local communities.

Derivative is a product developed or extracted from a biological resource; a derivative may include such products as plant varieties, oils, resins, gums, proteins etc.

Ex Situ Condition is the condition in which a biological resource is found outside its natural habitat. Under the present law, any lineage that is cultivated within its country of origin is not considered to be in an *ex situ* condition.

Innovation is any generation of a new, or an improvement of an existing, collective and/or cumulative knowledge or technology through alteration or modification, or the use of the properties, values or processes of any biological material or any part thereof, whether documented, recorded, oral, written or in whatever manner otherwise existing.

In Situ Condition is the condition in which a biological resource is found in its ecosystem or natural habitat. In the case of a domesticated or cultivated variety, its condition is *in situ* when that variety is found in the cultural context in which its specific properties have been developed.

Local Community is a human population in a distinct geographical area, with ownership over its biological resources, innovations, practices, knowledge, and technologies governed partially or completely by its own customs, traditions or laws.

National Competent Authority is the entity authorised by the State to supervise and watch over the implementation of one or more of the components of the present law.

Prior Informed Consent (PIC) is the giving by a collector of complete and accurate information, and, based on that information, the prior acceptance of that collector by the government and the concerned local community or communities to collect biological resources, or indigenous knowledge, or technologies.

Scope 2.

1) This legislation applies to:

- i) Biological resources in both *in situ* and *ex situ* conditions;
- ii) The derivatives of the biological resources;
- iii) Community knowledge and technologies;
- iv) Local and indigenous communities; and
- v) Plant breeders

2) This legislation shall not affect the following:

- i) The traditional systems of access, use or exchange of biological resources;
- ii) Access, use and exchange of knowledge and technologies by and between local communities;

3) The sharing of benefits based upon the customary practices of the concerned local communities, provided that the provisions of paragraph 2 shall not be taken to apply to any person or persons not living in the traditional and customary way of life relevant to the conservation and sustainable use of biological resources.

PART III

ACCESS TO BIOLOGICAL RESOURCES

Application for access to biological resources and to the knowledge and technologies of local communities

3.

1) Any access to any biological resources and knowledge or technologies of local communities in any part of the country shall be subject to an application for the necessary prior informed consent and written permit.

2) Any access to any biological resource in a protected area shall be subject to an application for the necessary prior informed consent and written permit.

3) All applications for the necessary consent and written permit to access any biological resource, community knowledge or technology, shall be directed to the National Competent Authority unless otherwise explicitly provided for by law.

4.

1) In making an application for access as provided in article 3 above, the following information shall be provided by the applicant:

- i) the identity of the applicant and the documents that testify to her/his legal capacity to contract, including, where appropriate, the identity of all partners with the contracting party;
- ii) the resources to which access is sought, including the sites from which it will be collected, its present and potential uses, its sustainability and the risks which may arise from access to it;
- iii) whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access;
- iv) the purpose for which access to the resource is requested including the type and extent of research, teaching or commercial use expected to be derived from it;
- v) description of the manner and extent of local and national collaboration in the research and development of the biological resource concerned;
- vi) the identification of the national institution or institutions which will participate in the research and be in charge of the monitoring process;
- vii) the identity of the location where the research and development will be carried out;
- viii) the primary destination of the resource and its probable subsequent destination(s);
- ix) the economic, social, technical, biotechnological, scientific, environmental or any other benefits that are intended, or may be likely to, accrue to the country and local communities providing the biological resource as well as the collector and the country or countries where he/she operates;
- x) the proposed mechanisms and arrangements for benefit sharing;
- xi) description of the innovation, practice, knowledge or technology associated with the biological resource; and
- xii) an environmental and socio-economic impact assessment covering at least the coming three generations, in cases where the collection is in large quantities.

2) Nothing in paragraph (1) shall prevent the National Competent Authority requesting for any other information which it may deem necessary for the effective implementation of this legislation.

Requirement of Consultation and Prior Informed Consent (PIC)

5.

1) Any access to biological resources, knowledge and or technologies of local communities shall be subject to the written prior informed consent of:

- i) the National Competent Authority; as well as that of
- ii) the concerned local communities, ensuring that women are also involved in decision making.

2) Any access carried out without the prior informed consent of the State and the concerned local community or communities shall be deemed to be invalid and shall be subject to the penalties provided in this legislation or any other legislation that deals with access to biological resources.

3) The National Competent Authority shall consult with the local community or communities in order to ascertain that its/their consent is sought and granted. Any access granted without consultation with the concerned community or communities shall be deemed to be invalid and in violation of the principle and requirement for prior informed consent as required under this Article.

Placement of Completed Application Form in Public Registry

6.

1) Upon completion of the application, the National Competent Authority shall place or cause to be placed, the said application in a public registry or gazette, or cause it to be published in a newspaper that is reasonably accessible to the public for a period of x days.

2) Any person may consult the public registry and comment on the application.

3) The National Competent Authority shall cause the wide and effective dissemination of the relevant information to the communities concerned and to other interested parties.

Granting of Access

7.

1) The granting of an access permit shall be carried out by the National Competent Authority or any person duly authorised to do so under the provisions of this legislation within a specified time limit.

2) Any access permit shall be granted through a signed written agreement, between the National Competent Authority and/or the concerned local community or communities on the one hand where

applicable, and, the applicant or collector on the other hand.

3) The access permit shall only be valid if there is a written prior informed consent.

Contents of the Agreement

8.

1) The agreement referred to in article 7 shall contain commitments undertaken or to be undertaken by the collector, as follows.

i) to adhere to a limit set by the National Competent Authority on the quantity and specification of the quality of the biological resource that the collector may obtain and/or export;

ii) to guarantee to deposit duplicates of, with complete field information on, each specimen of the biological resource or the records of community innovation, practice, knowledge or technology collected with the duly designated governmental agencies and, if so required, with local community organizations;

iii) to inform immediately the National Competent Authority and the concerned local community or communities of all findings from research and development on the resource;

iv) not to transfer the biological resource or any of its derivatives or the community innovation, practice, knowledge or technology to any third party without the authorization of the National Competent Authority and the concerned local community or communities;

v) not to apply for any form of intellectual property protection over the biological resource or parts or derivatives thereof and not to apply for intellectual property rights protection over a community innovation, practice, knowledge or technology without the prior informed consent of the original providers;

vi) to provide for the sharing of benefits;

vii) access shall be conditioned upon a commitment to contribute economically to the efforts of the State and concerned local community or communities in the regeneration and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought;

viii) submit to the National Competent Authority a regular status report of research and development on the resource concerned and where the biological resource is to be collected in large quantities on the ecological state of the area; and

ix) abide by the relevant laws of the country particularly those regarding sanitary control, biosafety and the protection of the environment as well as by the cultural practices, traditional values and customs of the local communities.

2) All efforts should be made for the research to be done in the country and in a manner that facilitates the participation of actors in the country of the provider of the biological resource.

Patents over Life Forms and Biological Processes

9.

- 1) Patents over life forms and biological processes are not recognized and cannot be applied for.
- 2) The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein.

Approval of Granting of Access

10.

The National Competent Authority shall approve the granting of access to the biological resource or the community innovation, practice, knowledge or technology in question with any conditions it may deem necessary. In granting access the National Competent Authority shall ensure that all the requirements under this legislation have been fulfilled.

Conditions Pertaining to Academic and Research Institutions, Public Agencies and Inter-governmental Institutions

11.

- 1) The National Competent Authority shall subject all applications for access to a biological resource, a community innovation, practice, knowledge or technology to the prior informed consent of the concerned community or communities.
- 2) The National Competent Authority shall determine the appropriate conditions to be met under the written agreement referred to in Article 8, by academic and research institutions, public agencies and inter-governmental institutions.
- 3) The application for access for research purposes shall clearly state the objective of the research and the relation of the applicant to industry. Neither the sample nor the associated information shall be transferred without a material transfer agreement reserving the prior rights of the State and/or community or communities.
- 4) Where the institutions referred to in this Article change their activities to be predominantly the commercialisation of a biological resource, the National Competent Authority shall cause the conditions and terms to be varied accordingly.

Benefit Sharing

12

1. The access permit should be subject to the payment, made before commencement of collection, of a fee the sum of which will depend on whether or not the collection is to be used for commercial purposes, and the number of samples, the area of collecting, the duration of collection and whether or not the collector is granted exclusive rights.

2. The State and the community or communities shall be entitled to a share of the earning derived from when any biological resource and/or knowledge collected generates, directly or indirectly, a product used in a production process.

Types of Permit to be Granted for Access

13.

1) Having ascertained that the conditions set by the prior informed consent procedure have been fulfilled, the National Competent Authority shall grant the applicant/collector the appropriate permit for access. This may be an academic research permit, a commercial research permit, or a commercial exploitation permit.

2) No person shall be in possession of and use two types of permit at the same time for the same resource unless granted written permission to do so.

3) Nothing in this Article shall be deemed to limit the National Competent Authority's power to issue any other type of access permit.

Revocation of Access Permit

14.

1) The National Competent Authority may unilaterally withdraw consent and repossess the written permit under the following conditions:

i) when there is evidence that the collector has violated any of the provisions of this legislation;

ii) when there is evidence that the collector has failed to comply with the agreed terms; and

iii) when there is failure to meet any of the conditions of access;

iv) for reasons of overriding public interest; or

v) for the protection of the environment and biological diversity.

2) Any termination or withdrawal of consent shall be done in consultation with the concerned local community or communities.

Restrictions on Activities Related to Access or Introduction of Biological Resources

15.

The National Competent Authority should establish restrictions to or prohibitions on those activities which are directly or indirectly related to access to or introduction of a biological resource, particularly in cases of:

- i) endangered taxa;
- ii) endemism or rarity;
- iii) adverse effects upon human health or upon the quality of life or the cultural values of local communities;
- iv) environmental impacts which are undesirable or difficult to control;
- v) danger of genetic erosion or loss of ecosystems, their resources or their components, which arise from undue or uncontrolled collection of biological resources;
- vi) non-compliance with rules on biosafety or food security; and
- vii) use of resources for purposes contrary to national interest and to relevant international agreements entered into by the country.

PART IV

COMMUNITY RIGHTS

Recognition of the Rights of Local and Indigenous Communities

16.

The State recognizes the rights of communities over the following:

- i) their biological resources;
- ii) the right to collectively benefit from the use of their biological resources;
- iii) their innovations, practices, knowledge and technologies acquired through generations;
- iv) the right to collectively benefit from the utilisation of their innovations, practices, knowledge and technologies;
- v) their rights to use their innovations, practices, knowledge and technologies in the conservation and sustainable use of biological diversity;
- vi) the exercise of collective rights as legitimate custodians and users of their biological resources;

Application of the Law on Community Rights

17.

The State recognizes and protects the community rights that are specified in Article 16 as they are enshrined and protected under the norms, practices and customary law found in, and recognized by, the concerned local and indigenous communities, whether such law is written or not.

Prior Informed Consent (PIC) of Local Communities

18.

Any access to a biological resource, innovation, practice, knowledge or technology, shall be subject to the prior informed consent (pic) of the concerned community or communities ensuring that women fully and equally participate in decision making.

Right to Refuse Consent and Access

19.

Local communities have the right to refuse access to their biological resources, innovations, practices, knowledge and technologies where such access will be detrimental to the integrity of their natural or cultural heritage.

Right to Withdraw or Place Restrictions on Consent and Access

20.

Local communities shall have the right to withdraw consent or place restrictions on the activities relating to access where such activities are likely to be detrimental to their socio-economic life, or their natural or cultural heritage.

Right to Traditional Access, Use and Exchange

21.

1) Local communities shall exercise their inalienable right to access, use, exchange or share their biological resources in sustaining their livelihood systems as regulated by their customary practices and laws.

2) No legal barriers shall be placed on the traditional exchange system of the local communities in the exercise of their rights as provided for in paragraph (1) above and in other rights that may be provided by the customary practices and laws of the concerned local communities.

Right to Benefit

22.

1) The State shall ensure that at least fifty per cent of benefits provided for in Article 12.2 shall be channeled to the concerned local community or communities in a manner which treats men and women equitably.

2) The sharing the benefits in paragraph 1) above shall involve the full participation and approval of the concerned local community or communities.

Recognition of Community Intellectual Rights

23.

1) The Community Intellectual Rights of the local communities, including traditional professional groups, particularly traditional practitioners, shall at all times remain inalienable, and shall be further protected under the mechanism established by this legislation.

2) An item of community innovation, practice, knowledge or technology, or a particular use of a biological or any other natural resource shall be identified, interpreted and ascertained by the local communities concerned themselves under their customary practice and law, whether such law is written or not.

3) Non-registration of any community innovations, practices, knowledge or technologies, is not to mean that these are not protected by Community Intellectual Rights.

4) The publication of a written or oral description of a biological resource and its associated knowledge and information, or the presence of these resources in a genebank or any other collection, or its local use, shall not preclude the local community from exercising its community intellectual rights in relation to those resources.

PART V

FARMERS' RIGHTS

Recognition of Farmers' Rights

24.

1) Farmers' Rights are recognized as stemming from the enormous contributions that local farming communities, especially their women members, of all regions of the world, particularly those in the centres of origin or diversity of crops and other agro-biodiversity, have made in the conservation,

development and sustainable use of plant and animal genetic resources that constitute the basis of breeding for food and agriculture production; and

2) For farmers to continue making these achievements, therefore, Farmers' Rights have to be recognized and protected.

Application of the Law on Farmers' Varieties

25.

1) Farmers' varieties and breeds are recognized and shall be protected under the rules of practice as found in, and recognized by, the customary practices and laws of the concerned local farming communities, whether such laws are written or not.

2) A variety with specific attributes identified by a community shall be granted intellectual protection through a variety certificate which does not have to meet the criteria of distinction, uniformity and stability. This variety certificate entitles the community to have the exclusive rights to multiply, cultivate, use or sell the variety, or to license its use without prejudice to the Farmers' Rights set out in this law.

Farmers' Rights

26.

1) Farmers' Rights shall, with due regard for gender equity, include the right to:

- a) the protection of their traditional knowledge relevant to plant and animal genetic resources;
- b) obtain an equitable share of benefits arising from the use of plant and animal genetic resources;
- c) participate in making decisions, including at the national level, on matters related to the conservation and sustainable use of plant and animal genetic resources;
- d) save, use, exchange and sell farm-saved seed/propagating material of farmers' varieties;
- e) use a new breeders' variety protected under this law to develop farmers' varieties, including material obtained from genebanks or plant genetic resource centres; and
- f) collectively save, use, multiply and process farm-saved seed of protected varieties.

2) Notwithstanding sub-paragraphs c) and d), the farmer shall not sell farm-saved seed/propagating material of a breeders' protected variety in the seed industry on a commercial scale.

3) Breeders' Rights on a new variety shall be subject to restriction with the objective of protecting food security, health, biological diversity and any other requirements of the farming community for propagation material of a particular variety.

Certification of Farmers' Varieties

27

1. Any product derived from the sustainable use a biological resource shall be granted a certificate or label of recognition.

2 A certificate of fair trade shall be granted to a product derived from a biological resource or knowledge or technology, when a significant part of the benefits derived from the product go back to the local community.

PART VI

PLANT BREEDERS' RIGHTS

Recognition of Plant Breeders' Rights

28.

Plant Breeders' Rights stem from the efforts and investments made by persons/institutions for the development of new varieties of plants, as defined in Article 41, being the basis for providing recognition and economic reward.

Characteristics of New Varieties

29.

A variety will be considered new if it:

a) is, by reason of one or more identifiable characteristics, clearly distinguishable from all varieties the existence of which is a matter of common knowledge at the effective date of application for the grant of a Plant Breeders' Rights.

b) is stable in its essential characteristics, in that after repeated reproduction or propagation or, where the applicant has defined a particular cycle of reproduction or multiplication, at the end of each cycle, remains true to its description;

c) is, having regard to its particular features of sexual reproduction or vegetative propagation, a sufficiently homogenous variety or is a well-defined multiline.

Rights of Plant Breeders

30.

1) A Plant Breeders' Rights, in respect of a new variety, is:

- a) the exclusive right to sell, including the right to license other persons to sell plants or propagating material of that variety;
 - b) the exclusive right to produce, including the right to license other persons to produce, propagating material of that variety for sale;
- 2) A Plant Breeders' Rights in respect of a plant variety is subject to the conditions provided in Part V, the Farmers' Rights Part of this Act.

Exemptions to the Rights

31.

- 1) Notwithstanding the existences of Plant Breeders' Rights in respect *of Breeders* of a plant variety, any person or farmers' community may:
- a) propagate, grow and use plants of that variety for purposes other than commerce;
 - b) sell plants or propagating material of that variety as food or for another use that does not involve the growing of the plants or the propagation of that variety;
 - c) sell within a farm or any other place at which plants of that variety are grown any plants or propagating material of that variety at that place.
 - d) use plants or propagating material of the variety as an initial source of variation for the purpose of developing another new plant variety except where the person makes repeated use of plants or propagating material of the first mentioned variety for the commercial production of another variety.
 - e) sprout the protected variety as food for home consumption or for the market.
 - f) use the protected variety in further breeding, research or teaching.
 - g) obtain, with the conditions of utilization, such a protected variety from gene banks or plant genetic resources centres.
- 2) Farmers will be free to save, exchange and use part of the seed from the first crop of plants which they have grown for sowing in their own farms to produce a second and subsequent crops subject to conditions specified in Part V, the Farmers' Rights Part of this Act.

Application of Breeders' Rights

32.

- 1) Subject to this Act, a breeder of a new plant variety may make an application to the National Competent Authority for a Plant Breeders' Rights in respect of the variety.

- 2) A breeder of a new variety, or his successor, has the right to make an application for a Plant Breeders' Rights in respect of that variety, whether or not the breeder is a citizen or foreigner, or is resident or not and whether the variety was bred locally or abroad.
- 3) Where two or more persons are entitled to make an application for a Plant Breeders' Rights in respect of a new variety, whether by reason that they bred the plant variety jointly or independently or otherwise, those persons or some of those persons may make a joint application for those rights.
- 4) Where two or more persons breed a new plant variety jointly, one of those breeders or a successor of one of those breeders shall not make an application for a Plant Breeders' Rights in respect of that variety otherwise than jointly with, or with the consent in writing of, the other person, or each other person, entitled to make an application for those Rights.
- 5) In the case of both public-financed and private institutions, the application can be made in the name of the institution.

Restrictions to Plant Breeders' Rights

33.

1) Where the Government considers it necessary, in the public interest, the Plant Breeders' Rights in respect of a new variety shall be subject to conditions restricting the realization of those rights.

These

restrictions may be imposed, *inter alia*:

- a) where problems with competitive practices of the Rights holder are identified;
 - b) where food security or nutritional or health needs are adversely affected;
 - c) where a high proportion of the plant variety offered for sale is being imported;
 - d) where the requirements of the farming community for propagating material of a particular variety are not met; and
 - e) where it is considered important to promote public interest for socio-economic reasons and for developing indigenous and other technologies;
- 2) Where restrictions are imposed on a Plant Breeders' Rights:
- a) the grantee shall be given a copy of the instrument setting out the conditions of the restriction;
 - b) a public notice shall be given;
 - c) the compensation to be awarded to the holder of the Rights shall be specified;
 - d) the Rights-holder may appeal against the compensation award.

3) In particular, and without prejudice to the generality of the foregoing provisions, the relevant Government authority shall have the right to convert the exclusive Plant Breeders' Rights granted under this Act to non-exclusive Plant Breeders' Rights (compulsory licence of right).

Duration of Plant Breeders' Rights

34.

Subject to this Act, a Plant Breeders' Rights in respect of a plant variety shall exist for a period of 20 years in the case of annual crops and 25 years in the case of trees, vines and other perennials commencing on the day on which the successful application for a Plant Breeders' Rights in respect of the plant variety was accepted.

Dispute Settlement

35.

Where conflicts arise on whether a plant variety qualifies as a new plant variety under the Act, they will be handled administratively through the National Competent Authority, an *ad hoc* tribunal and finally through the court of law.

Infringements of Plant Breeders' Rights

36.

1) An action or proceedings for an infringement of a Plant Breeders' Rights may be instituted in writing in a court or, if agreeable to both parties, it may be submitted to a binding arbitration.

2) A defendant in an action or proceeding for an infringement of a Plant Breeders' Rights in respect of a variety may apply by way of counterclaim for the revocation of that Plant Breeders' Rights:

a) on the grounds that the variety was not a new plant variety;

b) on the grounds that facts exist which, if known to the National Competent Authority before the grant of that Plant Breeders' Rights, would have resulted in the refusal of the grant.

3) If, in an action or proceedings for an infringement of a Plant Breeders' Rights in respect of a plant variety in which a defendant has applied by way of counter-claim for the revocation on the grounds referred to in paragraph 2)a) or b), the court is satisfied that the grounds exist, the court may revoke that Plant Breeders' Rights.

4) Where, in an action or proceedings for an infringement of a Plant Breeders' Rights, the court, on an application by the defendant by way of counter-claim, revokes the Plant Breeders' Rights, the

court shall order the defendant to serve on the National Competent Authority a copy of the order revoking that Plant Breeders' Rights.

National Competent Authority

37.

The State shall designate or establish a National Competent Authority which shall implement and enforce the provisions on Plant Breeders' Rights in this Act.

Registration of Plant Breeders' Rights

38.

The National Competent Authority shall:

- a) receive and examine applications for the registration of Plant Breeders' Rights;
- b) carry out the required trials for testing the applicant's variety;
- c) register and issue certificates for Plant Breeders' Rights;
- d) publish applications for Plant Breeders' Rights in the Official Gazette;
- e) hear opposition on the registration of any Plant Breeders' Rights;
- f) maintain the Register for Plant Breeders' Rights.

Register of Plant Breeders' Rights

39.

The National Competent Authority shall keep a National Register of Plant Breeders' Rights in which shall be entered particulars required by this Act or regulations.

Plant Genetic Resources Centres

40.

The Government shall declare or gazette specified plant genetic resources centre(s), as suitable centre(s) for storage and maintenance of germplasm material for the purpose of this Act.

Filing of Applications

41.

1) Where an application is filed in respect of a Plant Breeders' Rights:

- a) the application is accepted if the National Competent Authority is satisfied that:
 - i) the application complies with the requirements of Article 29;

and

ii) the specified fees have been paid; or

b) the application is rejected if the National Competent Authority is satisfied that it does not fulfil the prescribed requirements.

2) Where the National Competent Authority accepts an application it shall, within 30 days after accepting the application, give written notice to the applicant stating that the application has been accepted and it shall give public notice of the application.

3) Where the National Competent Authority rejects an application, it shall, within 30 days after rejecting the application, give written notice to the applicant stating that the application has been rejected and stating the grounds for rejection.

Uniform Testing and Assessment Procedures

42.

1) On the acceptance of an application, the National Competent Authority shall stipulate the quantity of seed/planting material that should be made available by the applicant for trials and testing.

2) The National Competent Authority shall arrange to get statistically valid trials conducted to evaluate the suitability of the variety for national release.

3) The assessment criteria shall include important economic, physiological, ecological and nutritive quality attributes.

4) The fees with respect to a Plant Breeders' Rights shall be fixed on the basis of the administrative and examination costs incurred.

Characteristics of Plant Varieties Originating from Outside the Country

43.

For the purpose of this Act, where a plant variety in respect of which an application has been accepted has originated from outside the country, the variety shall not be taken to have a particular characteristic unless:

a) statistically valid, multi-locational, variety trials carried out in the country for at least three growing seasons have demonstrated that the variety has the specific characteristic as claimed by the applicant; or

b) an exceptional crisis in food production so requires and the National Competent Authority is satisfied that:

- i) statistically valid trials on the variety carried out outside the country have demonstrated that the variety has that specified characteristic; and
- ii) the natural environment outside the country under which the statistically valid trials were carried is similar to the environment in the country.

Plant Varieties Trials

44.

- 1) Where, in dealing with an application in respect of a plant variety, the National Competent Authority considers it necessary that there should be a statistically valid trial or a further statistically valid trial of the variety, trials shall be carried out:
 - a) for the purpose of determining whether the plant variety is distinct, homogenous or stable;
 - b) for the purpose of determining whether the variety will, if grown in the country, exhibit the claimed distinctiveness, homogeneity and stability;
 - c) requiring the applicant to supply sufficient seed or propagation material of the variety, as the case requires, and with any necessary information, to enable the variety to be test grown for the purpose so specified.
- 2) After the completion of the trials on a plant variety, any plants or propagation material of plants used in, or resulting from, the trials that are capable of being transported shall be removed by the applicant for a Plant Breeders' Rights in respect of that plant variety.

Withdrawal of Application

45.

- 1) An application may be withdrawn by the applicant at any time before the publication of the application.
- 2) Where an application is withdrawn after its publication in the Official Gazette, but before the granting of a Plant Breeders' Rights, the National Competent Authority shall forthwith publicise that withdrawal.

Provisional Protection

46.

- 1) Where an application for a Plant Breeders' Rights in respect of a plant variety has been accepted, the applicant shall be deemed to be the owner of a Plant Breeders' Rights in respect of that plant variety during the period commencing on the date of filing of the application and ending on

whichever of the dates specified in a) and b) occurs first:

a) when the application is disposed of; or

b) where the National Competent Authority has given the applicant a notice at the expiration of the prescribed period, after the notice is given.

2) Steps to protect genetic materials of new varieties under testing will be taken, so as to prevent their use for non-research purposes.

Opposition to Grant of Plant Breeders' Rights

47.

1) Where official gazettelement of an application for a Plant Breeders' Rights in respect of a plant variety or of the variation of such a variety is given, any person who considers that:

a) commercial or public interests would be negatively affected by the grant of those rights to the applicant;

b) the application in relation to that variety does not fulfil the prescribed criteria for granting a Plant Breeders' Rights;

may within 6 months after publication of the application, or any further time before the application is disposed of, lodge with the National Competent Authority a written objection to the granting of the Rights setting out the particulars of the objection.

2) Where an opposition to the grant of a Plant Breeders' Rights is lodged under paragraph 1), the National Competent Authority shall cause a copy of that opposition to be given to the applicant for that Plant Breeders' Rights.

3) Any person may inspect an application, or an opposition lodged, at any reasonable time and is entitled, upon payment of such fee as is prescribed, to be given a copy of the application or of the opposition.

Grant of Plant Breeders' Rights

48.

1) Subject to this Article, an application for a Plant Breeders' Rights in respect of a plant variety is granted if the National Competent Authority is satisfied that:

i) there is such a plant variety;

ii) the plant variety is a new plant variety;

iii) the applicant is entitled to the application;

iv) the grant of those rights to the applicant is not prohibited by this Act;

- v) those rights have not been granted to another person;
 - vi) there has been no earlier application for those rights that has not been withdrawn or otherwise disposed of; and
 - vii) all fees payable under this Act in relation to the application have been paid;
- 2) If the National Competent Authority is not satisfied that the conditions in paragraph 1) above have been fulfilled, the National Competent Authority shall refuse to grant that Plant Breeders' Rights to the applicant.
- 3) The National Competent Authority shall not grant, or refuse to grant, a Plant Breeders' Rights in respect of a plant variety unless a period of six (6) months has elapsed since the publication of the application in the official gazette, or, if the application has been varied in a manner that the National Competent Authority considers to be significant, a period of 6 months has elapsed since the publication of particulars of the variation, or of the last such variation, as the case requires.
- 4) The National Competent Authority shall not refuse to grant a Plant Breeders' Rights unless it has given the applicant for that Plant Breeders' Rights a reasonable opportunity to make a written submission in relation to the application.
- 5) Where an opposition to the grant of a Plant Breeders' Rights has been lodged, the National Competent Authority shall not grant the Plant Breeders' Rights unless it has given the person who lodged the opposition a reasonable opportunity to make a written submission in relation to the objection.
- 6) A Plant Breeders' Rights shall be granted and issued by the National Competent Authority to the applicant in the form specified in its regulations.
- 7) Where a Plant Breeders' Rights over one variety is granted to persons, that Plant Breeders' Rights shall be granted to those persons jointly.
- 8) Where a Plant Breeders' Rights is granted to a public or private institution, it shall accrue to the institution represented by the designated person or persons.
- 9) Where the National Competent Authority refuses to grant a Plant Breeders' Rights in respect of a plant variety, the National Competent Authority shall, within 30 days after refusing, give written notice of the refusal to the applicant clearly setting out the grounds for the refusal.

Entry of Plant Breeders' Rights in the Register

49.

- 1) When the National Competent Authority grants a Plant Breeders' Rights in respect of a plant variety, it shall enter in the Register:
- a) a description, or a description and photograph, of the plant variety;
 - b) the name of the variety;
 - c) the pedigree of the variety (where possible);
 - d) the name of the grantee;
 - e) the name and address of the breeder;
 - f) the address for the service of documents on the grantee for the purpose of this Act, which is shown on the application for the Rights;
 - g) the date on which the Plant Breeders' Rights was granted;
 - h) a description of the communities/localities in the country entitled to Farmers' Rights in relation to the variety;
 - i) such other particulars relating to the grant as the National Competent Authority considers appropriate.

Publication of Grant of Plant Breeders' Rights

50.

Where a Plant Breeders' Rights has been granted, the National Competent Authority shall, within 30 days after granting, publish that Plant Breeders' Rights in the official gazette. The publication will also make reference to the entitlements under Farmers' Rights.

Effect of Grant on Certain Persons

51.

1) Where a Plant Breeders' Rights in respect of a plant variety has been granted to a person, another person who was entitled to make an application for that Plant Breeders' Rights, whether or not a person who developed that variety independently of the breeder, or the successor of such another person, is not entitled to any interest in that Plant Breeders' Rights because of the entitlement to make the application or because of the grounds of the entitlement, but nothing in this Article prevents a person from applying to the National Competent Authority for the revocation of that Plant Breeders' Rights or from instituting proceedings before a court in respect of that Plant Breeders' Rights.

2) Where:

a) a Plant Breeders' Rights in respect of a new plant variety has been granted to a person, and
b) another person (in this paragraph referred to as the 'eligible person') was entitled, at a law or in equity to have the right to make an application for that Plant Breeders' Rights assigned to the eligible person, then the eligible person is entitled to have that Plant Breeders' Rights assigned to her/him.

Nature of Plant Breeders' Rights

52.

- 1) A Plant Breeders' Rights is personal property and, subject to any conditions imposed under other paragraphs, is capable of assignment or of transmission by will or by operation of law.
- 2) An assignment of a Plant Breeders' Rights does not have effect unless it is in writing, signed by or on behalf of the assignor.

Assignment of Plant Breeders' Rights

53.

- 1) Where a Plant Breeders' Rights is assigned or transmitted to a person, that person shall, within 30 days after acquiring it, inform the National Competent Authority in writing that the person has acquired that Plant Breeders' Rights, giving particulars of the manner in which it was acquired, and the National Competent Authority, if satisfied that the Plant Breeders' Rights has been so assigned or transmitted, shall enter the name of that person on the Register as the grantee of that Plant Breeders' Rights.
- 2) Where in accordance with paragraph 1), the National Competent Authority enters on the Register as the grantee of a Plant Breeders' Rights the name of a person who claims to have acquired that Plant Breeders' Rights, it shall, within 30 days after entering the name in the Register, give written notice to the person newly entered and to the person who was the grantee before the new entry was made stating that the entry has been made.
- 3) Where the National Competent Authority is not satisfied that a Plant Breeders' Rights has been assigned or transmitted to a person who has informed the National Competent Authority in accordance with paragraph 1) that that Plant Breeders' Rights has been thus assigned or transmitted to the claimant, the National Competent Authority shall forthwith:
 - a) give written notice to the claimant:
 - i) stating that the National Competent Authority is not satisfied;
 - and

- ii) setting out the grounds on which the National Competent Authority is not so satisfied; and
- b) give written notice to the grantee of those rights:
 - i) setting out particulars of the information given by the claimant;
 - ii) stating that the National Competent Authority is not satisfied;
- and
- iii) setting out the grounds on which it is not so satisfied.

4) A person who informs the National Competent Authority in accordance with paragraph 1) that a Plant Breeders' Rights has been assigned or transmitted to her/him shall give written notice to the National Competent Authority of an address in the country for the service of documents in accordance with this Act; and

- a) where the National Competent Authority enters the name of that person on the Register in accordance with paragraph 1) and that address is different from the address already entered in the Register, it shall amend the Register so that the address so given is entered in the Register as the address for service of documents on the grantee for the purpose of this Act; or
- b) where the National Competent Authority is not satisfied that those rights have been assigned or transmitted to that person, the notice to that person under paragraph 3)a) shall be given by being posted.

Supply of Propagating Material

54.

1) A Plant Breeders' Rights in respect of a plant variety is subject to the condition that the grantee of the Rights shall comply with any notice given to her/him by the National Competent Authority.

2) Where a Plant Breeders' Rights are granted in respect of a plant variety, the National Competent Authority may give the grantee of the Plant Breeders' Rights written notice requiring the grantee, within 14 days of the giving of the notice or any other time that is allowed, to cause a specified quantity of propagating material of that variety to be delivered, at the expense of the grantee, to a specified plant genetic resources centre and a herbarium.

3) The quantity of the propagating material of a variety specified in a notice under paragraph 2) shall be the quantity that the National Competent Authority considers would be sufficient to enable that variety to be kept in existence if there were no other propagating material of that variety.

4) Where the propagating material is delivered to a plant genetic resources centre in accordance with the conditions imposed on Plant Breeders' Rights by paragraph 1), the National Competent

Authority shall, subject to paragraph 6), cause that material to be stored at a specified plant genetic resources centre.

5) The delivery and storing of the propagating material in accordance with this paragraph does not affect the ownership of the material but that the material shall not be dealt with otherwise than for the purposes of this Act.

6) The propagating material stored at a plant genetic resources centre may be used by the National Competent Authority for the purposes set out in this Act.

7) Without limiting paragraphs 5) and 6), where, the propagating material is stored at a plant genetic resources centre as gazetted by the Government according to Article 39 of this Act, the material shall

not form part of the national collection, and shall not be used for the purposes of that collection, until a decision on the application for a Plant Breeders' Rights is taken. Once the variety is accorded recognition, the propagating material can be provided for purposes of further research and breeding under the intimation of the depositor of the material.

Revocation of Plant Breeders' Rights

55.

1) The National Competent Authority shall revoke a Plant Breeders' Rights in respect of a plant variety if:

- a) it is satisfied that the plant variety was not new or that facts exist which, if known before the grant of that Plant Breeders' Rights, would have resulted in the refusal of the grant; or
- b) the grantee has failed to pay a prescribed fee payable in respect of that Plant Breeders' within 90 days after having been notified that the prescribed fee was due for payment.

2) The National Competent Authority may revoke a Plant Breeders' Rights if it is satisfied that:

- a) the grantee has failed to comply, in relation to that Plant Breeders' Rights, with the prescribed conditions; or
- b) a person to whom that Plant Breeders' Rights has been assigned or transmitted has failed to comply with the provisions of this Act.

3) Where the National Competent Authority revokes a Plant Breeders' Rights in respect of a plant variety in accordance with this Article, it shall, within 7 days after the decision is taken, give written notice of the revocation to the grantee setting out the grounds for the revocation.

4) The National Competent Authority shall not revoke a Plant Breeders Rights in accordance with this Article unless and until it has given the grantee and any person to whom it believes that Plant

Breeders' Rights has been assigned or transmitted, particulars of the grounds for the proposed revocation and given the grantee and any such person a reasonable opportunity to make a written submission in relation to the proposed revocation.

5) The revocation of a Plant Breeders' Rights in respect of a plant variety in accordance with this Article takes effect:

a) subject to paragraph 4), at the expiration of the period within which an application may be made to a court for a review of the revocation; or

b) if such an application is made to the court, at the time when the application is withdrawn or finally determined by a court.

6) Nothing in this Article shall be taken to affect the powers or the legal system.

7) Any person whose interests are affected by the granting of a Plant Breeders' Rights in respect of a plant variety may apply to the National Competent Authority for the revocation of that Plant Breeders' Rights in accordance with this section.

8) The National Competent Authority shall consider any application under paragraph 7) for the revocation of a Plant Breeders' Rights.

The decision of the National Competent Authority not to revoke the Plant Breeders' Rights shall be communicated to the applicant by a written notice within 7 days after the decision is taken, setting out the grounds for the decision.

Surrender of Plant Breeders' Rights

56.

1) Subject to paragraph 2) of Article 34, a grantee of a Plant Breeders' Rights may at any time, by giving notice to National Competent Authority, offer to surrender that Plant Breeders' Rights: the National Competent Authority, after giving public notice of the offer and giving all interested parties an opportunity to make a written submission in relation to the offer, may, if it finds fit, accept the offer and revoke those rights.

2) Where an action or proceeding in respect of a Plant Breeders' Rights is pending in a court, the National Competent Authority shall not accept an offer for the surrender of, or revoke, that Plant Breeders' Rights, except by leave of the court or by consent of the parties to the action or proceeding.

PART VII

INSTITUTIONAL ARRANGEMENTS

Establishment of the National Competent Authority

57.

The State shall designate or establish a National Competent Authority which shall implement and enforce the provisions of this legislation. Its duties shall include those set out in Article 29.

Duties of the National Competent Authority

58.

The duties of the National Competent Authority are, while ensuring gender equity, to:

- i) create and operate a regulatory mechanism that will ensure effective protection of Community Intellectual Rights and Farmers' Rights, and the regulation of access to biological resources;
- ii) carry out the process of consultation and participation of local communities, including farming communities, in the identification of their rights as provided for under the customary practices and laws of the communities;
- iii) identify types of Community Intellectual Rights and Farmers' Rights;
- iv) identify and define the requirements and procedures necessary for the recognition of Community Intellectual Rights and Farmers' Rights;
- v) develop criteria and mechanisms to standardise procedures;
- vi) develop a system of registration of items protected by Community Intellectual Rights and Farmers' Rights according to their customary practices and law;
- vii) issue licenses for the exploitation and commercialisation of biological resources, including protected species, varieties or lineages, and community innovations, practices, knowledge and technologies;
- viii) identify relevant technical institutions that will assist local communities, including farming communities, in the categorisation and characterisation of their biological resources, innovations, practices, knowledge and technologies.

Establishment of National Inter-Sectoral Coordination Body

59.

A National Inter-Sectoral Co-ordination Body at the highest level, composed of representatives from relevant public sectors, scientific and professional organizations, non-governmental and local community organizations, shall be created as a body to co-ordinate and follow-up the proper implementation of this legislation by the National Competent Authority.

Functions of the National Inter-Sectoral Coordination Body

60.

The functions of the National Inter-Sectoral Coordination Body shall be to:

- i) ensure that the minimum conditions for agreements with collectors are strictly observed and complied with;
- ii) ensure that the rights of local communities, including farming communities, are protected, with due regard for gender equity, wherever the activities relating to the accessing, collection or research on biological resources, community innovations, practices, knowledge and technologies are conducted, including verifying that the requirements of prior informed consent by the local communities are complied with;
- iii) recommend policies and laws on the sustainable use of biological resources including new laws on intellectual property rights, Community Intellectual Rights and Farmers' Rights over their biological resources, innovations, practices, knowledge and technologies; and
- iv) perform such other functions as may be necessary for the effective implementation of this legislation.

Composition of the National Inter-Sectoral Coordination Body

61.

The National Inter-Sectoral Co-ordination Body shall be composed of the following persons:

Here the functional composition of the body can be outlined, the qualifications, fields of expertise or specialisation, public interest qualities, industry, community based organizations and persons from relevant areas and fields with due regard for gender equity. This section seeks to fulfil the requirements set out in Article 29 above.

Appointment of Technical Advisory Body

62.

It is hereby appointed a body to be known as the Technical Advisory Body to support the work of the National Inter-Sectoral Co-ordination Body.

Functions of the Technical Advisory Body

63.

The functions of the Technical Advisory Body shall be to:

- i) formulate policy options that promote the protection of Community Intellectual Rights, Farmers' Rights, gender equity and the regulation of access to biological resources;
- ii) prepare lists of taxa threatened by deterioration and/or extinction and of the places threatened by serious loss of biological diversity;
- iii) monitor and evaluate, at regular intervals, the implementation of this legislation or actual or potential threats to biological diversity and the likely impacts on the pursuit towards sustainable development;
- iv) develop and recommend a mechanism to enable the identification and dissemination of information regarding threats to biological resources; and
- v) perform such other functions as may be necessary to implement this legislation.

Establishment of a National Information System

64.

- 1) It is hereby established that there shall be a National Information System with regard to biological resources, which includes the activities set out in the following Article.
- 2) Local communities may also establish databases on their biological resources together with their components and derivatives, and the knowledge and technologies of those communities.
- 3) Access to information in the National Information System and databases shall be regulated by a charter setting out the rights of the owners of the data.

Activities of the National Information System

65.

The activities of the National Information System shall include *inter alia* the following:

- i) the compilation and documentation of information on Community Intellectual Rights, Farmers' Rights, gender equity and access to biological resources, community innovations, practices, knowledge and technologies;
 - ii) the maintenance of an up-to-date system of information about research and development activities on biological resources and community innovations, practices, knowledge and technologies;
- and
- iii) the compilation of information on piracy of biological resources, community innovations, practices, knowledge and technologies, and the disseminating of this information to all relevant and concerned bodies.

Establishment of a Community Gene Fund

66.

- 1) The Community Gene Fund shall be established as an autonomous Trust. A Director shall be appointed to administer the Fund. The Director shall report to the National Competent Authority.
- 2) There shall be an autonomous Trust to administer a Community Gene Fund deriving its funds from the shares due to local farming communities under Article 27.1(b) in Part V on Farmers' Rights. The Fund, which will be exempted from income tax, can receive contributions from national and international bodies and others interested in strengthening genetic conservation by local communities.
- 3) A royalty to be fixed by the National Competent Authority based on the gross value of the Breeders' Rights protected seeds sold shall be credited to the Community Gene Fund for the benefit of farming communities whose farmers' varieties have been the basis for the breeding of breeders' varieties.
- 4) The gene fund shall be used to finance projects developed by the farming communities, ensuring equity for women, with or without the participation of experts to help them, aimed at solving their felt problems, including, but not restricted to, the development, conservation and sustainable use of agricultural genetic resources.
- 5) All salaries and administrative expenses relating to the establishment and administration of the Community Gene Fund will be met by the Government, in order to ensure that the entire proceeds of the Fund go to the farming local communities.
- 6) The Community Gene Fund will have a Fund Management Committee, comprising representatives of farming local communities, professionals, non-governmental organizations, and the public and private sector.

PART VIII

ENABLING PROVISIONS

Sanctions and Penalties

67.

- 1) Without prejudice to the existing agencies and authorities, the State shall establish appropriate agencies with the power to ensure compliance with the provisions of this law.
- 2) Without prejudice to the exercise of civil and penal actions which may arise from violations of the provisions of this legislation and subsequent regulations, sanctions and penalties to be provided may

include:

- i) written warning;
- ii) fines;
- iii) automatic cancellation / revocation of the permission for access;
- iv) confiscation of collected biological specimens and equipment;
- v) permanent ban from access to biological resources, community knowledge and technologies in the country.

3) The violation committed shall be publicized in the national and international media and shall be reported by the National Competent Authority to the secretariats of relevant international agreements and regional bodies.

4) When the collector conducts his/her operations outside of national jurisdiction, any alleged violations by such a collector may be prosecuted through the cooperation of the government under whose jurisdiction the collector operates based on the guarantee that the latter has provided.

Appeals

68.

Decisions on approval, disapproval or cancellation of agreements regarding access to biological resources, community knowledge or technologies may be appealed through appropriate administrative channels. Recourse to the courts shall be allowed after exhaustion of all administrative remedies

Comparison of African Model Legislation with common provisions of the Nagoya Protocol and WIPO agreements discussed in chapter 2

This legislation deals with plant breeder's rights and farmers' rights as well as genetic resources and traditional knowledge. At the same time it omits a number of matters relevant to our proposed draft.

Common provisions	Provision in this Instrument	Comments
1. subject matter of protection- traditional knowledge, traditional cultural expressions, genetic resources	PART I OBJECTIVES The main aim of this legislation shall be to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, and knowledge and technologies in order to maintain and improve their diversity as a means of sustaining all life support systems. The specific objectives of this legislation shall be to: a) recognize, protect and support the inalienable rights of local communities including farming communities over their biological resources, knowledge and technologies; b) recognize and protect the rights of breeders; c) provide an appropriate system of access to biological resources, community knowledge and technologies subject to the prior informed consent of the State and	Addresses genetic resources and traditional knowledge

	<p>the concerned local communities;</p> <p>d) promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, knowledge and technologies;</p> <p>e) ensure the effective participation of concerned communities, with a particular focus on women, in making decisions as regards the distribution of benefits which may derive from the use of their biological resources, knowledge and technologies;</p> <p>f) promote and encourage the building of national and grassroots scientific and technological capacity relevant to the conservation and sustainable use of biological resources;</p> <p>g) provide appropriate institutional mechanisms for the effective implementation and enforcement of the rights of local communities, including farming communities and breeders, and the conditions of access to biological resources, community knowledge and technologies;</p> <p>h) promote the conservation, evaluation and sustainable utilisation of biological resources with a particular focus on the major role women play;</p> <p>i) promote improvements in the productivity, profitability, stability and sustainability of major production systems through yield enhancement and maintenance of biological diversity;</p> <p>j) promote the supply of good quality seed/planting material to farmers; and</p> <p>k) ensure that biological resources are utilised in an effective and equitable manner in order to strengthen the food security of the nation.</p>	
<p>2. definition of terms- key terms used in the draft</p>	<p>PART II DEFINITIONS AND SCOPE Definitions 1. The use of the following terms shall take the meanings in this legislation, as defined below:</p> <p>Access is the acquisition of biological resources, their derivatives, community knowledge, innovations, technologies or practices as authorised by the National Competent Authority.</p> <p>Benefit Sharing is the sharing of whatever accrues from the utilisation of biological resources, community knowledge, technologies, innovations or practices.</p> <p>Biological resource includes genetic resources, organisms or parts thereof, populations, or any other component of ecosystems, including ecosystems themselves, with actual or potential use or value for humanity.</p> <p>Collector is any natural or legal person, entity or agent obtaining access to biological resources, local practices, innovations, knowledge or technologies under authority given by the National Competent Authority.</p> <p>Community Rights are those rights held by local communities over their biological resources or parts or derivatives thereof, and over their practices, innovations, knowledge and technologies.</p> <p>Community Knowledge or indigenous knowledge is the accumulated knowledge that is vital for conservation and sustainable use of biological resources and/or which is of socio-economic value, and which has been developed over the years in indigenous/local communities.</p> <p>Derivative is a product developed or extracted from a biological resource; a derivative may include such products as plant varieties, oils, resins, gums, proteins etc.</p> <p>Ex Situ Condition is the condition in which a biological resource is found outside its natural habitat. Under the present law, any lineage that is cultivated within its country of origin is not considered to be in an <i>ex situ</i> condition.</p> <p>Innovation is any generation of a new, or an improvement of an existing, collective and/or cumulative knowledge or technology through alteration or modification, or the use of the properties, values or processes of any biological material or any part thereof, whether documented, recorded, oral, written or in whatever manner otherwise existing.</p> <p>In Situ Condition is the condition in which a biological resource is found in its ecosystem or natural habitat. In the case of a domesticated or cultivated variety, its condition is <i>in situ</i> when that variety is found in the cultural context in which its specific properties have been developed.</p> <p>Local Community is a human population in a distinct geographical area, with ownership over its biological resources, innovations, practices, knowledge, and technologies governed partially or completely by its own customs, traditions or laws.</p> <p>National Competent Authority is the entity authorised by the State to supervise and watch over the implementation of one or more of the components of the present law.</p> <p>Prior Informed Consent (PIC) is the giving by a collector of complete and accurate</p>	<p>Note use of community rather than traditional knowledge</p>

	information, and, based on that information, the prior acceptance of that collector by the government and the concerned local community or communities to collect biological resources, or indigenous knowledge, or technologies.	
3. scope- what is covered, respect for traditional ownership, respect for sovereignty over genetic resources, moral rights	<p>Scope 2.</p> <p>1) This legislation applies to:</p> <ul style="list-style-type: none"> i) Biological resources in both <i>in situ</i> and <i>ex situ</i> conditions; ii) The derivatives of the biological resources; iii) Community knowledge and technologies; iv) Local and indigenous communities; and v) Plant breeders <p>2) This legislation shall not affect the following:</p> <ul style="list-style-type: none"> i) The traditional systems of access, use or exchange of biological resources; ii) Access, use and exchange of knowledge and technologies by and between local communities; 3) The sharing of benefits based upon the customary practices of the concerned local communities, provided that the provisions of paragraph 2 shall not be taken to apply to any person or persons not living in the traditional and customary way of life relevant to the conservation and sustainable use of biological resources. 	
4. beneficiaries- who should benefit	<p>Right to Benefit 22.</p> <p>1) The State shall ensure that at least fifty per cent of benefits provided for in Article 12.2 shall be channeled to the concerned local community or communities in a manner which treats men and women equitably.</p> <p>2) The sharing the benefits in paragraph 1) above shall involve the full participation and approval of the concerned local community or communities.</p>	
5. access - who speaks for country, process for granting or refusing access including 5a. prior informed consent - ensuring traditional owners are aware of their rights and significance of agreements made 5b. mutually agreed terms- ensuring the bargaining process is fair and equitable	<p>PART III</p> <p>ACCESS TO BIOLOGICAL RESOURCES</p> <p><i>Application for access to biological resources and to the knowledge and technologies of local communities</i></p> <p>3.</p> <ul style="list-style-type: none"> 1) Any access to any biological resources and knowledge or technologies of local communities in any part of the country shall be subject to an application for the necessary prior informed consent and written permit. 2) Any access to any biological resource in a protected area shall be subject to an application for the necessary prior informed consent and written permit. 3) All applications for the necessary consent and written permit to access any biological resource, community knowledge or technology, shall be directed to the National Competent Authority unless otherwise explicitly provided for by law. <p>4.</p> <p>1) In making an application for access as provided in article 3 above, the following information shall be provided by the applicant:</p> <ul style="list-style-type: none"> i) the identity of the applicant and the documents that testify to her/his legal capacity to contract, including, where appropriate, the identity of all partners with the contracting party; ii) the resources to which access is sought, including the sites from which it will be collected, its present and potential uses, its sustainability and the risks which may arise from access to it; iii) whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access; iv) the purpose for which access to the resource is requested including the type and extent of research, teaching or commercial use expected to be derived from it; v) description of the manner and extent of local and national collaboration in the research and development of the biological resource concerned; vi) the identification of the national institution or institutions which will participate in the research and be in charge of the monitoring process; vii) the identity of the location where the research and development will be carried out; viii) the primary destination of the resource and its probable subsequent destination(s); ix) the economic, social, technical, biotechnological, scientific, environmental or any other benefits that are intended, or may be likely to, accrue to the country and local communities providing the biological resource as well as the collector and the country or countries where he/she operates; x) the proposed mechanisms and arrangements for benefit sharing; xi) description of the innovation, practice, knowledge or technology associated with 	

	<p>the biological resource; and</p> <p>xii) an environmental and socio-economic impact assessment covering at least the coming three generations, in cases where the collection is in large quantities.</p> <p>2) Nothing in paragraph (1) shall prevent the National Competent Authority requesting for any other information which it may deem necessary for the effective implementation of this legislation.</p> <p>Requirement of Consultation and Prior Informed Consent (PIC)</p> <p>5.</p> <p>1) Any access to biological resources, knowledge and or technologies of local communities shall be subject to the written prior informed consent of:</p> <p>i) the National Competent Authority; as well as that of</p> <p>ii) the concerned local communities, ensuring that women are also involved in decision making.</p> <p>2) Any access carried out without the prior informed consent of the State and the concerned local community or communities shall be deemed to be invalid and shall be subject to the penalties provided in this legislation or any other legislation that deals with access to biological resources.</p> <p>3) The National Competent Authority shall consult with the local community or communities in order to ascertain that its/their consent is sought and granted. Any access granted without consultation with the concerned community or communities shall be deemed to be invalid and in violation of the principle and requirement for prior informed consent as required under this Article.</p> <p>Placement of Completed Application Form in Public Registry</p> <p>6.</p> <p>1) Upon completion of the application, the National Competent Authority shall place or cause to be placed, the said application in a public registry or gazette, or cause it to be published in a newspaper that is reasonably accessible to the public for a period of x days.</p> <p>2) Any person may consult the public registry and comment on the application.</p> <p>3) The National Competent Authority shall cause the wide and effective dissemination of the relevant information to the communities concerned and to other interested parties.</p> <p>Granting of Access</p> <p>7.</p> <p>1) The granting of an access permit shall be carried out by the National Competent Authority or any person duly authorised to do so under the provisions of this legislation within a specified time limit.</p> <p>2) Any access permit shall be granted through a signed written agreement , between the National Competent Authority and/or the concerned local community or communities on the one hand where applicable, and, the applicant or collector on the other hand.</p> <p>3) The access permit shall only be valid if there is a written prior informed consent.</p> <p>Contents of the Agreement</p> <p>8.</p> <p>1) The agreement referred to in article 7 shall contain commitments undertaken or to be undertaken by the collector, as follows.</p> <p>i) to adhere to a limit set by the National Competent Authority on the quantity and specification of the quality of the biological resource that the collector may obtain and/or export;</p> <p>ii) to guarantee to deposit duplicates of, with complete field information on, each specimen of the biological resource or the records of community innovation, practice, knowledge or technology collected with the duly designated governmental agencies and, if so required, with local community organizations;</p> <p>iii) to inform immediately the National Competent Authority and the concerned local community or communities of all findings from research and development on the resource;</p> <p>iv) not to transfer the biological resource or any of its derivatives or the community innovation, practice, knowledge or technology to any third party without the authorization of the National Competent Authority and the concerned local community or communities;</p> <p>v) not to apply for any form of intellectual property protection over the biological</p>	
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	<p>resource or parts or derivatives thereof and not to apply for intellectual property rights protection over a community innovation, practice, knowledge or technology without the prior informed consent of the original providers;</p> <p>vi) to provide for the sharing of benefits;</p> <p>vii) access shall be conditioned upon a commitment to contribute economically to the efforts of the State and concerned local community or communities in the regeneration and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought;</p> <p>viii) submit to the National Competent Authority a regular status report of research and development on the resource concerned and where the biological resource is to be collected in large quantities on the ecological state of the area; and</p> <p>ix) abide by the relevant laws of the country particularly those regarding sanitary control, biosafety and the protection of the environment as well as by the cultural practices, traditional values and customs of the local communities.</p> <p>2) All efforts should be made for the research to be done in the country and in a manner that facilitates the participation of actors in the country of the provider of the biological resource.</p> <p><i>Patents over Life Forms and Biological Processes</i></p> <p>9.</p> <p>1) Patents over life forms and biological processes are not recognized and cannot be applied for.</p> <p>2) The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein.</p> <p><i>Approval of Granting of Access</i></p> <p>10.</p> <p>The National Competent Authority shall approve the granting of access to the biological resource or the community innovation, practice, knowledge or technology in question with any conditions it may deem necessary. In granting access the National Competent Authority shall ensure that all the requirements under this legislation have been fulfilled.</p> <p><i>Conditions Pertaining to Academic and Research Institutions, Public Agencies and Inter- governmental Institutions</i></p> <p>11.</p> <p>1) The National Competent Authority shall subject all applications for access to a biological resource, a community innovation, practice, knowledge or technology to the prior informed consent of the concerned community or communities.</p> <p>2) The National Competent Authority shall determine the appropriate conditions to be met under the written agreement referred to in Article 8, by academic and research institutions, public agencies and inter-governmental institutions.</p> <p>3) The application for access for research purposes shall clearly state the objective of the research and the relation of the applicant to industry. Neither the sample nor the associated information shall be transferred without a material transfer agreement reserving the prior rights of the State and/or community or communities.</p> <p>4) Where the institutions referred to in this Article change their activities to be predominantly the commercialisation of a biological resource, the National Competent Authority shall cause the conditions and terms to be varied accordingly.</p> <p><i>Types of Permit to be Granted for Access</i></p> <p>13.</p> <p>1) Having ascertained that the conditions set by the prior informed consent procedure have been fulfilled, the National Competent Authority shall grant the applicant/collector the appropriate permit for access. This may be an academic research permit, a commercial research permit, or a commercial exploitation permit.</p> <p>2) No person shall be in possession of and use two types of permit at the same time for the same resource unless granted written permission to do so.</p> <p>3) Nothing in this Article shall be deemed to limit the National Competent Authority's power to issue any other type of access permit.</p>	
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	<p>Revocation of Access Permit</p> <p>14.</p> <p>1) The National Competent Authority may unilaterally withdraw consent and repossess the written permit under the following conditions:</p> <ul style="list-style-type: none"> i) when there is evidence that the collector has violated any of the provisions of this legislation; ii) when there is evidence that the collector has failed to comply with the agreed terms; and iii) when there is failure to meet any of the conditions of access; iv) for reasons of overriding public interest; or v) for the protection of the environment and biological diversity. <p>2) Any termination or withdrawal of consent shall be done in consultation with the concerned local community or communities.</p> <p>Prior Informed Consent (PIC) of Local Communities</p> <p>18.</p> <p>Any access to a biological resource, innovation, practice, knowledge or technology, shall be subject to the prior informed consent (pic) of the concerned community or communities ensuring that women fully and equally participate in decision making.</p> <p>Right to Refuse Consent and Access</p> <p>19.</p> <p>Local communities have the right to refuse access to their biological resources, innovations, practices, knowledge and technologies where such access will be detrimental to the integrity of their natural or cultural heritage.</p> <p>Right to Withdraw or Place Restrictions on Consent and Access</p> <p>20.</p> <p>Local communities shall have the right to withdraw consent or place restrictions on the activities relating to access where such activities are likely to be detrimental to their socio-economic life, or their natural or cultural heritage.</p>	
<p>6. benefit sharing- how are benefits shared, what types of benefit, dealing with technology transfer, capacity building</p>	<p>Benefit Sharing</p> <p>12</p> <p>1. The access permit should be subject to the payment, made before commencement of collection, of a fee the sum of which will depend on whether or not the collection is to be used for commercial purposes, and the number of samples, the area of collecting, the duration of collection and whether or not the collector is granted exclusive rights.</p> <p>2. The State and the community or communities shall be entitled to a share of the earning derived from when any biological resource and/or knowledge collected generates, directly or indirectly, a product used in a production process.</p> <p>Establishment of a Community Gene Fund</p> <p>66.</p> <p>1) The Community Gene Fund shall be established as an autonomous Trust. A Director shall be appointed to administer the Fund. The Director shall report to the National Competent Authority.</p> <p>2) There shall be an autonomous Trust to administer a Community Gene Fund deriving its funds from the shares due to local farming communities under Article 27.1(b) in Part V on Farmers' Rights. The Fund, which will be exempted from income tax, can receive contributions from national and international bodies and others interested in strengthening genetic conservation by local communities.</p> <p>3) A royalty to be fixed by the National Competent Authority based on the gross value of the Breeders' Rights protected seeds sold shall be credited to the Community Gene Fund for the benefit of farming communities whose farmers' varieties have been the basis for the breeding of breeders' varieties.</p> <p>4) The gene fund shall be used to finance projects developed by the farming communities, ensuring equity for women, with or without the participation of experts to help them, aimed at solving their felt problems, including, but not restricted to, the development, conservation and sustainable use of agricultural genetic resources.</p> <p>5) All salaries and administrative expenses relating to the establishment and administration of the Community Gene Fund will be met by the Government, in order to ensure that the entire proceeds of the Fund go to the farming local communities.</p> <p>6) The Community Gene Fund will have a Fund Management Committee, comprising representatives of farming local communities, professionals, non-governmental</p>	<p>Definition recognises non monetary benefits but these provisions deal with a fee</p>

	organizations, and the public and private sector.	
7. Sanctions and remedies- dealing with breaches	<p>PART VIII ENABLING PROVISIONS Sanctions and Penalties</p> <p>67. 1) Without prejudice to the existing agencies and authorities, the State shall establish appropriate agencies with the power to ensure compliance with the provisions of this law. 2) Without prejudice to the exercise of civil and penal actions which may arise from violations of the provisions of this legislation and subsequent regulations, sanctions and penalties to be provided may include: i) written warning; ii) fines; iii) automatic cancellation / revocation of the permission for access; iv) confiscation of collected biological specimens and equipment; v) permanent ban from access to biological resources, community knowledge and technologies in the country. 3) The violation committed shall be publicized in the national and international media and shall be reported by the National Competent Authority to the secretariats of relevant international agreements and regional bodies. 4) When the collector conducts his/her operations outside of national jurisdiction, any alleged violations by such a collector may be prosecuted through the cooperation of the government under whose jurisdiction the collector operates based on the guarantee that the latter has provided.</p> <p>Appeals 68. Decisions on approval, disapproval or cancellation of agreements regarding access to biological resources, community knowledge or technologies may be appealed through appropriate administrative channels. Recourse to the courts shall be allowed after exhaustion of all administrative remedies</p>	
8. competent authority- establishment of a body to administer the legislation, deal with education, model clauses, codes of conduct, databases	<p>PART VII INSTITUTIONAL ARRANGEMENTS Establishment of the National Competent Authority</p> <p>57. The State shall designate or establish a National Competent Authority which shall implement and enforce the provisions of this legislation. Its duties shall include those set out in Article 29.</p> <p>Duties of the National Competent Authority 58. The duties of the National Competent Authority are, while ensuring gender equity, to: i) create and operate a regulatory mechanism that will ensure effective protection of Community Intellectual Rights and Farmers' Rights, and the regulation of access to biological resources; ii) carry out the process of consultation and participation of local communities, including farming communities, in the identification of their rights as provided for under the customary practices and laws of the communities; iii) identify types of Community Intellectual Rights and Farmers' Rights; iv) identify and define the requirements and procedures necessary for the recognition of Community Intellectual Rights and Farmers' Rights; v) develop criteria and mechanisms to standardise procedures; vi) develop a system of registration of items protected by Community Intellectual Rights and Farmers' Rights according to their customary practices and law; vii) issue licenses for the exploitation and commercialisation of biological resources, including protected species, varieties or lineages, and community innovations, practices, knowledge and technologies; viii) identify relevant technical institutions that will assist local communities, including farming communities, in the categorisation and characterisation of their biological resources, innovations, practices, knowledge and technologies.</p> <p>Establishment of National Inter-Sectoral Coordination Body</p>	

	<p>59. A National Inter-Sectoral Co-ordination Body at the highest level, composed of representatives from relevant public sectors, scientific and professional organizations, non-governmental and local community organizations, shall be created as a body to co-ordinate and follow-up the proper implementation of this legislation by the National Competent Authority.</p> <p>Functions of the National Inter-Sectoral Coordination Body 60. The functions of the National Inter-Sectoral Coordination Body shall be to: i) ensure that the minimum conditions for agreements with collectors are strictly observed and complied with; ii) ensure that the rights of local communities, including farming communities, are protected, with due regard for gender equity, wherever the activities relating to the accessing, collection or research on biological resources, community innovations, practices, knowledge and technologies are conducted, including verifying that the requirements of prior informed consent by the local communities are complied with; iii) recommend policies and laws on the sustainable use of biological resources including new laws on intellectual property rights, Community Intellectual Rights and Farmers' Rights over their biological resources, innovations, practices, knowledge and technologies; and iv) perform such other functions as may be necessary for the effective implementation of this legislation.</p> <p>Composition of the National Inter-Sectoral Coordination Body 61. The National Inter-Sectoral Co-ordination Body shall be composed of the following persons: <i>Here the functional composition of the body can be outlined, the qualifications, fields of expertise or specialisation, public interest qualities, industry, community based organizations and persons from relevant areas and fields with due regard for gender equity. This section seeks to fulfil the requirements set out in Article 29 above.</i></p> <p>Appointment of Technical Advisory Body 62. It is hereby appointed a body to be known as the Technical Advisory Body to support the work of the National Inter-Sectoral Co-ordination Body.</p> <p>Functions of the Technical Advisory Body 63. The functions of the Technical Advisory Body shall be to: i) formulate policy options that promote the protection of Community Intellectual Rights, Farmers' Rights, gender equity and the regulation of access to biological resources; ii) prepare lists of taxa threatened by deterioration and/or extinction and of the places threatened by serious loss of biological diversity; iii) monitor and evaluate, at regular intervals, the implementation of this legislation or actual or potential threats to biological diversity and the likely impacts on the pursuit towards sustainable development; iv) develop and recommend a mechanism to enable the identification and dissemination of information regarding threats to biological resources; and v) perform such other functions as may be necessary to implement this legislation.</p> <p>Establishment of a National Information System 64. 1) It is hereby established that there shall be a National Information System with regard to biological resources, which includes the activities set out in the following Article. 2) Local communities may also establish databases on their biological resources together with their components and derivatives, and the knowledge and technologies of those communities. 3) Access to information in the National Information System and databases shall be regulated by a charter setting out the rights of the owners of the data.</p>	
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	<p>Activities of the National Information System 65. The activities of the National Information System shall include <i>inter alia</i> the following: i) the compilation and documentation of information on Community Intellectual Rights, Farmers' Rights, gender equity and access to biological resources, community innovations, practices, knowledge and technologies; ii) the maintenance of an up-to-date system of information about research and development activities on biological resources and community innovations, practices, knowledge and technologies; and iii) the compilation of information on piracy of biological resources, community innovations, practices, knowledge and technologies, and the disseminating of this information to all relevant and concerned bodies.</p>	
9. no single owner-addressing situations where traditional knowledge, cultural expressions, genetic resources are common to more than one group		Not addressed
10. exceptions – emergencies, traditional use, conservation	<p>Restrictions on Activities Related to Access or Introduction of Biological Resources 15. The National Competent Authority should establish restrictions to or prohibitions on those activities which are directly or indirectly related to access to or introduction of a biological resource, particularly in cases of: i) endangered taxa; ii) endemism or rarity; iii) adverse effects upon human health or upon the quality of life or the cultural values of local communities; iv) environmental impacts which are undesirable or difficult to control; v) danger of genetic erosion or loss of ecosystems, their resources or their components, which arise from undue or uncontrolled collection of biological resources; vi) non-compliance with rules on biosafety or food security; and vii) use of resources for purposes contrary to national interest and to relevant international agreements entered into by the country.</p> <p>PART IV COMMUNITY RIGHTS Recognition of the Rights of Local and Indigenous Communities 16. The State recognizes the rights of communities over the following: i) their biological resources; ii) the right to collectively benefit from the use of their biological resources; iii) their innovations, practices, knowledge and technologies acquired through generations; iv) the right to collectively benefit from the utilisation of their innovations, practices, knowledge and technologies; v) their rights to use their innovations, practices, knowledge and technologies in the conservation and sustainable use of biological diversity; vi) the exercise of collective rights as legitimate custodians and users of their biological resources; vi) the exercise of collective rights as legitimate custodians and users of their biological resources;</p> <p>Application of the Law on Community Rights 17. The State recognizes and protects the community rights that are specified in Article 16 as they are enshrined and protected under the norms, practices and customary law found in, and recognized by, the concerned local and indigenous communities, whether such law is written or not.</p>	

	<p><i>Right to Traditional Access, Use and Exchange</i> 21. 1) Local communities shall exercise their inalienable right to access, use, exchange or share their biological resources in sustaining their livelihood systems as regulated by their customary practices and laws. 2) No legal barriers shall be placed on the traditional exchange system of the local communities in the exercise of their rights as provided for in paragraph (1) above and in other rights that may be provided by the customary practices and laws of the concerned local communities.</p> <p><i>Recognition of Community Intellectual Rights</i> 23. 1) The Community Intellectual Rights of the local communities, including traditional professional groups, particularly traditional practitioners, shall at all times remain inalienable, and shall be further protected under the mechanism established by this legislation. 2) An item of community innovation, practice, knowledge or technology, or a particular use of a biological or any other natural resource shall be identified, interpreted and ascertained by the local communities concerned themselves under their customary practice and law, whether such law is written or not. 3) Non-registration of any community innovations, practices, knowledge or technologies, is not to mean that these are not protected by Community Intellectual Rights. 4) The publication of a written or oral description of a biological resource and its associated knowledge and information, or the presence of these resources in a genebank or any other collection, or its local use, shall not preclude the local community from exercising its community intellectual rights in relation to those resources.</p>	
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