

Annex: Disclosure Requirements Table

This table comprises a non-exhaustive selection of extracts from existing legislative texts which, in one way or another, provide for a specific disclosure requirement related to genetic resources and/or traditional knowledge. The extracts are taken directly from the legislative texts as contained in WIPO's global database, WIPO Lex. The table contains no interpretation or commentary. In order to facilitate the reading and comprehension of the table, some relevant parts of the extracts may appear in bold, but this highlighting does not appear in the original legislative texts. All information provided is for information purposes only, and is not a substitute for legal advice. The WIPO Secretariat makes every effort to ensure, but cannot guarantee, the accuracy of the data contained in this selection. In particular, WIPO assumes no responsibility for any discrepancy that may occur in the electronic manipulation of the said data. The WIPO Secretariat will continue to add to and update the table over time. Additional contributions to the table, and any corrections and comments, would be appreciated and may be sent to grtkf@wipo.int.

The current version of the Disclosure Requirements Table was updated as at January 1, 2022. Further updates will be made available on the WIPO website: www.wipo.int.

Country/ Region	Title	Subject Matter	Trigger of Disclosure	Content of Disclosure	Consequences of non- compliance
Belgium	Loi du 28 mars 1984 sur les brevets d'invention (Law of March 28, 1984 on Patents) (mise à jour le 22 décembre 2008) (https://wipolex.wipo.int/fr/legislation/details/11665)	Article 15 § 1er [...] La matière biologique d'origine végétale ou animale	Article 15 § 1er La demande de brevet doit contenir: [...] (6) une mention de l'origine géographique de la matière biologique d'origine végétale ou animale à partir de laquelle l'invention a été développée, lorsque celle-ci est connue.	Article 15 § 1er La demande de brevet doit contenir: [...] (6) une mention de l'origine géographique de la matière biologique d'origine végétale ou animale à partir de laquelle l'invention a été développée, lorsque celle-ci est connue.	
Brazil	Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge) (http://www.wipo.int/wipolex/en/details.jsp?id=15741)	Article 47 [...] concessão de direito de propriedade intelectual [...] sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado	Article 47 A concessão de direito de propriedade intelectual pelo órgão competente sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado	Article 47 A concessão de direito de propriedade intelectual pelo órgão competente sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado	

			fica condicionada ao cadastramento ou autorização, nos termos desta Lei.	fica condicionada ao cadastramento ou autorização, nos termos desta Lei.	
	Decreto nº 8.772 de 11 de maio de 2016 que regulamenta a Lei nº 13.123, de 20 de maio de 2015 (https://wipolex.wipo.int/en/legislation/details/16116)				<p>Art. 80. Requerer direito de propriedade intelectual resultante de acesso ao patrimônio genético ou conhecimento tradicional associado, no Brasil ou no exterior, sem realização de cadastro prévio.</p> <p>Multa mínima de R\$ 3.000,00 (três mil reais) e máxima de R\$ 30.000,00 (trinta mil reais), quando se tratar de pessoa natural.</p> <p>Multa mínima de R\$ 10.000,00 (dez mil reais) e máxima de R\$ 200.000,00 (duzentos mil reais), quando se tratar de pessoa jurídica enquadrada como microempresa, empresa de pequeno porte ou cooperativas de agricultores tradicionais com receita bruta anual igual ou inferior ao limite máximo estabelecido no inciso II do art. 3º</p>

					<p>da Lei Complementar nº 123, de 2006.</p> <p>Multa mínima de R\$ 20.000,00 (vinte mil reais) e máxima de R\$ 10.000.000,00 (dez milhões de reais), para as demais pessoas jurídicas.</p>
Burundi	<p>Law No. 1/13 of July 28, 2009 relating To Industrial Property in Burundi</p> <p>(https://wipolex.wipo.int/en/legislation/details/8324)</p>	<p>Article 21 genetic or biological resources, traditional knowledge</p>	<p>Article 21 The description must contain a clear indication of the origin of the genetic or biological resources collected in the territory of Burundi and used directly or indirectly in the making of the claimed invention as well as any element of the traditional knowledge which may or may not be linked to these resources that is protected under Title V of this part and that has been used directly or indirectly in the making of the claimed invention without the prior informed consent of its individual or joint creators.</p>	<p>Article 21 The description must contain a clear indication of the origin of the genetic or biological resources collected in the territory of Burundi and used directly or indirectly in the making of the claimed invention as well as any element of the traditional knowledge which may or may not be linked to these resources that is protected under Title V of this part and that has been used directly or indirectly in the making of the claimed invention without the prior informed consent of its individual or joint creators.</p>	<p>Article 406. The competent authority shall be entitled to claim ownership of any patent application filed or any patent granted in a manner which does not comply with the provisions of Article 21 concerning genetic resources.</p>
China	<p>Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the</p>	<p>Article 26 Genetic resources</p>	<p>Article 26. With regard to an</p>	<p>Article 26. With regard to an</p>	<p>Article 5. Patent rights shall not be granted for</p>

	<p>Revision of the Patent Law of the People's Republic of China)</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=5484)</p>		<p>invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources.</p>	<p>invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources.</p>	<p>inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations.</p> <p>Article 26. If the applicant cannot indicate the original source, he shall state the reasons.</p>
	<p>Implementing Rules of the Patent Law of the People's Republic of China (promulgated by Decree No. 306 of the State Council of China on June 15, 2001, and revised by the Decision of January 9, 2010, of the State Council on Amending the Rules for the Implementation of the Patent Law of the People's Republic of China)</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=6504)</p>	<p>Article 26 (Newly added) The genetic resources referred to in the Patent Law means any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention-creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources. Where the applicant seeks to apply for patent for such invention-creation</p>	<p>Article 26 (Newly added) The genetic resources referred to in the Patent Law means any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention-creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources. Where the applicant seeks to apply for patent for such invention-</p>	<p>Article 26 (Newly added) The genetic resources referred to in the Patent Law means any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention-creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources. Where the applicant seeks to apply for patent for such invention-creation</p>	<p>Rule 53 In accordance with the provisions of Article 38 of the Patent Law, the circumstances where an application for a patent for invention shall be rejected by the Patent Administration Department under the State Council after examination as to substance are as follows: [...] (2) Where the application does not comply with the provisions of [...] Article 26, paragraph [...] five [...] of the Patent Law [...]</p>

		completed on genetic resources, he or it shall so state in the request, fill in prescribed forms issued by the Patent Administration Department under the State Council.	creation completed on genetic resources , he or it shall so state in the request, fill in prescribed forms issued by the Patent Administration Department under the State Council.	completed on genetic resources, he or it shall so state in the request, fill in prescribed forms issued by the Patent Administration Department under the State Council.	
Costa Rica	Law No. 7788 of April 30, 1998, on Biodiversity (as amended by Law No. 8686 of November 21, 2008) (http://www.wipo.int/wipolex/en/details.jsp?id=11314)	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo.	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. La oposición fundada de la Oficina Técnica impedirá registrar la patente o	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación.	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación.

			protección de la innovación.		
Cuba	Decree-Law No. 290 of November 20, 2011, on Inventions and Industrial Designs and Models (http://www.wipo.int/wipolex/en/details.jsp?id=12026)	ARTÍCULO 26.1. material biológico	ARTÍCULO 26.1.- Para obtener una patente , el solicitante presenta ante la Oficina la correspondiente solicitud, que contiene los documentos siguientes: [...] j) copia de la previa y expresa autorización para el acceso a material biológico, expedida por la autoridad competente de conformidad con la legislación vigente en la materia, cuando la invención se refiere a dicho material, incluido el genético y sus partes o derivados del que Cuba es país de origen o que está presente en especies domesticadas y cultivadas en el país; k) declaración que exprese que el material biológico al que se refiere la invención no ha sido obtenido en el	ARTÍCULO 26.1.- Para obtener una patente , el solicitante presenta ante la Oficina la correspondiente solicitud, que contiene los documentos siguientes: [...] j) copia de la previa y expresa autorización para el acceso a material biológico, expedida por la autoridad competente de conformidad con la legislación vigente en la materia, cuando la invención se refiere a dicho material, incluido el genético y sus partes o derivados del que Cuba es país de origen o que está presente en especies domesticadas y cultivadas en el país; k) declaración que exprese que el material biológico al que se refiere la invención no ha sido obtenido en el territorio de la	ARTÍCULO 32.1.- En caso de detectarse cualquier omisión o irregularidad en la documentación, se expide requerimiento al solicitante para que, previo pago de la tarifa establecida, subsane la misma en un término de sesenta días, contado a partir de la notificación del requerimiento. No obstante, antes del vencimiento del mencionado término, el requerido puede solicitar a la Oficina por escrito que el plazo sea prorrogado por otros treinta días, previo pago de la tarifa correspondiente. 2. Si el solicitante no subsana la omisión o irregularidad en el término establecido, se entiende como abandonada la solicitud, sin que quede derecho subsistente, excepto cuando el requerimiento esté referido únicamente al requisito de unidad de invención, en cuyo caso el examen continúa respecto a la primera reivindicación independiente formulada y al conjunto

			<p>territorio de la Republica de Cuba, en cuyo caso debe indicarse el país de origen y fuente del material biológico y de los conocimientos tradicionales asociados a estos y el consentimiento fundamentado previo al acceso; [...]</p>	<p>Republica de Cuba, en cuyo caso debe indicarse el país de origen y fuente del material biológico y de los conocimientos tradicionales asociados a estos y el consentimiento fundamentado previo al acceso; [...]</p>	<p>de reivindicaciones que guarden unidad de invención con aquella.</p>
Denmark	<p>Order No. 25 of January 18, 2013, on Patents and Supplementary Protection Certificates</p> <p>https://wipolex.wipo.int/en/legislation/details/12938</p>	<p>Part I Chapter 2 3(5) biological material</p>	<p>Part I Chapter 2 <i>The contents and filing of applications</i> [...] 3.- [...] (5) If an invention relates to or makes use of a biological material, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the</p>	<p>Part I Chapter 2 <i>The contents and filing of applications</i> [...] 3.- [...] (5) If an invention relates to or makes use of a biological material, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not</p>	<p>Part I Chapter 2 <i>The contents and filing of applications</i> [...] 3.- [...] (5) If an invention relates to or makes use of a biological material, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other</p>

			examination and other processing of the patent application or the validity of the rights conferred by the granted patent.	affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.	processing of the patent application or the validity of the rights conferred by the granted patent.
Djibouti	<p>Law No. 50/AN/09/6th Lof July 19, 2009, on the Protection of Industrial Property</p> <p>https://wipolex.wipo.int/en/legislation/details/6124</p>	Article 34 genetic or biological resources, traditional knowledge	<p>Article 34 The description of the invention shall disclose the invention in a way that is sufficiently clear and complete to enable a person skilled in the art to carry it out. In particular, the description of the invention shall: [...] (b) indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention and the searching and examination of the invention in the event of a dispute, and, preferably, cite the documents reflecting such art. If the invention claimed has been developed or obtained directly from genetic or biological</p>	<p>Article 34 The description of the invention shall disclose the invention in a way that is sufficiently clear and complete to enable a person skilled in the art to carry it out. In particular, the description of the invention shall: [...] (b) indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention and the searching and examination of the invention in the event of a dispute, and, preferably, cite the documents reflecting such art. If the invention claimed has been developed or obtained directly from genetic or biological resources</p>	<p>Article 41 A patent application shall be refused if: [...] (g) its description or claims clearly do not meet the conditions provided for in Articles 34 and 35, particularly where claims are not based on the description; [...]</p>

			resources obtained from a particular source, or from the use of traditional knowledge obtained from a particular community , the description shall indicate the source of these resources or knowledge, as well as the way in which they have been obtained;	obtained from a particular source, or from the use of traditional knowledge obtained from a particular community, the description shall indicate the source of these resources or knowledge, as well as the way in which they have been obtained;	
Ecuador	Reglamento Nacional al Régimen Común de Acceso a los Recursos Genéticos en aplicación a la Decisión N° 391 de la Comunidad Andina (Decreto Ejecutivo N° 905 de 3 de octubre de 2011) (https://wipolex.wipo.int/en/legislation/details/11842)	DISPOSICIONES GENERALES PRIMERA un recurso genético o de un producto derivado del mismo	DISPOSICIONES GENERALES PRIMERA Previo al otorgamiento de un derecho de propiedad intelectual , el Instituto Ecuatoriano de Propiedad Intelectual solicitará la presentación del número del registro del contrato de acceso y copia del mismo, cuando existan indicios razonables o certeza de que los productos o procesos cuya protección se solicita hayan sido obtenidos a partir de un recurso genético o de un producto derivado	DISPOSICIONES GENERALES PRIMERA Previo al otorgamiento de un derecho de propiedad intelectual, el Instituto Ecuatoriano de Propiedad Intelectual solicitará la presentación del número del registro del contrato de acceso y copia del mismo , cuando existan indicios razonables o certeza de que los productos o procesos cuya protección se solicita hayan sido obtenidos a partir de un recurso genético o de un producto derivado del mismo, y que esté en	

			del mismo, y que esté en consonancia con lo establecido en la Constitución y normativa aplicable.	consonancia con lo establecido en la Constitución y normativa aplicable.	
Organic Code on the Social Economy of Knowledge, Creativity and Innovation (of December 9, 2016) (https://wipolex.wipo.int/en/legislation/details/16990)			<p>Artículo 282.- De la patente y la divulgación de origen.- De acuerdo a lo previsto en los tratados internacionales de los cuales el Ecuador es parte, este Código y su reglamento respectivo, en el caso de que el objeto de una solicitud de patente implique la utilización de recursos genéticos y los conocimientos tradicionales asociados, el solicitante deberá informar:</p> <p>1. El país donde se obtuvieron esos recursos o los conocimientos tradicionales asociados; y, 2. La fuente, con inclusión de pormenores respecto a la entidad, en su caso, de la que se obtuvieron esos</p>	<p>Artículo 282.- De la patente y la divulgación de origen.- De acuerdo a lo previsto en los tratados internacionales de los cuales el Ecuador es parte, este Código y su reglamento respectivo, en el caso de que el objeto de una solicitud de patente implique la utilización de recursos genéticos y los conocimientos tradicionales asociados, el solicitante deberá informar:</p> <p>1. El país donde se obtuvieron esos recursos o los conocimientos tradicionales asociados; y, 2. La fuente, con inclusión de pormenores respecto a la entidad, en su caso, de la que se obtuvieron esos</p>	<p>Artículo 303.- Nulidad absoluta de la patente.- La autoridad nacional competente en materia de derechos intelectuales, de oficio o a solicitud de cualquier persona que acredite legítimo interés, y en cualquier momento, declarará la nulidad absoluta de una patente, en los siguientes casos: [...] 7. De ser el caso, si no se hubiese presentado la copia del contrato de acceso, cuando los productos o procedimientos cuya patente se solicita han sido obtenidos o desarrollados a partir de recursos genéticos o de sus productos derivados de los que el Ecuador es país de origen; 8. De ser el caso, si no se hubiese presentado la copia del documento que acredite la licencia o autorización de uso de los conocimientos tradicionales de las comunidades</p>

		<p>recursos o los conocimientos tradicionales asociados. Deberá igualmente adjuntar copia de un certificado de cumplimiento con la legislación de acceso a recursos genéticos o los conocimientos tradicionales asociados reconocido internacionalmente. Si un certificado de cumplimiento reconocido internacionalmente no es aplicable en el país proveedor, el solicitante deberá proporcionar información pertinente en cuanto a la conformidad con el consentimiento fundamentado previo y el acceso y la participación justa y equitativa en los beneficios, tal como lo exija la legislación nacional del país que aporte los recursos genéticos y/o los conocimientos tradicionales asociados, que sea el país de origen de dichos recursos o un</p>	<p>recursos o los conocimientos tradicionales asociados. Deberá igualmente adjuntar copia de un certificado de cumplimiento con la legislación de acceso a recursos genéticos o los conocimientos tradicionales asociados reconocido internacionalmente. Si un certificado de cumplimiento reconocido internacionalmente no es aplicable en el país proveedor, el solicitante deberá proporcionar información pertinente en cuanto a la conformidad con el consentimiento fundamentado previo y el acceso y la participación justa y equitativa en los beneficios, tal como lo exija la legislación nacional del país que aporte los recursos genéticos y/o los conocimientos</p>	<p>indígenas, afroamericanas o locales del Ecuador o los países miembros de la Comunidad Andina, cuando los productos o procesos cuya protección se solicita han sido obtenidos o desarrollados a partir de dichos conocimientos de los que el Ecuador o cualquiera de los países miembros de la Comunidad Andina es país de origen; 9. Si la patente hubiese sido concedida en contravención del artículo 282; Cuando las causales indicadas anteriormente sólo afectaren alguna o partes de una reivindicación, la nulidad se declarará solamente con respecto a tales reivindicaciones o a tales partes de la reivindicación, según corresponda. La patente, la reivindicación o aquella parte de una reivindicación que fuese declarada nula se reputará nula y sin ningún valor desde la fecha de presentación de la solicitud de la patente.</p>
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			país que haya adquirido los recursos genéticos o los conocimientos tradicionales asociados de conformidad con el Convenio sobre la Diversidad Biológica y los demás tratados internacionales de los que Ecuador es parte.	tradicionales asociados, que sea el país de origen de dichos recursos o un país que haya adquirido los recursos genéticos o los conocimientos tradicionales asociados de conformidad con el Convenio sobre la Diversidad Biológica y los demás tratados internacionales de los que Ecuador es parte.	
Egypt	Law No. 82 of 2002 on the Protection of Intellectual Property Rights (http://www.wipo.int/wipolex/en/details.jsp?id=1301)	Article 13 biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage	Article 13 [...] Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage , the inventor should have acquired the sources in a legitimate manner. [...]	Article 13 [...] Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner. [...]	Article 14 The Patent Office may, as stipulated in the Regulations, require the applicant to make any amendments or complements which it shall deem necessary to comply with the provisions of Article 13. If the applicant fails to comply within three months of notification, he shall be considered as having withdrawn his application. The applicant may, within 30 days and in accordance with the conditions stipulated in the Regulations, appeal such request by the

					Patent Office before the Committee provided for in article 36.
	<p>Council of Ministers Resolution No. 1366 of 2003 issuing Implementing Regulations for Law No. 82 of 2002 on the Protection of Intellectual Property Rights, Books One, Two and Four</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=7299</p>	<p>Article 3 [...] plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage</p>	<p>Article 3 The patent application shall be accompanied by [...] 3. Where the application relates to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage, it shall be accompanied by documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt.</p>	<p>Article 3 The patent application shall be accompanied by [...] 3. Where the application relates to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage, it shall be accompanied by documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt.</p>	<p>Article 4. Documentation mentioned under items 3, 4, 5, 6 and 7 of Article 3 of these Regulations may be furnished within four months from the filing date of the application. [...]</p> <p>If the documents provided for by the first paragraph are not furnished in due time, as the case may be, the application shall be considered as non-existent.</p>
Ethiopia	<p>Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006</p> <p>https://wipolex.wipo.int/en/legislation/details/5559</p>	<p>Article 17. genetic resources, community knowledge</p>	<p>Article 17. Obligations of Access Permit Holder A person who shall be given an access</p>	<p>Article 17. Obligations of Access Permit Holder A person who shall be given an access</p>	

			<p>permit shall have the following obligations: [...] 12/ where he seeks to acquire intellectual property right over the genetic resources accessed or parts thereof, negotiate new agreement with the Institute based on the relevant laws of Ethiopia; 13/ not apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute; 14/ recognize the locality where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from; [...]</p>	<p>permit shall have the following obligations: [...] 12/ where he seeks to acquire intellectual property right over the genetic resources accessed or parts thereof, negotiate new agreement with the Institute based on the relevant laws of Ethiopia; 13/ not apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute; 14/ recognize the locality where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from; [...]</p>	
European Union	<p>Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions</p> <p>(http://www.wipo.int/wipolex/en/details.jsp?id=1440)</p>	(Paragraph 27 of the Preamble) biological material of plant or animal origin	Paragraph 27 of the Preamble. Whereas if an invention is based on biological material of plant or	Paragraph 27 of the Preamble. Whereas if an invention is based on biological material of plant or	Paragraph 27 of the Preamble. Whereas if an invention is based on biological material of plant or animal origin or

			<p>animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known;</p>	<p>animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known;</p>	<p>if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.</p>
France	<p>Loi n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages</p> <p>(http://www.wipo.int/wipolex/en/details.jsp?id=16565)</p>	<p>Art. L. 412-18.-II Ressources génétiques et de connaissances traditionnelles associées</p>	<p>Art. L. 412-18.-II Les utilisateurs de ressources génétiques et de connaissances traditionnelles associées présentent à la ou aux autorités compétentes mentionnées au premier alinéa du présent II les informations prévues à l'article 4 du règlement (UE) n° 511/2014 du 16 avril 2014 précité, dans les cas suivants : [...] 2° [...] Lorsque [l'utilisation de ressources génétiques et de connaissances traditionnelles associées aux ressources génétiques] conduit à une demande de</p>	<p>Art. L. 412-18.-II Les utilisateurs de ressources génétiques et de connaissances traditionnelles associées présentent à la ou aux autorités compétentes mentionnées au premier alinéa du présent II les informations prévues à l'article 4 du règlement (UE) n° 511/2014 du 16 avril 2014 [...]</p>	<p>Article 39 [...] Est puni d'un an d'emprisonnement et de 150 000 € d'amende : 1° Le fait d'utiliser des ressources génétiques ou des connaissances traditionnelles associées, au sens de l'article L. 4123 L. 4124, sans disposer des documents mentionnés au 3 de l'article 4 du règlement (UE) n° 511/2014 du Parlement européen et du Conseil, du 16 avril 2014, précité lorsqu'ils sont obligatoires ; 2° Le fait de ne pas rechercher, conserver ou transmettre aux utilisateurs ultérieurs les informations pertinentes sur l'accès et le partage des avantages pour les ressources génétiques et les connaissances traditionnelles</p>

			<p>brevet, les informations mentionnées au premier alinéa du présent II sont adressées à l'Institut national de la propriété industrielle à la seule initiative du déclarant. L'Institut national de la propriété industrielle procède aux démarches normales de l'examen de la demande de brevet et à l'attribution d'une date de dépôt et transmet les informations sans examen à l'autorité compétente chargée de l'application des règles édictées par l'Union européenne visant à ce que chaque Etat membre contrôle que l'utilisateur sur son territoire de ressources génétiques et, le cas échéant, de connaissances traditionnelles associées à ces ressources y a eu accès dans le respect de toute disposition législative ou réglementaire alors applicable.</p>		<p>associées en application du même article 4. L'amende est portée à un million d'euros lorsque l'utilisation des ressources génétiques ou des connaissances traditionnelles mentionnée au 1° du présent I a donné lieu à une utilisation commerciale. II. Les personnes physiques ou morales coupables des infractions prévues au I du présent article encourrent également, à titre de peine complémentaire, l'interdiction, pendant une durée ne pouvant excéder cinq ans, de solliciter, en application des articles L. 4128 et L. 4129, une autorisation d'accès aux ressources génétiques ou à certaines catégories d'entre elles et aux connaissances traditionnelles associées en vue de leur utilisation commerciale.</p>
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Germany	<p>Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 2 of the Act of 4 April 2016</p> <p>http://www.wipo.int/edocs/lexdocs/laws/en/de/de223en.pdf</p>	<p>Section 34a Biological material of plant or animal origin</p>	<p>[...]</p> <p>Section 34a (1) Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. [...]</p>	<p>Section 34a (1) Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. [...] (2) If the application includes information on the geographical origin pursuant to the first sentence of subsection (1), the German Patent and Trade Mark Office shall notify this application to the Federal Agency for Nature Conservation (Bundesamt für Naturschutz) as the competent authority within the meaning of section 6 (1) of the Act Implementing the Obligations Under the Nagoya Protocol and Transposing Regulation (EU) No 511/2014 of 25 November 2015 (Federal Law Gazette I p. 2092)</p>	<p>Section 34a (1) [...] This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents. [...]</p>
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				following publication of the information pursuant to section 32 (5).	
India	The Patents Act, 1970 (as amended up to Patents (Amendment) Act, 2005) (http://www.wipo.int/wipolex/en/details.jsp?id=13104)	Article 10(4)(ii)(D) Biological material	Article 10(4)(ii)(D) (ii) If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:— [...] (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.	Article 10(4)(ii)(D) (ii) If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:— [...] (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.	Article 25 Opposition to the patent. — (1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground [...] (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; [...] but on no other ground, and the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed. (2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may

					<p>give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely: — [...] (j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention; [...].</p> <p>Article 64 Revocation of patents. (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds , that is to say— [...] (p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; [...]</p>
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Indonesia	<p>Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=16392</p>	<p>Article 26 Genetic resources and/or traditional knowledge</p>	<p>Article 26 (1) If an invention as being associated with and/or derived from a genetic resource and/ or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/ or traditional knowledge mentioned in sub article (1) is endorsed by a competent authority authorized by the government. (3) Benefit sharing and/or access for the utilization of a genetic resource and/or traditional knowledge substantiated in sub article (1) is conducted based on national laws and international laws in the realm of genetic resources and traditional knowledge.</p>	<p>Article 26 (1) If an invention as being associated with and/or derived from a genetic resource and/ or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/ or traditional knowledge mentioned in sub article (1) is endorsed by a competent authority authorized by the government. (3) Benefit sharing and/or access for the utilization of a genetic resource and/or traditional knowledge substantiated in sub article (1) is conducted based on national laws and international laws in the realm of genetic resources and traditional knowledge.</p>	
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Italy	<p>Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Decree-Law No. 1 of January 24, 2012, converted into law with changes by Law No. 27 of March 24, 2012)</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=13123</p>	<p>Article 170 bis. biological material of animal or plant origin</p>	<p>Article 170 bis. Requirements concerning biotechnological inventions [...] 2. The provenance of biological material of animal or plant origin, which is the basis of the invention, is to be declared together with the application of the patent both with reference to the country of origin, in order to verify compliance with import and export legislation, and in relation to the biological organism from which it was isolated. [...].</p>	<p>Article 170 bis. Requirements concerning biotechnological inventions [...] 2. The provenance of biological material of animal or plant origin, which is the basis of the invention, is to be declared together with the application of the patent both with reference to the country of origin, in order to verify compliance with import and export legislation, and in relation to the biological organism from which it was isolated. [...]</p>	<p>Article 170 bis. Requirements concerning biotechnological inventions [...] 7. If the Italian Patent and Trademark Office ascertains the lack of the conditions for patenting a biotechnological invention or the failure to file the declarations under paragraphs 2, 3 and 4, shall proceed in accordance with Article 173, paragraph 7, and in the event it determines the absence of the conditions for patenting as set forth by Articles 81-quater, 81-quinquies and Article 162, it shall reject the application. [<i>Article added by paragraph 1 of Article 87, Legislative Decree No. 131 of 13 August 2010.</i>]</p> <p>Art. 170-ter. Sanctions [...] 2. Unless the action constitutes a crime, whoever, in the declaration required by Article 170-bis, paragraph 2, makes false statements concerning the provenance of biological material of animal or</p>
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					<p>plant origin, shall be punished with an administrative fine from 10.000,00 to 100.000,00 Euros. [...]</p> <p>4. Within the minimum and maximum limits established by this article, the amount of the administrative fines shall be determined taking account the criteria set forth by Article 11 of Law No. 689 of 24 November 1981, the different potential for causing harm to the protected interest that each violation has in the abstract, the specific personal qualities and the property advantage that the violation can bring to the guilty party or the person or entity in whose interest he acts. [...]</p> <p>Article 173. Observations</p> <p>7. Before rejecting in full or in part an application or a related request, for reasons that were not set forth in observations pursuant to paragraph 1, the Italian Patent and Trademark Office assigns the applicant a term of two months to submit observations.</p>
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					Once that term has expired, if no observations have been submitted or if the Office does not believe that it can accept those submitted, the application or request is rejected in full or in part.
Kyrgyzstan	<p>Law of the Kyrgyz Republic No. 116 of July 31, 2007, on the Protection of Traditional Knowledge</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=5571</p>	Traditional knowledge	<p>Article 8. Patenting of subject-matters created on the base of Traditional Knowledge</p> <p>[...] When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public. [...]</p>	<p>Article 8. Patenting of subject-matters created on the base of Traditional Knowledge</p> <p>[...] When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public. [...]</p> <p>Article 9. Application for registration and granting the right to use Traditional Knowledge or for granting the right</p>	

				<p>to use registered Traditional Knowledge</p> <p>[...]</p> <p>An application shall contain the following:</p> <p>1) application for traditional knowledge registration and granting the right to use Traditional Knowledge or granting the right to use registered Traditional Knowledge stating the applicant as well as his location and place of residence;</p> <p>2) specific and complete description of Traditional Knowledge, including: point of origin of Traditional Knowledge (borders of a geographic object); description of genetic resource, which is being used in connection with particular traditional knowledge; field of application and expected positive result of traditional</p>	
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				<p>knowledge used; information relevant to previously issued publications regarding a particular traditional knowledge.</p> <p>The following documents shall be attached to the application:</p> <ol style="list-style-type: none">1) An official document granted by the competent authority confirming a practical applicability of Traditional Knowledge and positive result of use thereof in appropriate field of activity.2) Conclusion of the competent body (bodies) confirming membership of the applicant in a local community and/or is located in geographic object for which Traditional Knowledge is pertained to. <p>In case of filing the application for registration of Traditional Knowledge by State bodies, the said</p>	
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				conclusion shall not be required. 3) For foreign applicant a document confirming his/her right for the claimed Traditional Knowledge in the country of origin. [...]	
Namibia	Industrial Property Act, 2012 (Act No. 1 of 2012) https://wipolex.wipo.int/en/legislation/details/16331	Application for a patent Section 24 (2) biological resources or associated indigenous or traditional knowledge	Application for a patent Section 24 (2) Where the subject matter of a patent application is derived from or developed with biological resources or associated indigenous or traditional knowledge , the applicant must disclose in the application for a patent the country providing the resources or associated indigenous or traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin and any other	Application for a patent Section 24 (2) Where the subject matter of a patent application is derived from or developed with biological resources or associated indigenous or traditional knowledge, the applicant must disclose in the application for a patent the country providing the resources or associated indigenous or traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin and any other information	Invalidation of patent Section 65 [...] (3) Subject to section 67, the Tribunal must invalidate the patent if the person requesting the invalidation proves that any one of the following grounds for invalidation applies to the patent, namely – [...] (e) that any of the requirements of sections [...] 24 [...] has not been complied with

			information regarding the source or nature of the resources as may be prescribed.	regarding the source or nature of the resources as may be prescribed.	
Norway	<p>Patents Act (Act No. 9 of December 15, 1967) (consolidated version of 2016)</p> <p>(http://www.wipo.int/wipolex/en/details.jsp?id=15925)</p> <p>(Official English version available at https://www.patentstyret.no/en/norwegian-patents-act)</p> <p>2018 version also available in WIPO Lex: https://wipolex.wipo.int/en/legislation/details/17711</p>	<p>Chapter 2</p> <p>Section 8b.</p> <p>Biological material and traditional knowledge</p>	<p>Chapter 2</p> <p>Section 8b.</p> <p>If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.</p> <p>If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the</p>	<p>Chapter 2</p> <p>Section 8b.</p> <p>If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.</p> <p>If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the</p>	<p>Chapter 2</p> <p>Section 8b.</p> <p>[...]</p> <p>Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.</p>

			<p>application shall also state the country of origin. [...] If the national law in the country of origin requires that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.</p> <p>[...]</p> <p>When the biological material is acquired in accordance with Art. 12 No. 2 and 3 of the International Treaty on Plant Genetic Resources for Food and Agriculture of November, 3, 2001, a copy of a standard material transfer agreement according to Art 12.4 of the Treaty shall accompany the patent application instead of the</p>	<p>application shall also state the country of origin. [...] If the national law in the country of origin requires that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.</p> <p>The duty to disclose information concerning biological material under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. When the biological material is acquired in accordance with Art. 12 No. 2 and 3 of the International Treaty on Plant</p>	
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			information mentioned in paragraphs two and three. [...]	Genetic Resources for Food and Agriculture of November, 3, 2001, a copy of a standard material transfer agreement according to Art 12.4 of the Treaty shall accompany the patent application instead of the information mentioned in paragraphs two and three. [...]	
	Patent Regulations (Regulations No. 1417 of December 14, 2007, to the Norwegian Patents Act) (consolidated version of 2017, status as at September 1, 2017) (https://wipolex.wipo.int/en/legislation/details/18482)	Contents of the patent applications	Chapter 1. National Patent Applications Section 2. Contents of the Application The application shall contain the following: [...] 8. information about the providing country and the country of origin for biological material in accordance with section 8b of the Patents Act [...]	Chapter 1. National Patent Applications Section 2. Contents of the Application The application shall contain the following: [...] 8. information about the providing country and the country of origin for biological material in accordance with section 8b of the Patents Act [...]	
Panama	Executive Decree No. 257 of October 17, 2006 regulating Article 71 of the General Law on Environment (Law No. 41 of July 1, 1998) (http://www.wipo.int/wipolex/en/text.jsp?file_id=189178)	Artículo 23 [...] (f) material genético. recurso genético y/o biológico	Artículo 23: Todos los Contratos de Acceso serán válidos por el periodo que determine la UNARGEN en consulta con el CCT e incluirán las	Artículo 23: Todos los Contratos de Acceso serán válidos por el periodo que determine la UNARGEN en consulta con el CCT e incluirán las	Artículo 52: El incumplimiento de las disposiciones establecidas en el presente Decreto Ejecutivo será sancionado con:

			<p>siguientes obligaciones con el Estado: [...]</p> <p>f) Toda solicitud de patente de invención o procedimiento que sea elevada a la Dirección General de Propiedad Industrial del Ministerio de Comercio e Industrias y/o cualquier oficina de patentes de los países miembros de la Organización Mundial de la Propiedad Intelectual (OMPI) deberá comunicar por escrito el origen y procedencia del material genético. recurso genético y/o biológico utilizado en el desarrollo de la invención o el procedimiento, a título de información; [...]</p>	<p>siguientes obligaciones con el Estado: [...]</p> <p>f) Toda solicitud de patente de invención o procedimiento que sea elevada a la Dirección General de Propiedad Industrial del Ministerio de Comercio e Industrias y/o cualquier oficina de patentes de los países miembros de la Organización Mundial de la Propiedad Intelectual (OMPI) deberá comunicar por escrito el origen y procedencia del material genético. recurso genético y/o biológico utilizado en el desarrollo de la invención o el procedimiento, a título de información; [...]</p>	<p>a) Amonestación escrita; b) Multa impuesta por la ANAM de acuerdo a lo previsto en el artículo 114 de la Ley 41 de 1998. Cuando se trata de persona jurídica, la multa se fijará de conformidad al tipo de actividad y beneficios que se obtengan de los productos obtenidos; c) Cierre temporal o definitivo del establecimiento o laboratorio; d) Inhabilitación para contratar con el Estado para lograr acceso a los recursos genéticos y biológicos; e) Cancelación temporal o definitiva del permiso de acceso.</p>
Peru	<p>Decision No. 486 Establishing the Common Industrial Property Regime (2000)</p> <p>https://wipolex.wipo.int/en/legislation/details/18829</p>		See Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000)	See Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000)	
	Legislative Decree No. 1075 on Approval of Supplementary Provisions of Decision No. 486 of the Andean Community				Artículo 120-A.- Incumplimiento de las

	<p>Commission Establishing the Common Regime on Industrial Property (as amended by Law No. 29316)</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=6541</p>				<p>reglas aplicables a recursos genéticos y conocimientos tradicionales</p> <p>El incumplimiento del solicitante de una patente del requerimiento del contrato referido en el artículo 26, literales h) e i), de la Decisión 486 de la Comisión de la Comunidad Andina, y desarrollado en los artículos 20 y 21 del Reglamento de Acceso a Recursos Genéticos, dará lugar a una o más de las siguientes sanciones, a menos que el solicitante desista del procedimiento de otorgamiento de la patente o provea una explicación satisfactoria de que la invención no utiliza tal conocimiento tradicional o recurso genético del cual el Perú es país de origen:</p> <p>a) Multa de hasta 1 000 UIT. b) Compensación. c) Distribución justa y equitativa de beneficios, incluyendo distribución de regalías y/o otras medidas monetarias o no monetarias.</p>
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					<p>d) Transferencia de Tecnología y fortalecimiento de capacidades. e) Autorizaciones de uso. Siempre que se trate de licencias obligatorias en materia de patentes, serán de aplicación desde el artículo 61 hasta el artículo 69 de la Decisión 486 de la Comisión de la Comunidad Andina y el artículo 40 del decreto legislativo de la presente Ley. (*)</p> <p>(*) Artículo incorporado por el Artículo 8 de la Ley N° 29316, publicada el 14 enero 2009.</p>
<p>Law No. 27811 of 24 July 2002, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=3420</p>	<p>Collective knowledge</p> <p>Article 2(b) “Collective knowledge” means the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity. The intangible components referred to in Decision 391 of</p>	<p>COMPLEMENTARY PROVISIONS SECOND.- Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit</p>	<p>COMPLEMENTARY PROVISIONS SECOND.- Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as</p>	<p>COMPLEMENTARY PROVISIONS SECOND. Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the</p>	

		<p>the Commission of the Cartagena Agreement include this type of collective knowledge.</p> <p>COMPLEMENTARY PROVISIONS SECOND. Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.</p>	<p>a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.</p>	<p>a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.</p>	<p>collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.</p>
Philippines	<p>Philippine Technology Transfer Act of 2009 (Republic Act No. 10055)</p> <p>https://wipolex.wipo.int/en/legislation/details/9605</p>		<p>Article III, Sec. 8(c) The following are the rights and responsibilities of the</p>	<p>Article III, Sec. 8(c) The following are the rights and responsibilities of the</p>	

			<p>[research and development institutes and/or institutions] RDIs that availed of research funds from [Government Funding Agencies] GFAs: [...] (c) Notify the GFA within a reasonable time of all IPR applications, licenses and assignments made. All applications for IP protection shall disclose any biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices as these terms are defined in Republic Act No. 8371 or the Indigenous Peoples Rights Act and Republic Act No. 9.147 or The Wildlife Act [...]</p>	<p>[research and development institutes and/or institutions] RDIs that availed of research funds from [Government Funding Agencies] GFAs: [...] (c) Notify the GFA within a reasonable time of all IPR applications, licenses and assignments made. All applications for IP protection shall disclose any biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices as these terms are defined in Republic Act No. 8371 or the Indigenous Peoples Rights Act and Republic Act No. 9.147 or The Wildlife Act [...]</p>	
	<p>Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010) http://www.wipo.int/wipolex/en/details.jsp?id=9629</p>	<p>Rule 12 [...] Section 3 [...] (c) [...] biodiversity, genetic resources or materials associated</p>	<p>Rule 12 [...] Section 3. Disclosures. Disclosure of potential IPRs and/or all biodiversity and</p>	<p>Rule 12 [...] Section 3. Disclosures. Disclosure of potential IPRs and/or all biodiversity and</p>	<p>Rule 12 [...] Section 3. Disclosures. iii. Where the RDI, for reasons beyond its control, does not have</p>

		<p>traditional knowledge, and indigenous knowledge, systems and practices.</p>	<p>genetic resource, traditional knowledge, and indigenous knowledge, systems and practices shall be governed by the following rules: [...] (c) With respect to biodiversity, genetic resources or materials associated Traditional knowledge, and indigenous knowledge, systems and practices, the following provisions shall govern: i. The [Research and Development Institutes] RDI shall provide the [Government Funding Agencies] GFA with a written disclosure on the following: (1) any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the</p>	<p>genetic resource, traditional knowledge, and indigenous knowledge, systems and practices shall be governed by the following rules: [...] (c) With respect to biodiversity, genetic resources or materials associated Traditional knowledge, and indigenous knowledge, systems and practices, the following provisions shall govern: i. The [Research and Development Institutes] RDI shall provide the [Government Funding Agencies] GFA with a written disclosure on the following: (1) any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the</p>	<p>the necessary information to fulfill the disclosure requirement pertaining to any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices, such as, for instance, where a plant stored in a gene bank was collected decades ago and no information about its source exists, the RDI shall submit an affidavit from its researcher/s that the latter do not have the necessary information or that the source is unknown, and state the reasons thereof. The GFA shall review the affidavit to determine if this will constitute compliance with the disclosure requirement under this rule. [...] v. A national or international IPR application filed by the RDI before the appropriate IP office shall include in the abstract and/or description of said application the same disclosure on biodiversity, genetic resources or materials,</p>
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			<p>development of the subject matter contained in the IPR application; (2) the primary source of any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the subject matter contained in the IPR application; or (3) the secondary source, if no information about the primary source is available.</p> <p>ii. The disclosure requirement under this section shall apply when the subject matter contained in a national or international IPR application is directly based on any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices to which the RDI has had access to prior to</p>	<p>development of the subject matter contained in the IPR application; (2) the primary source of any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the subject matter contained in the IPR application; or (3) the secondary source, if no information about the primary source is available. [...]</p> <p>iii. Where the RDI, for reasons beyond its control, does not have the necessary information to fulfill the disclosure requirement pertaining to any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices, such</p>	<p>associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the development of the subject matter contained in the said application, notwithstanding that such disclosure may not be required for the grant or issuance of certificate of IPR registration.</p>
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			<p>the filing of the IPR application. The subject matter contained in the IPR application must depend on the specific properties of, or must be consciously derived from, such biodiversity and genetic resource or materials, traditional knowledge, and indigenous knowledge, systems and practices.</p> <p>iii. Where the RDI, for reasons beyond its control, does not have the necessary information to fulfill the disclosure requirement pertaining to any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices, such as, for instance, where a plant stored in a gene bank was collected decades ago and no information about its source exists, the RDI shall submit an</p>	<p>as, for instance, where a plant stored in a gene bank was collected decades ago and no information about its source exists, the RDI shall submit an affidavit from its researcher/s that the latter do not have the necessary information or that the source is unknown, and state the reasons thereof. The GFA shall review the affidavit to determine if this will constitute compliance with the disclosure requirement under this rule.</p> <p>[...]</p> <p>v. A national or international IPR application filed by the RDI before the appropriate IP office shall include in the abstract and/or description of said application the same disclosure on biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge,</p>	
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			<p>affidavit from its researcher/s that the latter do not have the necessary information or that the source is unknown, and state the reasons thereof. The GFA shall review the affidavit to determine if this will constitute compliance with the disclosure requirement under this rule. [...]</p> <p>v. A national or international IPR application filed by the RDI before the appropriate IP office shall include in the abstract and/or description of said application the same disclosure on biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the development of the subject matter contained in the said application, notwithstanding that such disclosure may</p>	<p>systems and practices utilized in or which formed as basis in the development of the subject matter contained in the said application, notwithstanding that such disclosure may not be required for the grant or issuance of certificate of IPR registration.</p>	
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			not be required for the grant or issuance of certificate of IPR registration.		
	<p>Rules and Regulations on Intellectual Property Rights Application and Registration Protecting the Indigenous Knowledge Systems and Practices of the Indigenous Peoples and Indigenous Cultural Communities (approved by Joint IPOPHL-NCIP Administrative Order No. 01, 2016)</p> <p>https://wipolex.wipo.int/en/legislation/details/19227</p>	<p>RULE 2</p> <p>Scope These Rules and Regulations apply to the examination and registration of intellectual property rights applications in the IPOPHL that use the IKSP of the indigenous and cultural communities and encourage tradition-based creations and innovations.</p> <p>RULE 4</p> <p>Definition of terms “Indigenous Knowledge Systems and Practices” and “IKSP” refer to systems, institutions, mechanisms and technologies comprising a unique body of knowledge evolved through time that embody patterns of relationships between and among peoples and between peoples, their lands and resource</p>	<p>RULE 2</p> <p>Scope These Rules and Regulations apply to the examination and registration of intellectual property rights applications in the IPOPHL that use the IKSP of the indigenous and cultural communities and encourage tradition-based creations and innovations.</p>	<p>RULE 6</p> <p>Disclosures on intellectual property rights applications a) An intellectual property right application filed in the IPOPHL shall disclose any IKSP that is used in the subject matter of the application including the source or geographical origin of the IKSP used in the application. The intellectual property right application shall contain the disclosure of IKSP including a statement of compliance to the requirement of free and prior informed consent of the indigenous cultural communities concerned.</p>	<p>RULE 6</p> <p>Disclosures on intellectual property rights applications d) The registration for an intellectual property right that uses IKSP in the subject matter of the application shall only be effected upon compliance with the disclosure requirement under these Rules and Regulations, particularly, the required free and prior informed consent of the indigenous cultural communities, notwithstanding that such disclosure is not required for the grant of certificate of intellectual property right registration. In case a registration has been issued in violation of these Rules and Regulations, the IPOPHL may, in accordance with its rules and regulations, cancel the registration.</p>

		<p>environment, including such spheres of relationships which may include social, political, cultural, economic, religious spheres, and which are the direct outcome of the indigenous peoples' responses to certain needs consisting of adaptive mechanisms which have allowed indigenous peoples to survive and thrive within their given socio-cultural and biophysical conditions (<i>Rule II Section 1(f) NCIP Administrative Order No. 01-98</i>).</p> <p>The reference to IKSP also means traditional cultural expressions or traditional knowledge and covers distinctive signs and symbols associated with the indigenous peoples and indigenous cultural communities and shall not be limited to a specific technical field, and may include agricultural,</p>			
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		environmental and medical knowledge and knowledge associated with genetic resources.			
Romania	Implementing Regulations of the Patent Law No. 64/1991 (approved by Government Decision No. 547/2008) http://www.wipo.int/wipolex/en/details.jsp?id=8457	<p>ARTICLE 16</p> <p>Description of the invention</p> <p>Traditional knowledge</p>	<p>ARTICLE 16</p> <p>Description of the invention</p> <p>(1) The description of the invention according to Art. 14 paragraph (1) letter c) of the Law shall contain the following: [...] c) presentation of the prior art considered by the applicant to be useful for understanding, performing the documentary search and examining the claimed invention, with the indication of the documents which substantiate it; at least one solution considered to be the closest to the claimed invention shall be presented; where the prior art also contains traditional knowledge, this and its source, if known, shall explicitly be indicated in the description;</p>	<p>ARTICLE 16</p> <p>Description of the invention</p> <p>(1) The description of the invention according to Art. 14 paragraph (1) letter c) of the Law shall contain the following: [...] c) presentation of the prior art considered by the applicant to be useful for understanding, performing the documentary search and examining the claimed invention, with the indication of the documents which substantiate it; at least one solution considered to be the closest to the claimed invention shall be presented; where the prior art also contains traditional knowledge, this and its source, if known, shall explicitly be</p>	

			[...]	indicated in the description; [...]	
	<p>Law No. 64/1991 on Patents (as amended up to Law No. 83/2014)</p> <p>(https://wipolex.wipo.int/en/legislation/details/15734)</p>				<p>Art. 53 – (1) Failure to meet one or more of the formal requirements concerning the patent application shall only constitute grounds for revocation or cancellation of the patent, either wholly or in part, where said failure resulted from fraudulent intentions.</p> <p>(2) A patent shall not be revoked or cancelled, either wholly or in part, without giving the owner the possibility to present observations concerning the revocation or cancellation and to make, in a reasonable period of time, amendments or corrections allowed by the Law and the corresponding implementing regulations.</p>
Samoa	<p>Intellectual Property Act 2011</p> <p>(http://www.wipo.int/wipolex/en/details.jsp?id=13492)</p>	<p>Article 7 biological material or knowledge available within any local or indigenous community</p>	<p>Article 7- Application for a patent [...] (3) An application must contain the following: [...] (g) a statement stating whether or not the invention for</p>	<p>Article 7- Application for a patent [...] (3) An application must contain the following: [...] (g) a statement stating whether or not the invention</p>	<p>Article 7- Application for a patent [...] (12) If an applicant fails to provide evidence as directed by the Registrar under subsection (10), the Registrar may, cease to deal further with the application.</p>

			<p>which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; (h) a statement disclosing the source and geographical origin of any biological material used for the invention; [...] (10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge. [...]</p> <p>22. Application for an innovation patent [...] (3) An application must contain: [...]</p>	<p>for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; (h) a statement disclosing the source and geographical origin of any biological material used for the invention; [...] (10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge. [...]</p> <p>22. Application for an innovation patent [...] (3) An application must contain:</p>	<p>17. Invalidation- (1) Any interested person may apply to the Supreme Court to invalidate a patent. (2) The Supreme Court must invalidate the patent if the applicant proves that: (a) any of the requirements of sections 5 and sections 7 to 10 are not fulfilled; [...]</p> <p>22. Application for an innovation patent [...] (12) When an applicant fails to provide evidence as directed by the Registrar under subsection (10), the Registrar may cease to deal further with the application.</p> <p>28. Invalidation-(1) Any interested person may apply to the Registrar to invalidate an innovation patent. (2) The Registrar must invalidate the innovation patent if the applicant proves that: [...] (b) the description and the claims do not comply with the</p>
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			<p>(g) a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; and</p> <p>(h) a statement disclosing the source and geographical origin of any biological material used for the invention;</p> <p>[...]</p> <p>(10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge.</p>	<p>[...]</p> <p>(g) a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; and</p> <p>(h) a statement disclosing the source and geographical origin of any biological material used for the invention;</p> <p>[...]</p> <p>(10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge.</p>	<p>requirements of section 20 and sections 22, to 25;</p> <p>[...]</p>
South Africa	<p>Patents Amendment Act 2005 (Act No. 20 of 2005)</p> <p>http://www.wipo.int/wipolex/en/details.jsp?id=5765</p>	(Section 2) genetic resource	Amendment of section 30 of Act 57 of 1978, as amended	Amendment of section 30 of Act 57 of 1978, as amended	Section 61 (1) Any person may at any time apply in the

		<p>indigenous biological resource traditional knowledge</p> <p>Genetic resource means (a) any indigenous genetic material; or (b) the genetic potential or characteristics of any indigenous species.</p> <p>Indigenous biological resource means an indigenous biological resource as defined in section 1 of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004).</p> <p>Traditional knowledge means the knowledge that an indigenous community has regarding the use of an indigenous biological resource or a genetic resource.</p>	<p>by section 33 of Act 38 of 1997 2. Section 30 of the principal Act is hereby amended by the insertion after subsection 25 (3) of the following subsections:</p> <p>“(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. (3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the</p>	<p>by section 33 of Act 38 of 1997 2. Section 30 of the principal Act is hereby amended by the insertion after subsection 25 (3) of the following subsections:</p> <p>“(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. (3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous</p>	<p>prescribed manner for the revocation of a patent on any of the following grounds only, namely [...] (g) that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the declaration statement or representation was made.</p>
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			traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. ”.	biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. ”.	
Spain	Ley N° 24/2015, de 24 de julio de 2015, de Patentes (modificada por la Ley N° 6/2018, de 3 de julio de 2018) (https://wipolex.wipo.int/en/legislation/details/16711)	Artículo 23(2) materia biológica	Artículo 23. Requisitos de la solicitud. [...] 2. Cuando la invención se refiera a materia biológica de origen vegetal o animal la solicitud deberá incluir la mención de su origen geográfico o la fuente de procedencia de dicha materia si estos datos fueran conocidos. Esta información no prejuzgará la validez de la patente. [...]	Artículo 23. Requisitos de la solicitud. [...] 2. Cuando la invención se refiera a materia biológica de origen vegetal o animal la solicitud deberá incluir la mención de su origen geográfico o la fuente de procedencia de dicha materia si estos datos fueran conocidos. Esta información no prejuzgará la validez de la patente. En los supuestos previstos en el Reglamento (UE) n.º 511/2014 del Parlamento Europeo	Artículo 23. Requisitos de la solicitud. [...] 2. Cuando la invención se refiera a materia biológica de origen vegetal o animal la solicitud deberá incluir la mención de su origen geográfico o la fuente de procedencia de dicha materia si estos datos fueran conocidos. Esta información no prejuzgará la validez de la patente. En los supuestos previstos en el Reglamento (UE) n.º 511/2014 del Parlamento Europeo y del Consejo, de 16 de abril de 2014, relativo a las medidas de cumplimiento de los usuarios del Protocolo

				<p>y del Consejo, de 16 de abril de 2014, relativo a las medidas de cumplimiento de los usuarios del Protocolo de Nagoya sobre el acceso a los recursos genéticos y participación justa y equitativa en los beneficios que se deriven de su utilización en la Unión, la solicitud de patente deberá asimismo contener, en la medida en que reglamentariamente se determine, la información que los usuarios de tales recursos vienen obligados a conservar con arreglo a lo previsto en la norma citada. La referida información tampoco prejuzgará la validez de la patente.</p>	<p>de Nagoya sobre el acceso a los recursos genéticos y participación justa y equitativa en los beneficios que se deriven de su utilización en la Unión, la solicitud de patente deberá asimismo contener, en la medida en que reglamentariamente se determine, la información que los usuarios de tales recursos vienen obligados a conservar con arreglo a lo previsto en la norma citada. La referida información tampoco prejuzgará la validez de la patente.</p>
Sweden	<p>Regulation (2004:162) Amending the Patents Decree http://www.wipo.int/wipolex/en/details.jsp?id=3672</p>	<p>Article 5a biological material of plant or animal origin</p>	<p>Article 5a. If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such</p>	<p>Article 5a. If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin</p>	<p>Article 5a. If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such material, if this is known. If the</p>

			<p>material, if this is known. If the origin is not known, this shall be indicated.</p> <p>Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.</p>	<p>of such material, if this is known. If the origin is not known, this shall be indicated.</p> <p>Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.</p>	<p>origin is not known, this shall be indicated.</p> <p>Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.</p>
Switzerland	<p>Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)</p> <p>(http://www.wipo.int/wipolex/en/details.jsp?id=11895)</p>	<p>Article 49a Genetic resource; traditional knowledge of indigenous or local communities</p>	<p>Article 49a 1. The patent application must contain information on the source: a. of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b. of traditional knowledge of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge.</p>	<p>Article 49a 1. The patent application must contain information on the source: a. of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b. of traditional knowledge of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge. 2. If the source is unknown to the</p>	<p>Article 59 [...] 2. If the patent application does not meet the other requirements of this Act or the Ordinance, the Institute shall set a time limit for the patent applicant by which the deficiencies must be remedied.</p> <p>Article 59(a) 3. The Institute shall reject the patent application if: [...] b. the deficiencies mentioned in Article 59 paragraph 2 have not been remedied.</p> <p>Art. 81a 1. Any person who wilfully provides false</p>

				inventor or the patent applicant, the patent applicant must confirm this in writing.	information under Article 49a is liable to a fine of up to 100,000 francs. 2. The court may order the publication of the judgment.
Uganda	The Industrial Property Act, 2014 https://wipolex.wipo.int/en/legislation/details/16480	21. Application for a patent. [...] (8) biological resources, traditional knowledge	21. Application for a patent. [...] (8) The description shall contain a clear identification of the origin of genetic or biological resources collected in the territory of Uganda and that were directly or indirectly used in the making of the claimed invention as well as of any element of traditional knowledge associated or not with those resources and that was directly or indirectly used in the making of the claimed invention without the prior informed consent of its individual or collective creators.	21. Application for a patent. [...] (8) The description shall contain a clear identification of the origin of genetic or biological resources collected in the territory of Uganda and that were directly or indirectly used in the making of the claimed invention as well as of any element of traditional knowledge associated or not with those resources and that was directly or indirectly used in the making of the claimed invention without the prior informed consent of its individual or collective creators.	Section 90 [...] (3) The court shall revoke or invalidate the registration of the patent or the utility model or industrial design on any of the following grounds that— [...] (f) the patent does not fully describe and ascertain the invention and the manner in which it is to be performed;
Vanuatu	Patents Act No. 2 of 2003 http://www.wipo.int/wipolex/en/details.jsp?id=10727	PART 12 INDIGENOUS KNOWLEDGE	PART 12 INDIGENOUS KNOWLEDGE	PART 12 INDIGENOUS KNOWLEDGE	PART 12 INDIGENOUS KNOWLEDGE

		REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [...] Indigenous knowledge [...]	REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [...] (2) The Registrar must not grant a patent for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge unless: (a) the custom owners of the indigenous knowledge have given their prior informed consent to the grant; and (b) the applicant and the custom owners have entered into an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent.	REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [...] (2) The Registrar must not grant a patent for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge unless: (a) the custom owners of the indigenous knowledge have given their prior informed consent to the grant; and (b) the applicant and the custom owners have entered into an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent.	REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [...] (4) If an agreement mentioned in subsection (2) or (3) has not been entered into within 12 months after the patent application has been lodged: (a) the Registrar may grant the patent; and (b) the owner may exploit the patent; and (c) the Registrar is to determine the amount payable to the custom owners or the National Council of Chiefs by the owner of the patent, being payment of an equitable share of the benefits from exploiting the patent.
Viet Nam	Circular No. 01/2007/TT-BKHCHN of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, detailing and guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property http://www.wipo.int/wipolex/en/details.jsp?id=5013	Article 23.11 Gene source and/or traditional knowledge	Article 23.11 Additional provisions applicable to applications for registration of inventions concerning gene source or traditional knowledge	Article 23.11 Additional provisions applicable to applications for registration of inventions concerning gene source or traditional knowledge	Article 23.11 [...] If the inventor or the applicant cannot identify the origin of the gene source and/or traditional knowledge, he/she shall so declare and bear responsibility for the

			<p>Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of an invention concerning gene source or traditional knowledge must also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or traditional knowledge. [...]</p>	<p>Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of an invention concerning gene source or traditional knowledge must also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or traditional knowledge. [...]</p>	truthfulness of his/her declaration
Zambia	<p>The Patents Act, 2016 (Act No. 40 of 2016) https://wipo.lex.wipo.int/en/legislation/details/18207</p>	<p>28. [...] invention which utilises genetic resources or associated traditional knowledge or both [...]</p>	<p>28. Where an application for the grant of a patent involves an invention which utilises genetic resources or associated traditional knowledge or both, the applicant shall disclose — (a) the country of origin of the genetic</p>	<p>28. Where an application for the grant of a patent involves an invention which utilises genetic resources or associated traditional knowledge or both, the applicant shall disclose — (a) the country of origin of the genetic resources or associated</p>	<p>PART V Examination, publication and opposition 51. [...] (3) Where the Registrar is of the opinion, after conducting an examination, referred to in subsection (1), that an application is not compliant with the requirements of this Act, the Registrar shall</p>

			<p>resources or associated traditional knowledge in accordance with the Convention on Bio-Diversity; and (b) the source in the country providing the genetic resources or associated traditional knowledge.</p>	<p>traditional knowledge in accordance with the Convention on Bio-Diversity; and (b) the source in the country providing the genetic resources or associated traditional knowledge.</p>	<p>notify the applicant, in writing, to make relevant amendments to the application, within a prescribed period. (4) Where the applicant fails to, after the notification referred to in subsection (3), make the relevant amendments, the Registrar shall, in writing, refuse the application. [...] 56. A person, including the State, may oppose the grant of a patent at any time, within a period of three months from the date an application for a grant of a patent is advertised, or within such further period as the Registrar may allow, and before the sealing of the patent, by filing a written notice of opposition to the Registrar, stating any of the following grounds: [...] (I) that the complete specification does not disclose or wrongly mentions the source or the geographical origin or biological material used for the invention; [...]</p>
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					(s) that the application is for an invention which is traditional knowledge.
	<p>The Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act, 2016 (Act No. 16 of 2016)</p> <p>https://wipolex.wipo.int/en/legislation/details/16181</p>	<p>36. [...] product developed from the genetic resource [...]</p>	<p>36. An access permit holder shall have the following obligations: [...] (l) recognise the locality where the genetic resource or traditional knowledge has been accessed in an application for protection of the product developed from the genetic resource; [...]</p>	<p>36. An access permit holder shall have the following obligations: [...] (l) recognise the locality where the genetic resource or traditional knowledge has been accessed in an application for protection of the product developed from the genetic resource; [...]</p>	