

## Disclosure Requirements Table related to genetic resources and/or traditional knowledge

In this table you will find a non-exhaustive selection of extracts from existing legislative texts which include specific disclosure requirement related to genetic resources and/or traditional knowledge.<sup>1</sup>

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Regions: [Andean Community](#), [European Union](#)

Individual countries: [Belgium](#), [Brazil](#), [Burundi](#), [China](#), [Costa Rica](#), [Cuba](#), [Denmark](#), [Djibouti](#), [Ecuador](#), [Egypt](#), [Ethiopia](#), [France](#), [Germany](#), [India](#), [Indonesia](#), [Italy](#), [Iran](#), [Kyrgyzstan](#), [Namibia](#), [Norway](#), [Panama](#), [Peru](#), [Philippines](#), [Romania](#), [Samoa](#), [South Africa](#), [Spain](#), [Sweden](#), [Switzerland](#), [Uganda](#), [Vanuatu](#), [Viet Nam](#), and [Zambia](#)

Country/ Region	Title	Subject Matter	Trigger of Disclosure	Content of Disclosure	Consequences of non- compliance
Andean Community	Decision No. 391 of the Commission of the Andean Community Establishing the Common Regime on Access to Genetic Resources  ( <a href="https://www.wipo.int/wipolex/en/text/223610">https://www.wipo.int/wipolex/en/text/223610</a> )	<b>Title 1 Definitions</b>  <b>Biological Resources: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its byproducts (...)</b> <b>Genetic Resources: all biological material that contains genetic</b>	<b>Complementary Provisions</b>  (...) Second. The Member Countries shall not acknowledge rights, <b>including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity</b> that does not comply	<b>Complementary Provisions</b>  (...) Third. The Competent National Offices on Intellectual Property shall require the applicant to give the <b>registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right</b> , when they are certain or there are reasonable indications that the products or processes	<b>Complementary Provisions</b>  (...) Second. The Member Countries shall <b>not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.</b>

<sup>1</sup> The extracts are taken directly from the legislative texts as contained in WIPO's global database, WIPO Lex, and the table contains no interpretation or commentary. Some relevant parts of the extracts are highlighted to facilitate the reading and comprehension. The table was last updated on January 10, 2024, and we welcome additional contributions, corrections and comments (grtkf@wipo.int).

		<b>information of value or of real or potential use</b>	with the provisions of this Decision. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.	whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.	Furthermore, the Member Country affected may request <b>nullification</b> and <b>bring such actions</b> as are appropriate in countries that have conferred rights or granted protective title documents.
Belgium	Code of Economic Law (updated on April 21, 2022) ( <a href="https://www.wipo.int/wipolex/en/legislation/details/21384">https://www.wipo.int/wipolex/en/legislation/details/21384</a> )	<b>Article XI.16 § 1st [...] biological material of plant or animal origin</b>	<b>Article XI.16 § 1st</b> <b>The patent application shall contain the following: [...]</b> <b>(6) a statement of the geographical origin of the biological material of plant or animal origin, from which the invention was developed, where such origin is known.</b>	<b>Article XI.16 § 1st</b> <b>The patent application shall contain the following: [...]</b> <b>(6) a statement of the geographical origin of the biological material of plant or animal origin, from which the invention was developed, where such origin is known.</b>	
Brazil	Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge) ( <a href="http://www.wipo.int/wipolex/en/details.jsp?id=15741">http://www.wipo.int/wipolex/en/details.jsp?id=15741</a> )	<b>Article 47</b> [...] granting of an intellectual property right [...] in respect of a finished product or of reproductive material obtained through access to genetic heritage or the associated traditional knowledge	<b>Article 47</b> The granting of an intellectual property right by the competent body in respect of a finished product or of reproductive material obtained through access to genetic heritage or the associated traditional knowledge is conditional upon registration or authorization, in	<b>Article 47</b> The granting of an intellectual property right by the competent body in respect of a finished product or of reproductive material obtained through access to genetic heritage or the associated traditional knowledge is conditional <b>upon registration or authorization, in accordance with the</b>	

			accordance with the provisions of this Act.	provisions of this Act.	
	<p>Decree No. 8.772 of May 11, 2016, implementing Act No. 13.123 of May 20, 2015</p> <p>(<a href="https://wipolex.wipo.int/en/legislation/details/16116">https://wipolex.wipo.int/en/legislation/details/16116</a>)</p>				<p><b>Art. 80.</b> - Requesting intellectual property rights resulting from access to genetic heritage or associated traditional knowledge, in Brazil or abroad, without prior registration.</p> <p><b>Minimum fine of R\$ 3,000.00 (three thousand reais) and maximum of R\$ 30,000.00 (thirty thousand reais), in the case of a natural person.</b></p> <p><b>Minimum fine of R\$ 10,000.00 (ten thousand reais) and maximum of R\$ 200,000.00 (two hundred thousand reais), in the case of legal entities classified as micro- or small businesses or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established under Article 3, paragraph II, of Complementary Act No. 123 of 2006.</b></p>

					<b>Minimum fine of R\$ 20.000,00 (twenty thousand reais) and maximum of R\$ 10.000.000,00 (ten million reais) for other legal entities.</b>
Burundi	Law No. 1/13 of July 28, 2009 relating To Industrial Property in Burundi <a href="https://wipolex.wipo.int/en/legislation/details/8324">https://wipolex.wipo.int/en/legislation/details/8324</a>	<b>Article 21</b> genetic or biological resources, traditional knowledge	<b>Article 21</b> The description must contain a clear indication of the origin of the <b>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</b> that is protected under Title V of this part and that has been used directly or indirectly in the making of the claimed invention <b>without the prior informed consent of its individual or joint creators.</b>	<b>Article 21</b> The description must contain a clear indication of the <b>origin of the genetic or biological resources collected in the territory of Burundi</b> and used directly or indirectly in the making of the claimed invention as well as <b>any element of the traditional knowledge</b> 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.	<b>Article 406.</b> 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.
	Patent Law of the People's Republic of China (as amended up to October 17, 2020, regarding the	<b>Article 26</b> Genetic resources	<b>Article 26.</b> With regard to an	<b>Article 26.</b> With regard to an	<b>Article 5.</b> No patent right shall be

China	<p>Revision of the Patent Law of the People's Republic of China)</p> <p>(<a href="https://www.wipo.int/wipolex/en/legislation/details/21027">https://www.wipo.int/wipolex/en/legislation/details/21027</a>)</p>		<p><b>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.</b></p>	<p>invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, <b>indicate the direct and original source of the genetic resources.</b></p>	<p>granted for any invention-creation where the acquisition or utilization of the genetic resources, on which the development of the invention-creation relies, violates the provisions of laws or administrative regulations.</p> <p><b>Article 26.</b> 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>(<a href="https://www.wipo.int/wipolex/en/legislation/details/6504">https://www.wipo.int/wipolex/en/legislation/details/6504</a>)</p>	<p><b>Article 26</b> The genetic resources referred to in the Patent Law means <b>any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value</b>; 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</p>	<p><b>Article 26</b> 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. <b>Where the applicant seeks to apply for patent for</b></p>	<p><b>Article 26</b> 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</p>	<p><b>Rule 53</b> In accordance with the provisions of Article 38 of the Patent Law, <b>the circumstances where an application for a patent for invention shall be rejected</b> 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 [...] <b>Article 26, paragraph [...] five</b> [...] of the Patent Law [...]</p>

		invention-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.	<b>such invention-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.</b>	invention-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.	
Costa Rica	<p>Law No. 7788 of April 30, 1998, on Biodiversity (as amended up to Law No. 10133 of March 14, 2022)</p> <p>(<a href="https://www.wipo.int/wipolex/en/legislation/details/21875">https://www.wipo.int/wipolex/en/legislation/details/21875</a>)</p>	<p><b>ARTICLE 80.</b> Mandatory prior consultation Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting <b>protection of intellectual or industrial property to innovations involving components of biodiversity.</b> They must always provide the certificate of origin issued by the Technical Office and the prior informed consent.</p>	<p><b>ARTICLE 80.</b> Mandatory prior consultation Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission <b>before granting protection of intellectual or industrial property to innovations involving components of biodiversity.</b> They must always provide the certificate of origin issued by the Technical Office and the prior informed consent. Reasoned opposition on the part of the Technical Office shall be sufficient to refuse registration of the patent or protection for the innovation.</p>	<p><b>ARTICLE 80.</b> Mandatory prior consultation Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. <b>They must always provide the certificate of origin issued by the Technical Office and the prior informed consent.</b> Reasoned opposition on the part of the Technical Office shall be sufficient to refuse registration of the patent or protection for the innovation.</p>	<p><b>ARTICLE 80.</b> Mandatory prior consultation Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent. <b>Reasoned opposition on the part of the Technical Office shall be sufficient to refuse registration of the patent or protection for the innovation.</b></p>

Cuba	Decree-Law No. 290 of November 20, 2011, on Inventions and Industrial Designs and Models  ( <a href="http://www.wipo.int/wipolex/en/details.jsp?id=12026">http://www.wipo.int/wipolex/en/details.jsp?id=12026</a> )	<b>Article 26.1.</b> Biological material	<b>Article 26.1.- To obtain a patent,</b> the applicant shall submit the appropriate application to the Office, together with the following documents: [...] (j) copy of the prior express authorization to access biological material, issued by the competent authority in accordance with the applicable legislation, <b>where the invention concerns such material, including genetic material and parts and derivatives thereof for which Cuba is the country of origin or which is present as a domesticated or cultivated species in Cuba;</b>  (k) declaration stating that the <b>biological material to which the invention refers was</b>	<b>Article 26.1.- To obtain a patent,</b> the applicant shall submit the appropriate application to the Office, together with the following documents: [...] (j) <b>copy of the prior express authorization to access biological material,</b> issued by the competent authority in accordance with the applicable legislation, where the invention concerns such material, including genetic material and parts and derivatives thereof for which Cuba is the country of origin or which is present as a domesticated or cultivated species in Cuba;  (k) declaration stating that the <b>biological material to which the invention refers was obtained in the territory of the</b>	<b>ARTICLE 32.1.-</b> Where the submitted documents are found to contain omissions or errors, the applicant shall be notified thereof and asked, upon payment of the appropriate fee, to correct those issues within a period of 60 days from the date of notification. The applicant may, nonetheless, apply to the Office prior to expiry of the deadline for an extension thereto for a further 30 days, upon payment of the appropriate fee. 2. Where the applicant fails to correct said omissions or errors within the deadline, the application shall be <b>deemed abandoned</b> , with no remaining rights, except where the applicant has been asked for corrections relating only to the unity of invention requirement, in which case the examination proceeds in respect of the first independent claim made and all related claims that comply with the unity of invention requirement.
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			<p><b>obtained in the territory of the Republic of Cuba</b>, in which case it should indicate the country of origin and source of the biological material and of the traditional knowledge associated with such material, together with the prior informed consent to access it; [...]</p>	<p><b>Republic of Cuba</b>, in which case it should indicate the country of origin and source of the biological material and of the traditional knowledge associated with such material, together with the prior informed consent to access it; [...]</p>	
Denmark	<p>Order No. 2111 of November 24, 2021, on Patents and Supplementary Protection Certificates</p> <p>(<a href="https://www.wipo.int/wipolex/en/text/584476">https://www.wipo.int/wipolex/en/text/584476</a>)</p>	<p><b>Part I Chapter 2 3(5) (...) biological material</b></p>	<p><b>Part I Chapter 2</b> <i>The contents and filing of applications</i> [...] 3.- [...] (4) If an invention relates to or makes use of a <b>biological material</b>, 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</p>	<p><b>Part I Chapter 2</b> <i>The contents and filing of applications</i> [...] 3.- [...] (4) If an invention relates to or makes use of a biological material, <b>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</b></p>	<p><b>Part I Chapter 2</b> <i>The contents and filing of applications</i> [...] 3.- [...] (4) 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. <b>Lack of information about the geographical origin of the material or about</b></p>



			the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.	<b>application.</b> Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.	<b>the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.</b>
Djibouti	Law No. 50/AN/09/6th Lof July 19, 2009, on the Protection of Industrial Property  ( <a href="https://wipolex.wipo.int/en/legislation/details/6124">https://wipolex.wipo.int/en/legislation/details/6124</a> )	<b>Article 34 genetic or biological resources, traditional knowledge</b>	<b>Article 34</b> 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. <b>If</b>	<b>Article 34</b> 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. <b>If</b>	<b>Article 41</b> A patent application shall be <b>refused</b> if: [...] (g) <b>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;</b> [...]

			the invention claimed has been developed or obtained directly from genetic or biological 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.	the invention claimed has been developed or obtained directly from genetic or biological 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.	
Ecuador	<p>National Regulations of the Common Regime Governing Access to Genetic Resources, pursuant to Decision No. 391 of the Andean Community (Executive Decree No. 905 of October 3, 2011)</p> <p>(<a href="https://www.wipo.int/wipolex/en/legislation/details/11842">https://www.wipo.int/wipolex/en/legislation/details/11842</a>)</p>	<p><b>GENERAL PROVISIONS</b></p> <p><b>ARTICLE 1.</b> A genetic resource or a product derived therefrom</p>	<p><b>GENERAL PROVISIONS</b></p> <p><b>ARTICLE 1.</b> Prior to the granting of an intellectual property right, the Ecuadorian Intellectual Property Institute shall request the registration number of the access contract and a copy thereof, <b>where there are reasonable indications or there is certainty that the products or processes for which protection is</b></p>	<p><b>GENERAL PROVISIONS</b></p> <p><b>ARTICLE 1.</b> Prior to the granting of an intellectual property right, the Ecuadorian Intellectual Property Institute shall <b>request the registration number of the access contract and a copy thereof,</b> where there are reasonable indications or there is certainty that the products or processes for which protection is sought</p>	

			sought have been obtained from a genetic resource or a product derived therefrom, in accordance with the Constitution and the applicable law.	have been obtained from a genetic resource or a product derived therefrom, in accordance with the Constitution and the applicable law.	
	Organic Code on the Social Economy of Knowledge, Creativity and Innovation (of December 9, 2016)  ( <a href="https://wipolex.wipo.int/en/legislation/details/16990">https://wipolex.wipo.int/en/legislation/details/16990</a> )		<b>Article 282.- Patent and disclosure of origin.</b> In accordance with the provisions of the international treaties to which Ecuador is a party, this Code and its respective regulations, in the event that the subject matter of a <b>patent application involves the utilization of genetic resources and associated traditional knowledge</b> , the applicant shall make known: 1. The country where such resources or associated traditional knowledge were obtained; and, <b>2. The source, including details of the entity, if any, from which such resources or</b>	<b>Article 282.- Patent and disclosure of origin.</b> In accordance with the provisions of the international treaties to which Ecuador is a party, this Code and its respective regulations, in the event that the subject matter of a patent application involves the utilization of genetic resources and associated traditional knowledge, the applicant shall make known: 1. The country where such resources or associated traditional knowledge were obtained; and, <b>2. The source, including details of the entity, if any, from which such resources or associated</b>	<b>Article 303.- Absolute invalidity of the patent.</b> The competent national authority in matters relating to IP rights shall, ex officio or at the request of any person demonstrating a legitimate interest, and at any time, declare <b>the absolute invalidity of a patent</b> where: [...] 7. If applicable, where a copy of the access contract has not been submitted, when the products or processes for which a patent application has been filed have been obtained or developed from genetic resources, or their derivative products, of which Ecuador is the country of origin; 8. If applicable, where a copy of the license or authorization to use the traditional knowledge of Indigenous, Afro-American or local communities of

			<p><b>associated traditional knowledge were obtained. A copy of an internationally recognised certificate of compliance with the law on access to genetic resources or associated traditional knowledge shall</b> also be attached. If an internationally recognised certificate of compliance is not applicable in the provider country, the applicant shall provide relevant information regarding compliance with prior informed consent, access and fair and equitable benefit-sharing, as required by the national law of the country providing the genetic resources and/or associated traditional knowledge, which is the country of origin of such resources or a country that has acquired the genetic resources or</p>	<p><b>traditional knowledge were obtained. A copy of an internationally recognised certificate of compliance with the law on access to genetic resources or associated traditional knowledge</b> shall also be attached. If an internationally recognised certificate of compliance is not applicable in the provider country, the applicant shall <b>provide relevant information regarding compliance with prior informed consent, access and fair and equitable benefit-sharing, as required by the national law of the country providing the genetic resources and/or associated traditional knowledge, which is the country of origin of such resources or a country that has</b></p>	<p>Ecuador or member States of the Andean Community has not been submitted, when the products or processes for which protection is sought have been obtained or developed from such knowledge, of which Ecuador or any member State of the Andean Community is the country of origin; 9. Where the patent has been granted in breach of Article 282; Where the grounds specified above affect only some of the claims or parts of a claim, invalidity shall be declared only in respect of such claims or such parts of the claim, as the case may be. The patent, the claim or that part of a claim which is declared invalid shall be deemed to be null and void as from the filing date of the patent application.</p>
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			associated traditional knowledge in accordance with the Convention on Biological Diversity and other international treaties to which Ecuador is a party.	<b>acquired the genetic resources or associated traditional knowledge in accordance with the Convention on Biological Diversity and other international treaties to which Ecuador is a party.</b>	
Egypt	Law No. 82 of 2002 on the Protection of Intellectual Property Rights <a href="http://www.wipo.int/wipolex/en/details.jsp?id=1301">http://www.wipo.int/wipolex/en/details.jsp?id=1301</a>	<b>Article 13</b> biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage	<b>Article 13</b> [...] <b>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.</b> [...]	<b>Article 13</b> [...] Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, <b>the inventor should have acquired the sources in a legitimate manner.</b> [...]	<b>Article 14</b> 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. <b>If the applicant fails to comply within three months of notification, he shall be considered as having withdrawn his application.</b> 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.
	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	<b>Article 3</b> [...] plant or animal biological material, traditional medicinal,	<b>Article 3 The patent application shall be accompanied by [...]</b>	<b>Article 3</b> The patent application shall be accompanied by [...]	<b>Article 4.</b> Documentation mentioned under items 3, 4, 5, 6 and 7 of

	<a href="http://www.wipo.int/wipolex/en/details.jsp?id=7299">http://www.wipo.int/wipolex/en/details.jsp?id=7299</a>	agricultural, industrial or handicraft knowledge, or cultural or environmental heritage	<b>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,</b> 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.	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, <b>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.</b>	Article 3 of these Regulations may be furnished within four months from the filing date of the application. [...]  <b>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.</b>
Ethiopia	Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006  <a href="https://wipolex.wipo.int/en/legislation/details/5559">https://wipolex.wipo.int/en/legislation/details/5559</a>	<b>Article 17.</b> genetic resources, community knowledge	<b>Article 17. Obligations of Access Permit Holder</b> A person who shall be given an access permit shall have the following obligations: [...] 12/ where he seeks to acquire intellectual property right over the genetic resources accessed or parts	<b>Article 17. Obligations of Access Permit Holder</b> A person who shall be given an access permit shall have the following obligations: [...] 12/ where he seeks to acquire intellectual property right over the genetic resources accessed or parts thereof,	

			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; [...]	<b>negotiate new agreement with the Institute based on the relevant laws of Ethiopia;</b> 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/ <b>recognize the locality</b> where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from; [...]	
European Union	Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions  ( <a href="http://www.wipo.int/wipolex/en/details.jsp?id=1440">http://www.wipo.int/wipolex/en/details.jsp?id=1440</a> )	<b>(Paragraph 27 of the Preamble)</b> biological material of plant or animal origin	<b>Paragraph 27 of the Preamble.</b> Whereas <b>if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such</b>	<b>Paragraph 27 of the Preamble.</b> Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, <b>where appropriate, include information on the geographical origin of such material, if</b>	<b>Paragraph 27 of the Preamble.</b> Whereas if an invention is based on biological material of plant or 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; <b>whereas this is without prejudice to</b>



			material, if known.	known.	the processing of patent applications or the validity of rights arising from granted patents.
France	Act No. 2016-1087, of 8 August 2016, on the Restoration of Biodiversity, Nature and the Countryside  ( <a href="http://www.wipo.int/wipolex/en/details.jsp?id=16565">http://www.wipo.int/wipolex/en/details.jsp?id=16565</a> )	<b>Art. L. 412-18.-II</b> Genetic resources and associated traditional knowledge	<b>Art. L. 412-18.-II</b> Users of genetic resources and associated traditional knowledge shall make available to the competent authority or authorities referred to in subparagraph (a) of this paragraph the information required under Article 4 of Regulation (EU) No. 511/2014 of 16 April 2014 in the following cases: [...] (b) [...] Where a <b>patent application arises from [the use of genetic resources and traditional knowledge]</b> associated with those genetic resources], the applicant shall, on his or her own initiative, make the information referred to in subparagraph (a) available to the National Industrial Property Institute (INPI). INPI then conducts the	<b>Art. L. 412-18.-II</b> Users of genetic resources and associated traditional knowledge shall make available to the competent authority or authorities referred to in subparagraph (a) the <b>information required under Article 4 of Regulation (EU) No. 511/2014 of 16 April 2014.</b> [...]	<b>Article 39</b> [...] The following acts are punishable by <b>imprisonment</b> for one year <b>and a fine of €150,000</b> : (a) The use of genetic resources or associated traditional knowledge, as set forth in Articles L. 4123 and L. 4124, without the requisite documents referred to in paragraph 3 of Article 4 of Regulation (EU) No. 511/2014 of 16 April 2014; (b) Failure to identify, preserve or make available to subsequent users relevant information regarding access and benefit-sharing for genetic resources and associated traditional knowledge in line with Article 4 of the Regulation. The fine shall be increased to <b>one million euros</b> where the use of genetic resources or traditional knowledge in the sense of subparagraph (a) has given rise to their commercial use.

			customary procedures to examine the application and record a filing date, and makes the information, without prior examination, available to the competent authority responsible for applying the regulations issued by the European Union with a view to each member State ensuring that users in its territory of genetic resources and, where applicable, of traditional knowledge associated with those resources, obtained access thereto in line with the laws and regulations concerned.		II. Natural or legal persons found guilty of the offences referred to in paragraph I of this article shall also be <b>prohibited, for a period not exceeding five years, from applying for authorization</b> under articles L. 4128 and L. 4129 <b>to obtain access to genetic resources</b> or certain categories thereof <b>and associated traditional knowledge</b> with a view to their commercial use.
Germany	Patent Act (as amended up to Act of 30 August 2021) ( <a href="https://www.wipo.int/wipolex/en/text/586963">https://www.wipo.int/wipolex/en/text/586963</a> )	<b>Section 34a</b> <b>Biological material of plant or animal origin</b>	<b>Section 34a</b> (1) Where an <b>invention is based</b> on biological material of plant or animal origin <b>or if it uses such material</b> , the application should include information on the geographical origin of such material, if known. [...]	<b>Section 34a</b> (1) Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should <b>include information on the geographical origin of such material</b> , if known.	<b>Section 34a</b> (1) [...] <b>This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents.</b> [...]

				<p>[...]</p> <p><b>(2) If the application includes information on the geographical origin</b> pursuant to the first sentence of subsection (1), <b>the German Patent and Trade Mark Office shall notify this application to the Federal Agency for Nature Conservation</b> (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) <b>following publication of the information</b> pursuant to section 32 (5).</p>	
India	<p>The Patents Act, 1970 (as amended up to Patents (Amendment) Act, 2005)</p> <p>(<a href="https://www.wipo.int/wipolex/en/legislation/details/20694">https://www.wipo.int/wipolex/en/legislation/details/20694</a>)</p>	<p><b>Article 10(4)(ii)(D)</b></p> <p>Biological material</p>	<p><b>Article 10(4)(ii)(D)</b></p> <p>(ii) If the applicant mentions a biological material in the</p>	<p><b>Article 10(4)(ii)(D)</b></p> <p>(ii) If the applicant mentions a biological material in the</p>	<p><b>Article 64 Revocation of patents.</b></p> <p>(1) Subject to the provisions contained in this Act, a patent,</p>

			<p>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:—</p> <p>[...]</p> <p>(D) disclose the source and geographical origin of the biological material in the specification, <b>when used in an invention.</b></p>	<p>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:—</p> <p>[...]</p> <p>(D) <b>disclose the source and geographical origin of the biological material</b> in the specification, when used in an invention.</p>	<p>whether granted before or after the commencement of this Act, may, <b>be revoked</b> 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> <p>[...]</p> <p>(p) that the complete <b>specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;</b></p> <p>[...]</p>
Indonesia	<p>Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents</p> <p>(<a href="http://www.wipo.int/wipolex/en/details.jsp?id=16392">http://www.wipo.int/wipolex/en/details.jsp?id=16392</a>)</p>	<p><b>Article 26</b> Genetic resources and/or traditional knowledge</p>	<p><b>Article 26</b></p> <p>(1) <b>If an invention as being associated with and/or derived from a genetic resource and/ or traditional knowledge</b>, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in</p>	<p><b>Article 26</b></p> <p>(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 <b>origin of the genetic resource and/or traditional knowledge in question in a clear</b></p>	

			<p>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.</p> <p>) 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><b>and true manner in its patent description.</b> (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. <b>(3) Benefit sharing</b> 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>	
Italy	<p>Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Law No. 102 of July 24, 2023)</p> <p>(<a href="https://www.wipo.int/wipolex/en/legislation/details/21556">https://www.wipo.int/wipolex/en/legislation/details/21556</a>)</p>	<p><b>Article 170 bis.</b> biological material of animal or plant origin</p>	<p><b>Article 170 bis.</b> <b>(( Duties regarding biotechnological inventions ))</b> [...] 2. The provenance of <b>biological material</b> of animal or plant origin, <b>which is the basis of the invention</b>, is to be declared together with the application of the patent both</p>	<p><b>Article 170 bis.</b> <b>(( Duties regarding biotechnological inventions ))</b> [...] 2. <b>The provenance</b> 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</p>	<p><b>Article 170 bis.</b> <b>(( Duties regarding biotechnological inventions ))</b> [...] 7. If it detects the absence of the conditions for patentability of the biotechnological invention or the failure to file the declarations referred to in paragraphs 2, 3 and 4, the Italian</p>

			<p>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><b>with reference to the country of origin</b>, in order to verify compliance with import and export legislation, <b>and in relation to the biological organism from which it was isolated</b>. [...]</p>	<p>Patent and Trademark Office takes action pursuant to article 173, paragraph 7, and , in the case of the absence of the patentability conditions referred to in articles 81-quater, 81-quinquies and article 162, <b>rejects the application</b>.</p> <p><b>Article 170 ter. ((Sanctions))</b> [...] 2. Unless the fact constitutes a crime, anyone who, in the declaration referred to in article 170- bis, paragraph 2, <b>falsely certifies the origin of the biological material of animal or plant origin, is punished with a pecuniary administrative sanction ranging from 10,000 to 100,000 EUR</b> [...] 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</p>
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					<p>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><b>Article 173. Observations</b> 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. Once that term has expired, if no observations have been submitted or if the Office does not believe that it can accept those submitted, <b>the application or request is rejected in full or in part.</b></p>
Iran	<p>Regulations of the Law on Preservation and Utilization of Genetic Resources (2021) (as amended in 2023)</p> <p>( <a href="http://nazarat.shorarc.ir/Forms/FileLoad.aspx?id=qLFdp8+nQ+w=&amp;TN=I7tLyhyOobj0SooAFUE3m3zd2MHOJ7gNcJaMEmrHM4=&amp;NF=bH ilRfspeW0=">http://nazarat.shorarc.ir/Forms/FileLoad.aspx?id=qLFdp8+nQ+w=&amp;TN=I7tLyhyOobj0SooAFUE3m3zd2MHOJ7gNcJaMEmrHM4=&amp;NF=bH ilRfspeW0=</a> )</p>	<p><b>Article 4:</b> The following matters shall not be regarded as invention which is the subject of this law or shall be out of the scope of patent protection: 5- Plants, animals,</p>	<p><b>Article 15:</b> The following documents <b>shall be annexed</b> to the application: Notice: With regard to biological resources which belong to other countries, <b>subject</b></p>	<p><b>Article 16:</b> <b>Where the invention is related to biotechnology and genetic resources, an applicant is required to file the following</b></p>	<p><b>Article 67:</b> The competent court <b>shall invalidate a patent</b> where: Notice 1: With regard to the genetic and biological resources and components which are patentable</p>



		<p>microorganisms and their components as they are found in nature, plant and animal varieties and their genetic components, natural biological derivatives and also procedures which are basically biological and natural.</p> <p>Notice 1: Genetically manipulated microorganisms and microbiological procedures of their production and duplication which are achieved through direct human interference in genetic composition and have characteristics which cannot be achieved from natural species normally and also biological procedures based on technical design and interference and possessing patenting conditions, shall not be regarded as matters cited in this paragraph.</p>	<p><b>to reciprocity,</b> permit of access <b>shall be required</b> from the applicant.</p>	<p><b>information and documents as annexes to his/her application:</b></p> <p>1- Declaration of the geographical origin of the natural biological resource used for carrying out the invention and the manner of access to the resources,</p> <p>2- Declaration of the place of preservation and the manner of access with regard to the biological resources whose geographical origin is unknown,</p> <p>3- Certification of deposit of genetic or biological samples with preservation centers for genetic and biological storages, when, upon discretion of the patent office, their description is impossible.</p>	<p>according to this Act, <b>furnishing of false information as to the geographical origin, the place of preservation or the manner of access to the applied genetic resource and also non-compliance with the laws and regulations related to the manner of access to genetic resources</b> shall result in invalidation of patent.</p> <p><b>Article 8:</b></p> <p>The following acts shall constitute offence and the perpetrator shall be <b>condemned to the following punishments</b> relevantly by the sentence of the competent court:</p> <p>a) Access to and utilization of genetic resources without compliance with the provisions of this law and exportation of genetic resources for the purpose of access to and utilization of genetic resources without authorization of the related responsible institution shall,</p>
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					respectively, result in condemnation to one or several types of level 5 and 6 of Discretionary Punishments. (...)
Kyrgyzstan	<p>Law of the Kyrgyz Republic No. 116 of July 31, 2007, on the Protection of Traditional Knowledge</p> <p>(<a href="http://www.wipo.int/wipolex/en/details.jsp?id=5571">http://www.wipo.int/wipolex/en/details.jsp?id=5571</a>)</p>	Traditional knowledge	<p><b>Article 8. Patenting of subject-matters created on the base of Traditional Knowledge</b></p> <p>[...]  <b>When patenting the subject-matters created on the base of Traditional Knowledge</b>, 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><b>Article 8. Patenting of subject-matters created on the base of Traditional Knowledge</b></p> <p>[...]  When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain <b>reveal of origin of Traditional Knowledge which is used as prior art or prototype</b>. The applicant shall indicate the source of making Traditional Knowledge available to the public.  [...]</p> <p><b>Article 9. Application for registration and granting the right to use Traditional Knowledge or for granting the right to use registered Traditional Knowledge</b></p>	

				<p>[...]</p> <p>An application shall contain the following:</p> <p><b>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;</b></p> <p><b>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 knowledge used; information relevant to previously issued publications regarding a particular traditional knowledge.</b></p>	
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				<p>The following documents shall be attached to the application:</p> <p>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.</p> <p>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> <p>In case of filing the application for registration of Traditional Knowledge by State bodies, the said conclusion shall not be required.</p> <p><b>3) For foreign applicant a document confirming his/her right for the claimed Traditional Knowledge in the country of origin.</b></p> <p>[...]</p>	
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Namibia	<p>Industrial Property Act, 2012 (Act No. 1 of 2012) (Amended by Act No. 8 of 2016)</p> <p>(<a href="https://www.wipo.int/wipolex/en/legislation/details/21942">https://www.wipo.int/wipolex/en/legislation/details/21942</a>)</p>	<p><b>Application for a patent</b></p> <p><b>Section 24 (2)</b> biological resources or associated indigenous or traditional knowledge</p>	<p><b>Application for a patent</b></p> <p><b>Section 24 (2)</b> Where the <b>subject matter of a patent application is derived from or developed with biological resources or associated indigenous or traditional knowledge</b>, 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 regarding the source or nature of the resources as may be prescribed.</p>	<p><b>Application for a patent</b></p> <p><b>Section 24 (2)</b> Where the subject matter of a patent application is derived from or developed with biological resources or associated indigenous or traditional knowledge, <b>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 regarding the source or nature of the resources as may be prescribed.</b></p>	<p><b>Invalidation of patent</b></p> <p><b>Section 65</b> [...] <b>(3)</b> 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.</p>
Norway	<p>Patents Act (Act No. 9 of December 15, 1967)(consolidated version of 2019)</p> <p>(<a href="https://www.wipo.int/wipolex/en/legislation/details/19563">https://www.wipo.int/wipolex/en/legislation/details/19563</a>)</p>	<p><b>Chapter 2</b></p> <p><b>Section 8b.</b></p>	<p><b>Chapter 2</b></p> <p><b>Section 8b.</b> <b>If an invention concerns or uses biological material</b></p>	<p><b>Chapter 2</b></p> <p><b>Section 8b.</b> If an invention concerns or uses biological material or</p>	<p><b>Chapter 2</b></p> <p><b>Section 8b.</b> [...] Breach of the duty to disclose information is</p>

	<p>(Official English version available at <a href="https://www.patentstyret.no/en/norwegian-patents-act">https://www.patentstyret.no/en/norwegian-patents-act</a>)</p>	<p>Biological material and traditional knowledge</p>	<p><b>or traditional knowledge</b>, 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><b>If the providing country is not the same as the country of origin of the biological material or the traditional knowledge</b>, the application shall also state the country of origin. [...]</p> <p><b>If the national law in the country of origin requires that access to biological material or use of traditional</b></p>	<p>traditional knowledge, the patent application shall include <b>information on the country from which the inventor collected or received the material or the knowledge (the providing country)</b>. 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, <b>the application shall state whether such consent has been obtained</b>.</p> <p>If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state <b>the country of origin</b>. [...]</p> <p>If the national law in the country of origin requires that access to biological material or use of traditional knowledge shall be</p>	<p>subject to <b>penalty</b> in accordance with the General Civil Penal Code § 221. <b>The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.</b></p>
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			<p><b>knowledge shall be subject to prior consent</b>, the application shall state whether such consent has been obtained. <b>If the information set out in this subsection is not known</b>, the applicant shall state that.</p> <p>[...]</p> <p><b>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</b>, 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.</p> <p>[...]</p>	<p>subject to prior consent, the application shall state <b>whether such consent has been obtained</b>. If the information set out in this subsection is not known, <b>the applicant shall state that</b>.</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 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</p>	
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				the patent application instead of the information mentioned in paragraphs two and three. [...]	
	<p>Patent Regulations (Regulations No. 1417 of December 14, 2007, to the Norwegian Patents Act) (consolidated version of 2017, status as at September 1, 2017)</p> <p>(<a href="https://wipolex.wipo.int/en/legislation/details/18482">https://wipolex.wipo.int/en/legislation/details/18482</a>)</p>	Contents of the patent applications	<p><b>Chapter 1. National Patent Applications</b></p> <p><b>Section 2. Contents of the Application</b> 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. [...]</p>	<p><b>Chapter 1. National Patent Applications</b></p> <p><b>Section 2. Contents of the Application</b> The application shall contain the following: [...] <b>8. information about the providing country and the country of origin for biological material</b> in accordance with section 8b of the Patents Act. [...]</p>	
Panama	<p>Executive Decree No. 257 of October 17, 2006 regulating Article 71 of the General Law on Environment (Law No. 41 of July 1, 1998)</p> <p>(<a href="http://www.wipo.int/wipolex/en/text.jsp?file_id=189178">http://www.wipo.int/wipolex/en/text.jsp?file_id=189178</a>)</p>	<p><b>Article 23</b> [...] (f) genetic material, genetic and/or biological resources</p>	<p><b>Article 23:</b> All Access Contracts shall be valid for the period set by the Genetic Resources Access Unit (UNARGEN) in consultation with the Scientific Technical Committee and shall entail the following obligations vis-à-vis the State: [...] <b>(f) Any application to patent a product or process filed with the Department for the</b></p>	<p><b>Article 23:</b> All Access Contracts shall be valid for the period set by the Genetic Resources Access Unit (UNARGEN) in consultation with the Scientific Technical Committee and shall entail the following obligations vis-à-vis the State: [...] (f) Any application to patent a product or process filed with the Department for the</p>	<p><b>Article 52:</b> Failure to comply with the provisions of this Executive Decree shall be punishable by: (a) <b>Written warning;</b> (b) <b>Fine</b> imposed by the National Environment Authority pursuant to Article 114 Act No. 41 of 1998. In the case of a legal entity, the amount of the fine shall be set in accordance with the nature of the</p>

			<b>Registration of Industrial Property, Ministry of Trade and Industry, and/or with any patent office of the Member States of the World Intellectual Property Organization (WIPO)</b> shall contain, for information purposes, written confirmation of the origin of the genetic material or genetic and/or biological resources used to develop the invention or process. [...]	Registration of Industrial Property, Ministry of Trade and Industry, and/or with any patent office of the Member States of the World Intellectual Property Organization (WIPO) shall contain, for <b>information purposes</b> , written confirmation of the <b>origin of the genetic material or genetic and/or biological resource used to develop the invention or process</b> . [...]	activity and the profit obtained from the products obtained; (c) <b>Temporary or definitive closure</b> of the establishment or laboratory; (d) <b>Prohibition from entering into contracts with the State</b> to obtain access to genetic and biological resources; <b>Temporary or definitive cancellation of access permit.</b>
Peru	Law No. 27811 of 24 July 2002, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources  <a href="http://www.wipo.int/wipolex/en/details.jsp?id=3420">http://www.wipo.int/wipolex/en/details.jsp?id=3420</a>	Collective knowledge  <b>Article 2(b)</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 the Commission of	<b>COMPLEMENTARY PROVISIONS SECOND.-</b> Submission of the license contract as a requirement for obtaining a patent. <b>Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge</b> , the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights	<b>COMPLEMENTARY PROVISIONS SECOND.-</b> 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 <b>submit a copy of the license contract</b> as a prior requirement for the	<b>COMPLEMENTARY PROVISIONS SECOND.</b> 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

		<p>the Cartagena Agreement include this type of collective knowledge.</p> <p><b>COMPLEMENTARY PROVISIONS</b></p> <p><b>SECOND.</b></p> <p>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, <b>except where the collective knowledge concerned is in the public domain.</b> 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>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>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>where the collective knowledge concerned is in the public domain.</p> <p><b>Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.</b></p>
Philippines	<p>Philippine Technology Transfer Act of 2009 (Republic Act No. 10055)</p> <p><a href="https://wipolex.wipo.int/en/legislation/details/9605">https://wipolex.wipo.int/en/legislation/details/9605</a></p>		<p><b>Article III, Sec. 8(c)</b></p> <p>The following are the rights and responsibilities of the [research and</p>	<p><b>Article III, Sec. 8(c)</b></p> <p>The following are the rights and responsibilities of the [research and</p>	

			<p>development institutes and/or institutions] <b>RDI</b>s that availed of <b>research funds from [Government Funding Agencies] GFAs:</b> [...] (c) Notify the GFA within a reasonable time of all IPR applications, licenses and assignments made. <b>All applications for IP protection</b> 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>development institutes and/or institutions] RDI)s 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 <b>biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices</b> 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)</p> <p>(<a href="http://www.wipo.int/wipolex/en/details.jsp?id=9629">http://www.wipo.int/wipolex/en/details.jsp?id=9629</a>)</p>	<p><b>Rule 12</b> [...] <b>Section 3</b> [...] <b>(c)</b> [...] biodiversity, genetic resources or materials associated traditional</p>	<p><b>Rule 12</b> [...] <b>Section 3.</b> <b>Disclosures.</b> Disclosure of potential IPRs and/or all biodiversity and</p>	<p><b>Rule 12</b> [...] <b>Section 3.</b> <b>Disclosures.</b> Disclosure of potential IPRs and/or all biodiversity and</p>	<p><b>Rule 12</b> [...] <b>Section 3.</b> <b>Disclosures.</b> iii. Where the RDI, for reasons beyond its control, does not have the necessary</p>

		<p>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 development of the subject matter contained in the IPR application; (2) 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) <b>any 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</b></p>	<p>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. <b>The GFA shall review the affidavit to determine if this will constitute compliance with the disclosure requirement under this rule.</b> [...] 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</p>
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			<p>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 the filing of the IPR application. The subject matter contained in the IPR application must depend on the</p>	<p><b>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.</b> [...]</p> <p><b>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.</b></p>	<p>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 <b>such disclosure may not be required for the grant or issuance of certificate of IPR registration.</b></p>
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			<p>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 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</p>		
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			<p>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 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	<b>RULE 2</b>  <b>Scope</b> These Rules and Regulations apply to	<b>RULE 2</b>  <b>Scope</b> These Rules and Regulations apply to	<b>RULE 6</b>  <b>Disclosures on intellectual property rights</b>	<b>RULE 6</b>  <b>Disclosures on intellectual property rights applications</b>

	<p>No. 01, 2016)</p> <p><a href="https://wipolex.wipo.int/en/legislation/details/19227">https://wipolex.wipo.int/en/legislation/details/19227</a></p>	<p>the examination and registration of intellectual property rights applications in the IPOP HL that use the <b>IKSP of the indigenous and cultural communities</b> and encourage tradition-based creations and innovations.</p> <p><b>RULE 4</b></p> <p><b>Definition of terms</b>  “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 environment, including such spheres of relationships which may include social, political, cultural, economic, religious spheres, and which are the direct</p>	<p>the examination and registration of <b>intellectual property rights applications</b> in the IPOP HL that use the <b>IKSP</b> of the indigenous and cultural communities and encourage tradition-based creations and innovations.</p>	<p><b>applications</b>  a) An intellectual property right application filed in the IPOP HL <b>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.</b> The intellectual property right application <b>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.</b></p>	<p>d) The registration for an intellectual property right that uses IKSP in the subject matter of the application <b>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,</b> notwithstanding that such disclosure is not required for the grant of certificate of intellectual property right registration. <b>In case a registration has been issued in violation of these Rules and Regulations, the IPOP HL may, in accordance with its rules and regulations, cancel the registration.</b></p>
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		<p>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 (Rule II Section 1(f) NCIP Administrative Order No. 01-98).</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, environmental and medical knowledge and knowledge associated with genetic resources.</p>			
Romania	Implementing Regulations of the Patent Law No. 64/1991 (approved by Government Decision No. 547/2008)	<p><b>ARTICLE 16</b></p> <p><b>Description of the invention</b></p>	<p><b>ARTICLE 16</b></p> <p><b>Description of the invention</b></p>	<p><b>ARTICLE 16</b></p> <p><b>Description of the invention</b></p>	

	<a href="http://www.wipo.int/wipolex/en/details.jsp?id=8457">http://www.wipo.int/wipolex/en/details.jsp?id=8457</a>	Traditional knowledge	<p>(1) The description of the invention according to Art. 14 paragraph (1) letter c) of the Law shall contain the following: [...]</p> <p>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; <b>where the prior art also contains traditional knowledge</b>, this and its source, if known, shall explicitly be indicated in the description.</p>	<p>(1) The description of the invention according to Art. 14 paragraph (1) letter c) of the Law shall contain the following: [...]</p> <p>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, <b>this and its source, if known, shall explicitly be indicated in the description.</b> [...]</p>	
	<p>Law No. 64/1991 on Patents (as amended up to Law No.83/2014)</p> <p><a href="https://wipolex.wipo.int/en/legislation/details/15734">https://wipolex.wipo.int/en/legislation/details/15734</a></p>				<p><b>Art. 53 – (1)</b> Failure to meet one or more of the formal requirements concerning the patent application shall only constitute grounds for <b>revocation or cancellation of the patent, either wholly or in part, where said</b></p>

					<p><b>failure resulted from fraudulent intentions.</b></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 (as amended up to PropertyAmendment Act 2018, Act No. 16 of 2018)</p> <p>(<a href="http://www.wipo.int/wipolex/en/details.jsp?id=13492">http://www.wipo.int/wipolex/en/details.jsp?id=13492</a>)</p>	<p><b>Article 7</b></p> <p>biological material or knowledge available within any local or indigenous community</p>	<p><b>Article 7- Application for a patent</b></p> <p>[...]</p> <p>(3) An application must contain the following:</p> <p>[...]</p> <p>(g) a statement stating whether or not the <b>invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere;</b></p> <p>(h) a statement disclosing the source and geographical origin of <b>any biological material</b></p>	<p><b>Article 7- Application for a patent</b></p> <p>[...]</p> <p>(3) An application must contain the following:</p> <p>[...]</p> <p>(g) <b>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;</b></p> <p>(h) <b>a statement disclosing the source and geographical origin</b></p>	<p><b>Article 7- Application for a patent</b></p> <p>[...]</p> <p>(12) If an applicant fails to provide evidence as directed by the Registrar under subsection (10), the Registrar may, <b>cease to deal further with the application.</b></p> <p><b>17. Invalidation-</b> (1) Any interested person may apply to the Supreme Court to <b>invalidate a patent.</b></p> <p>(2) The Supreme Court must invalidate the patent if the applicant proves that:</p> <p>(a) any of the requirements of sections 5 and</p>

			<p><b>used for the invention;</b> [...] (10) Subject to subsection (11), <b>if the application is based on or derived from biological material or knowledge available within any local or indigenous community</b> 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><b>22. Application for an innovation patent</b> [...] (3) An application must contain: [...] (g) a statement stating whether or not the <b>invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere</b>; and (h) a statement disclosing the source and geographical</p>	<p><b>of any biological material used for the invention;</b> [...] (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 <b>furnish evidence as to the applicant's title or authority to make use of such material or knowledge.</b> [...]</p> <p><b>22. Application for an innovation patent</b> [...] (3) An application must contain: [...] (g) <b>a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous</b></p>	<p>sections 7 to 10 are not fulfilled; [...]</p> <p><b>22. Application for an innovation patent</b> [...] (12) When an applicant fails to provide evidence as directed by the Registrar under subsection (10), the Registrar may <b>cease to deal further with the application.</b></p> <p><b>28. Invalidation-</b>(1) Any interested person may apply to the Registrar to <b>invalidate an innovation patent.</b> (2) The Registrar must invalidate the innovation patent if the applicant proves that: [...] (b) the description and the claims do not comply with the requirements of section 20 and sections 22, to 25; [...]</p>
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			<p>origin of <b>any biological material used for the invention</b>;</p> <p>[...]</p> <p>(10) Subject to subsection (11), <b>if the application is based on or derived from biological material or knowledge available within any local or indigenous community</b> 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><b>community whether from Samoa or elsewhere</b>; and</p> <p>(h) <b>a statement disclosing the source and geographical origin of any biological material used for the invention</b>;</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 <b>furnish evidence as to the applicant's title or authority to make use of such material or knowledge</b>.</p>	
South Africa	<p>Patents Amendment Act 2005 (Act No. 20 of 2005)</p> <p>(<a href="http://www.wipo.int/wipolex/en/details.jsp?id=5765">http://www.wipo.int/wipolex/en/details.jsp?id=5765</a>)</p>	<p><b>(Section 2)</b></p> <p>genetic resource indigenous biological resource traditional knowledge</p> <p>Genetic resource means</p> <p>(a) any indigenous genetic material; or</p> <p>(b) the genetic potential or characteristics of</p>	<p>“(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, <b>before acceptance of the application</b>, lodge with the registrar a statement in the prescribed manner stating</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 <b>a statement in the prescribed manner</b></p>	<p>Section 61</p> <p>(1) Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely</p> <p>[...]</p> <p>(g) that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in</p>

		<p>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>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.</p> <p>(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 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."</p>	<p><b>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.</b></p> <p>(3B) The registrar shall call upon the applicant to <b>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 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."</b></p>	<p>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>
Spain	Act No. 24/2015, of July 24, 2015, on patents (Patents Act), as amended by Act No. 6/2018, of July 3, 2018	<b>Article 23(2)</b> Biological material	<b>Article 23.</b> Application requirements.	<b>Article 23.</b> Application requirements.	<b>Article 23.</b> Application requirements. [...]



	<a href="https://wipolex.wipo.int/en/legislation/details/16711">           (https://wipolex.wipo.int/en/legislation/details/16711)         </a>		<p>[...]</p> <p>2. <b>Where the invention relates to biological material of vegetable or animal origin</b>, the application shall include a mention of its geographical origin or the source of origin of such material if that information is known. The information shall be without prejudice to patent's validity.</p> <p>[...]</p>	<p>[...]</p> <p>2. Where the invention relates to biological material of vegetable or animal origin, <b>the application shall include a mention of its geographical origin or the source of origin of such material if that information is known</b>. The information shall be without prejudice to patent's validity.</p> <p>In the cases provided for in Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users of the Nagoya Protocol on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilisation within the Union, the patent application shall also contain, to the extent determined by regulation, the <b>information that users of such</b></p>	<p>2. Where the invention relates to biological material of vegetable or animal origin, the application shall include a mention of its geographical origin or the source of origin of such material if that information is known. <b>The information shall be without prejudice to patent's validity.</b></p> <p>In the cases provided for in Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users of the Nagoya Protocol on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilisation within the Union, the patent application shall also contain, to the extent determined by regulation, the information that users of such resources are obliged to keep in accordance with the provisions of the aforementioned regulation. <b>Such information shall also be without prejudice to the validity of the</b></p>
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				resources are obliged to keep in accordance with the provisions of the aforementioned regulation. Such information shall also be without prejudice to the validity of the patent.	patent.
Sweden	Regulation (2004:162) Amending the Patents Decree ( <a href="http://www.wipo.int/wipolex/en/details.jsp?id=3672">http://www.wipo.int/wipolex/en/details.jsp?id=3672</a> )	<b>Article 5a</b> biological material of plant or animal origin	<b>Article 5a.</b> 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 origin is not known, this shall be indicated. 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.	<b>Article 5a.</b> 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 origin is not known, this shall be indicated. 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.	<b>Article 5a.</b> 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 origin is not known, this shall be indicated. 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.
Switzerland	Federal Act of June 25, 1954 on Patents for Inventions (status as of April 1, 2019) ( <a href="https://www.wipo.int/wipolex/en/legislation/details/18795">https://www.wipo.int/wipolex/en/legislation/details/18795</a> )	<b>Article 49a</b> Genetic resource; traditional knowledge of	<b>Article 49a</b> 1. The patent application must contain information	<b>Article 49a</b> 1. The patent application must contain information	<b>Article 59</b> [...] 2. If the patent application does not

		indigenous or local communities	on the source: a. of the genetic resource <b>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 <b>to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge.</b>	<b>on the source:</b> a. <b>of the genetic resource</b> to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b. <b>of traditional knowledge of indigenous or local communities</b> to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge. <b>2. If the source is unknown to the inventor or the patent applicant, the patent applicant must confirm this in writing.</b>	meet the other requirements of this Act or the Ordinance, <b>the Institute shall set a time limit for the patent applicant by which the deficiencies must be remedies.</b>  <b>Article 59(a)</b> 3. The Institute shall <b>reject the patent application</b> if: [...] b. the deficiencies mentioned in Article 59 paragraph 2 have not been remedied.  <b>Art. 81a</b> 1. Any person who wilfully provides false 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 <a href="https://wipo.int/en/legislation/details/16480">https://wipo.int/en/legislation/details/16480</a>	<b>21. Application for a patent.</b> [...] <b>(8)</b> biological resources, traditional knowledge	<b>21. Application for a patent.</b> [...] <b>(8)</b> 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	<b>21. Application for a patent.</b> [...] <b>(8)</b> The description shall contain a <b>clear identification of the origin of genetic or biological resources collected in the territory of Uganda and that were directly or indirectly used in</b>	<b>Section 90</b> [...] <b>(3)</b> The court shall <b>revoke or invalidate</b> 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

			<p>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.</p>	<p><b>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</b> without the prior informed consent of its individual or collective creators.</p>	<p>which it is to be performed.</p>
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Vanuatu	<p>Patents Act No. 2 of 2003</p> <p>(<a href="http://www.wipo.int/wipolex/en/details.jsp?id=10727">http://www.wipo.int/wipolex/en/details.jsp?id=10727</a>)</p>	<p><b>PART 12 INDIGENOUS KNOWLEDGE REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE</b> 47. [...] Indigenous knowledge[...]</p>	<p><b>PART 12 INDIGENOUS KNOWLEDGE REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE</b> 47. [...] (2) The Registrar must not grant a patent for an <b>invention that is based on, arose out of, or incorporates elements of, indigenous knowledge</b> 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.</p>	<p><b>PART 12 INDIGENOUS KNOWLEDGE REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE</b> 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: <b>(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.</b></p>	<p><b>PART 12 INDIGENOUS KNOWLEDGE REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE</b> 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: <b>(a) the Registrar may grant the patent; and (b) the owner may exploit the patent; and 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.</b></p>
Viet Nam	<p>Circular No. 01/2007/TT-BKHCN 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</p>	<p><b>Article 23.11</b> Gene source and/or traditional knowledge</p>	<p><b>Article 23.11</b> Additional provisions applicable to applications for registration of</p>	<p><b>Article 23.11</b> Additional provisions applicable to applications for registration of</p>	<p><b>Article 23.11</b> [...] If the inventor or the applicant cannot identify the origin of the gene</p>

	<p>Industrial Property</p> <p>(<a href="http://www.wipo.int/wipolex/en/details.jsp?id=5013">http://www.wipo.int/wipolex/en/details.jsp?id=5013</a>)</p>		<p>inventions concerning gene source or traditional knowledge</p> <p>Apart from the general requirements for invention registration applications specified at Points 23.1 through 23.7 of thisCircular, an application for registration of an <b>invention concerning gene source or traditional knowledge</b> 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>inventions concerning gene source or traditional knowledge</p> <p>Apart from the general requirements for invention registration applications specified at Points 23.1 through 23.7 of thisCircular, an application for registration of an invention concerning gene source or traditional knowledge must also contain <b>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.</b> [...]</p>	<p>source and/or traditional knowledge, he/she shall so declare and <b>bear responsibility</b> for the truthfulness of his/her declaration.</p>
Zambia	<p>The Patents Act, 2016 (Act No. 40 of 2016)</p> <p>(<a href="https://wipolex.wipo.int/en/legislation/details/18207">https://wipolex.wipo.int/en/legislation/details/18207</a>)</p>	<p>28. [...] invention which utilises genetic resources or associated traditional knowledge or both [...]</p>	<p><b>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</b></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, <b>the</b></p>	<p><b>PART V</b></p> <p><b>Examination, publication and opposition</b></p> <p><b>51. [...]</b></p> <p>(3) Where the Registrar is of the opinion, after conducting an examination, referred to in subsection (1), that an application is not</p>

			<p>disclose —</p> <p>(a) the country of origin of the genetic resources or associated traditional knowledge in accordance with the Convention on Bio-Diversity; and</p> <p>(b) the source in the country providing the genetic resources or associated traditional knowledge.</p>	<p><b>applicant shall disclose —</b></p> <p><b>(a) the country of origin of the genetic resources or associated traditional knowledge in accordance with the Convention on Bio-Diversity; and</b></p> <p><b>(b) the source in the country providing the genetic resources or associated traditional knowledge.</b></p>	<p>compliant with the requirements of this Act, the Registrar shall notify the applicant, in writing, to make relevant amendments to the application, within a prescribed period.</p> <p>(4) Where the applicant fails to, after the notification referred to in subsection (3), make the relevant amendments, the Registrar shall, in writing, <b>refuse the application.</b></p> <p>[...]</p> <p><b>56.</b> A person, including the State, may <b>oppose the grant of a patent</b> 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:</p> <p>[...]</p> <p><b>(I) that the complete specification does not disclose or wrongly mentions the source or the geographical origin or biological material used for the</b></p>
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					invention; [...] (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>(<a href="https://wipolex.wipo.int/en/legislation/details/16181">https://wipolex.wipo.int/en/legislation/details/16181</a>)</p>	<p><b>36.</b> [...] product developed from the genetic resource [...]</p>	<p><b>36.</b> An access permit holder shall have the following obligations: [...] (l) recognise the locality where the genetic resource or traditional knowledge has been accessed <b>in an application for protection of the product developed from the genetic resource.</b> [...]</p>	<p><b>36.</b> An access permit holder shall have the following obligations: [...] (l) <b>recognise the locality where the genetic resource or traditional knowledge has been accessed</b> in an application for protection of the product developed from the genetic resource. [...]</p>	



