

Assessment of the draft 2010 Domestic Policy Guidance for Canada (Managing Genetic Resources in the 21st Century)* vis-à-vis obligations of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization to the Convention on Biological Diversity

**The draft 2010 Domestic Policy Guidance for Canada was developed jointly by the Federal – Provincial – Territorial Task Force in 2009 and 2010 and approved by the Deputy Ministers FPT Committee on Biodiversity . The draft Domestic Policy Guidance is used in the present document for reference purpose only. It is not and should not be considered Government of Canada policy.*

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<p><i>Genetic resources</i> are plant, animal, and microbial materials that contain functioning genes that have actual or potential economic, environmental or social value.</p>	<p>Article 2 (Use of Terms) stipulates that terms defined in Article 2 of the Convention apply to the Protocol</p> <p>Article 2 of the Convention defines <i>genetic resources</i> as “genetic material of actual or potential value” and <i>genetic material</i> as “any material of plant, animal or microbial or other origin containing functional units of heredity”.</p>	<p>“Functioning genes” are the equivalent of “functional units of heredity”. The two definitions are compatible with one distinction: the definition in the draft Domestic Policy Guidance does not address material of “other” origin than plants, animal or microbial material.</p>
<p>The objectives of ABS policy in Canada are: 1) promoting the conservation and sustainable use of Canada’s biodiversity; 2) improving Canada’s competitiveness in the bio-based economy; 3) support ethical scientific research and development; 4) support Canada’s foreign policy objectives; 5) Contribute to the improvement of the health of Canadians.</p> <p>The main goals of the draft Policy Guidance are to facilitate the <i>sustainable access</i> to genetic resources and to provide for the fair and equitable <i>sharing of benefits</i> arising from their use among Canadians.</p>	<p>Article 1 (Objective): The objective of the Nagoya Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.</p>	<p>The objectives and goals of the draft Domestic Policy Guidance are consistent with the objective of the Protocol.</p>

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<p>Scope: all genetic resources in Canada, both in the wild (referred to as <i>in situ</i>) and in collections (referred to as <i>ex situ</i>), with the exception of those genetic resources noted below, which should not be subject to any requirements developed under access and benefit sharing policy in Canada;</p> <ul style="list-style-type: none"> • human genetic resources; • genetic resources beyond Canada’s borders; • genetic resources acquired for personal use or consumption; and • genetic resources purchased or traded as commodities (for example, trees used for lumber) 	<p>Article 3 (Scope): The Protocol applies to genetic resources within the scope of Article 15 of the Convention (i.e., Access to Genetic Resources) and to benefits arising from their utilization.</p> <p>The Convention excludes: Human genetic resources (as per COP Decision II/11);</p> <p>Genetic resources beyond the national jurisdiction of Parties (Convention Article 4(a)).</p>	<p>The Protocol does not specifically exclude genetic resources acquired for personal use or consumption or genetic resources purchased or traded as commodities.</p> <p>However, the Protocol is restricted to access to genetic resources <i>for their utilization</i> and benefit-sharing to <i>benefit arising from their utilization</i>. In Article 2 (Use of Terms) of the Protocol, utilization of genetic resources is defined as “means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention”.</p>
<p>Scope: The draft Domestic Policy Guidance addresses traditional knowledge associated with genetic resources, with the exception of traditional knowledge associated with genetic resources that is in the public domain;</p>	<p>Article 3 (Scope): The Protocol applies to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.</p>	<p>Article 8(j) of the Convention refers to the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.</p> <p>Contrary to the draft Domestic Policy Guidance, the Protocol does not explicitly include or exclude traditional knowledge associated with genetic resources that is in the public domain.</p>
<p>Relationship with other agreements: The draft Domestic Policy Guidance states that access and benefit sharing policy in Canada should recognize international agreements or arrangements dealing with the subject matter that are relevant to Canada and in harmony with access and benefit sharing</p>	<p>Article 4 (Relationship with International Agreements and Instruments) stipulates that the Protocol shall not affect rights and obligations of Parties pursuant to other international agreements and shall not prevent the development and implementation of other agreements on access and benefit</p>	<p>Article 4 of the Protocol does not contradict the draft Domestic Policy Guidance. However, the key difference between the draft Policy Guidance and the Protocol is that the latter is an obligation (i.e., should vs. shall).</p>

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<p>policy in Canada.</p>	<p>sharing provided they are supportive of and do not run counter to the objectives of the Convention and the Protocol. The Nagoya Protocol will not apply to a more specialized instrument (i.e. legally or non-legally binding) which itself applies to specific genetic resources, provided that the instrument is consistent with, and does not run counter to, the objectives of the CBD and the Nagoya Protocol.</p>	
<p>Prior Informed Consent (PIC) The draft Domestic Policy Guidance stipulates that Canada’s governments agree that the development and implementation of their measures to manage access to genetic resources and benefit-sharing should be founded on PIC. Specifically, it states that:</p> <p>1.1 Access to genetic resources in Canada is provided by the entity that is legally entitled to grant access at the location where the genetic resource is found – land, water or facility such as a collection maintained <i>ex situ</i>;</p> <p>1.2 Access to <i>in situ</i> genetic resources should be granted only with and after the documented prior informed consent of the party providing access;</p> <p>1.3 The process for obtaining prior informed consent for access to genetic resources should depend on the mechanism established by the competent authority providing access; and</p> <p>1.4 That prior informed consent involving access to genetic resources granted by an individual landowner or other private</p>	<p>Article 6 (Access to Genetic Resources) specifies that access to genetic resources is subject to the access and benefit-sharing legislation and regulatory requirements. It also commits the Parties that require PIC for access to some or all of their genetic resources or genetic resources held by indigenous and local communities to take legislative, administrative or policy measures – as appropriate - to implement the requirements listed in Article 6.3 of the Protocol with respect to the relevant genetic resources.</p> <p>Article 13.2 (National Focal Points and Competent National Authority) addresses the Competent National Authority. The Competent National Authority is responsible for granting access or issuing written evidence that access requirements have been met and advises on applicable procedures and requirements for obtaining PIC and entering into Mutually Agreed Terms (MAT). Parties can designate one or more Competent National Authority.</p>	<p>The requirements of the Protocol addressing prior informed consent appear to be consistent with the draft Domestic Policy Guidance. The key difference between the draft Policy Guidance and the Protocol is that the Protocol obligation requires a potential user to obtain Prior Informed Consent to access genetic resources, and establishment of a Competent National Authority that grants access to genetic resources.</p> <p>The draft Domestic Policy Guidance recommends that prior informed should be granted by the entity that is legally entitled to grant access at the location where the genetic resources is found. This entity would be a designated Competent National Authority.</p>

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<p>authority will be best negotiated under existing common or civil law practices (that is, property and contract law). In most cases involving private landowners, therefore, there will be no need to obtain prior informed consent by means of a new legal instrument.</p>		
<p>Mutually Agreed Terms 2.1 Those accessing and those providing genetic resources should establish mutually agreed terms which clearly identify how the genetic resource is to be accessed and how the benefits arising from the use will be shared, or, as appropriate, should use those terms established at the international level where Canada has agreed to a relevant intergovernmental agreement (e.g. the <i>International Treaty on Plant genetic Resources for Food and Agriculture</i>).</p> <p>2.2 Jurisdictions should not be prescriptive about the content of the mutually agreed terms such as the precise nature of the benefit sharing measures and their level of detail, such as any minimum requirements on monetary or non-monetary benefits.</p> <p>2.3 Jurisdictions should encourage, to the extent possible, the use of non-legally binding model clauses and standardized benefits that parties can use in the development of their mutually agreed terms, so as to promote more effective and efficient implementation of measures to manage ABS across Canada.</p> <p>2.4 Access to <i>ex situ</i> genetic resources (e.g. those in botanical gardens or other collections) should not be subject to</p>	<p>Article 5.1 (Fair and Equitable Benefit-Sharing) provides that the sharing of benefits arising from the utilization of genetic resources shall be on mutually agreed terms. Article 4.4 (Relationship with International Agreements and Instruments) provides that if a specialized ABS instrument exists that is consistent with the Protocol, this instrument continues to apply for the Parties to it.</p> <p>Article 6.1 (Access to Genetic Resources) specifies that access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing the resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, subject to domestic access and benefit-sharing legislation and unless otherwise determined by that Party. The Protocol allows the use of existing documents as evidence of PIC and MAT where the required information matches. These documents are “equivalent” of permits (Article 6.3(g)).</p> <p>Article 5.2 (Fair and Equitable Benefit-Sharing) provides that the sharing of benefits arising from the utilization of genetic resources held by indigenous and local communities (in accordance with domestic legislation and established rights of these communities over genetic resources) shall be on mutually agreed terms.</p>	<p>The requirements of the Protocol appear to be consistent draft Domestic Policy Guidance on mutually agreed terms. However, the key difference between the draft Policy Guidance and the Protocol is that the latter is an obligation (i.e., should vs. shall). The Protocol does not make the same distinction as the draft Domestic Policy Guidance with regard to <i>ex situ</i> genetic resources not being subject to prior informed consent (see draft Domestic Policy Guidance paragraph 2.4) but this distinction does not appear to be inconsistent or in conflict with the Protocol (see Article 6.1 of the Protocol).</p> <p><i>The International Treaty on Plant Genetic Resources for Food and Agriculture</i> is mentioned expressly in the Preamble. Given its interpretive value, we are of the view that the ITPGR would be a specialized instrument in the sense of Article 4.4.</p>

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<p>measures for prior informed consent, but should be subject to the establishment of mutually agreed terms, including benefit sharing agreements or arrangements, between the provider and the user of the genetic resource, or, as appropriate, at the international level where Canada has agreed to a relevant intergovernmental agreement (for example, the <i>International Treaty on Plant Genetic Resources for Food and Agriculture</i> concerning government-managed collections of crop plant germplasm).</p>	<p>The Protocol does not make any prescription with regard to mutually agreed terms except that they must be in writing (Article 6.3(g)). It is suggested that the terms may include provisions addressing dispute settlement (including applicable law, jurisdiction, alternative dispute resolution (Article 18.1)), benefit-sharing, including in relation to IP rights, third party use and change of intent (Article 6.3(g)). Article 9 also provides that Parties should encourage users and providers to direct benefits towards conservation and sustainable use.</p> <p>Article 19 (Model Contractual Clauses) requires Parties to encourage the development, update and use of sectoral and cross-sectoral model clauses for mutually agreed terms.</p>	
<p>Traditional knowledge 3.1 Access and Benefit Sharing policy in Canada should recognize and take into account that Aboriginal peoples hold traditional knowledge associated with genetic resources. This knowledge has been gained over generations of experience and practices with the natural environment and its biological resources.</p> <p>3.2 Access to traditional knowledge associated with genetic resources should require separate provisions from those for access to genetic resources.</p> <p>3.3 Aboriginal peoples and communities should be entitled to</p>	<p>Article 7 (Access To Traditional Knowledge Associated With Genetic Resources): In accordance with domestic law, Parties have to take measures “with the aim of ensuring” that traditional knowledge associated with genetic resources is accessed with the prior and informed consent or approval and involvement of the holders of that knowledge and that mutually agreed terms have been established.</p> <p>Article 5.5 (Fair and Equitable Benefit-Sharing): Parties have to take legislative, administrative or policy measures, as appropriate so that benefits arising from the utilization of traditional knowledge associated with genetic resources are shared with the holders of the knowledge on mutually agreed</p>	<p>The Nagoya Protocol’s provisions on traditional knowledge associated with genetic resources appear to be consistent with the draft Domestic Policy Guidance. However, the key difference between the draft Policy Guidance and the Protocol is that the latter is an obligation (i.e., should vs. shall).</p> <p>The obligation on a Party to take into consideration customary laws, community protocols and procedures is subject to domestic law and to what is applicable in the particular domestic circumstances of the Party. This provides considerable flexibility to each Party to determine whether and how to take customary laws, community</p>

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<p>determine whether and how to share the traditional knowledge that they hold, which is associated with genetic resources.</p> <p>3.4 Jurisdictions should adopt measures and tools, as appropriate for the development of mutually agreed terms between the users and providers of traditional knowledge associated with genetic resources in the form of a contract. Jurisdictions should not be prescriptive about the content of the contracts.</p> <p>3.5 Jurisdictions should encourage, to the extent possible, the development and use of voluntary measures such as guidelines, best practices, model contracts, awareness raising and capacity building to facilitate the negotiation of mutually agreed terms related to accessing and using traditional knowledge associated with genetic resources.</p>	<p>terms.</p> <p>Article 12 (Traditional Knowledge Associated with Genetic Resources): In accordance with their domestic law and as applicable, Parties must take into consideration the customary laws, community protocols and procedures applicable with respect to traditional knowledge associated with genetic resources. Parties should also endeavour to support the development by indigenous and local communities of community protocols for access to traditional knowledge associated with genetic resources, minimum requirements for mutually agreed terms and benefit sharing and model contractual clauses for benefit sharing from the utilization of traditional knowledge.</p> <p>In collaboration with indigenous and local communities, Parties have to put in place mechanisms to inform users of their obligations on access to traditional knowledge associated with genetic resources and the sharing of benefits its utilization (e.g. through the focal point as per Article 13.1(b), competent national authorities or the clearing-house mechanism). Parties also may take measures to raise awareness with regard to community protocols and procedures of indigenous and local communities (Article 21(i)).</p> <p>Article 16 (Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing for Traditional Knowledge Associated with Genetic Resources): The Parties have to take appropriate effective and proportionate legislative, administrative or policy measures to provide that traditional knowledge associated with genetic resources utilized</p>	<p>protocols and procedures into account.</p>

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	<p>within their jurisdiction has been accessed with the prior informed consent or approval and involvement of the holders and that mutually agreed terms have been established as required by the domestic legislation or regulation of the party where these holders are located. Parties have to address situations of non-compliance and cooperate as far as possible in cases of alleged violation.</p>	
Possible implementation tools		
<p>Access measures Jurisdictions will consider the development and application of appropriate tools to facilitate access to genetic resources in Canada. These tools could include:</p> <ul style="list-style-type: none"> • <i>a single window entry</i> website that directs parties to the relevant competent authority and jurisdiction; and • <i>simplified procedures</i> that enable convenient access for non-commercial purposes (such as non-commercial scientific research). 	<p>Article 13 (National Focal Points and Competent National Authorities) requires Parties to designate a national focal point that will, among other things, make information available to applicants seeking access to genetic resources and traditional knowledge associated with genetic resources.</p> <p>Article 13 also requires each Party to designate one or more competent national authorities on access and benefit sharing that will be responsible for granting access or issuing written evidence that access requirements have been met and for advising on procedures and requirements for obtaining PIC and entering into MAT.</p> <p>Article 21(d) (Awareness-Raising) invites Parties to make information on genetic resources and associated traditional knowledge available and related access and benefit-sharing issues through a national clearing-house.</p> <p>Article 8 (Special Considerations) requires Parties, when they develop their domestic legislation, to create conditions to promote and encourage research contributing to the conservation and sustainable use of biological diversity, including through simplified measures on access for non-</p>	<p>The Nagoya Protocol establishes specific obligations for the Parties to designate a national focal point and one or more competent national authorities.</p> <p>The draft Domestic Policy Guidance does not develop the concept of information sharing beyond implementation tools that jurisdictions could consider to facilitate access to genetic resources.</p> <p>The draft Domestic Policy Guidance recommends that prior informed should be granted by the entity that is legally entitled to grant access at the location where the genetic resources is found. This entity would be a designated Competent National Authority.</p>

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<p>Administrative Measures Jurisdictions will consider the development and application of cost effective administrative measures to promote consistency and efficiency in access and benefit sharing policies in Canada. These measures could include:</p> <ul style="list-style-type: none"> • a voluntary <i>certificate of compliance</i> or similar agreement that provides parties with evidence that access to genetic resources has been granted in compliance with access and benefit sharing policy in Canada and any specific requirements under the jurisdiction; • a <i>national registry</i> of access to genetic resources in each Canadian jurisdiction; and • <i>model contracts, best practices and guidelines</i>. 	<p>commercial research.</p> <p>Article 6.3(e) (Access to Genetic Resources) requires Parties that require prior informed consent for access to their genetic resources to provide a permit or equivalent at the time of access, as evidence that prior informed consent has been granted and mutually agreed terms established.</p> <p>Article 14 (Access and Benefit-sharing Clearing House and Information Sharing) Notification of issuance (of a permit or equivalent) is given to the Access and Benefit-sharing Clearing-house as required by Article 14.2(c) at which point it constitutes an internationally recognized certificate of accordance serving as evidence that genetic resources have been accessed in compliance with prior informed consent and that mutually agreed terms have been established in accordance with domestic access and benefit-sharing legislation (Article 17.3).</p> <p>Article 17 (Monitoring the Utilization of Genetic Resources) addresses utilization of genetic resources. Article 17.1(a)(i) requires Parties to designate one or more checkpoint(s) that will collect or receive the relevant information on access to genetic resources (e.g. information on prior informed consent, on the source of genetic resources, on the establishment of mutually agreed terms, and/or utilization of genetic resources).</p> <p>Article 19 (Model Contractual Clauses) and 20 (Codes of Conduct, Guidelines and Best Practices and/or Standards) require Parties to encourage the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms and the use of voluntary codes of</p>	<p>The provisions of the Nagoya Protocol seem consistent with the implementation tools regarding administrative measures proposed for consideration in the draft Domestic Policy Guidance. However the permit or equivalent issued under Article 6.3(e) is not voluntary.</p> <p>The permit or equivalent is issued by a Competent Authority at the time of access. The protocol specifies that submission of the permit or equivalent issued at the time of access to the Access and Benefit-sharing Clearing House transforms the permit or equivalent into an internationally recognized certificate of compliance with the requirement to obtain PIC and to establish MAT.</p>

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<p>Advisory Mechanisms To strengthen approaches regarding traditional knowledge associated with genetic resources, jurisdictions will consider establishing a <i>panel of regional Aboriginal experts</i>.</p> <p>Jurisdictions also will consider establishing an <i>advisory panel</i> representing industry, the scientific community, civil society organizations and other interests to provide ongoing advice to Governments on approaches to managing genetic resources in Canada.</p>	<p>conduct, guidelines and best practices and/or standards.</p> <p>Article 12 (Traditional Knowledge Associated with Genetic Resources) requires Parties to collaborate with indigenous and local communities in a manner that allows them to effectively participate in the establishment by a Party of mechanisms to inform users of traditional knowledge associated with genetic resources about their obligations.</p>	<p>There are no requirements or provisions in the Protocol addressing panels, panels of Aboriginal experts or advisory panels. Although such an initiative is not mandated by any of the provisions of the Protocol, they would likely be viewed favourably as facilitating ‘effective participation’ of indigenous groups as per Article 12.</p>