High-Level Working Group on U.S.-Ecuador Relations

Traditional Knowledge and International Trade

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HIGH-LEVEL WORKING GROUP ON U.S.-ECUADOR RELATIONS

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INTRODUCTION

The United States and Ecuador have long been connected. The two countries established diplomatic relations in the 1820s, not long after both countries had won independence from Europe. In subsequent decades, the United States and Ecuador deepened relations on the basis of values enshrined in the Inter-American System, such as democracy, the rule of law, and human rights. Whether culturally or economically, the threads that bind the countries together are many.

Economic ties in particular have contributed to shared prosperity for the people of the United States and Ecuador. Today, the United States is Ecuador’s principal trading partner—making Ecuador one of only three countries in South America for which trade with the United States surpasses trade with China. The United States’ principal exports to Ecuador include petroleum, machinery, computers, fertilizer, and cereals and grains. In return, Ecuador sends crude oil, seafood, bananas, cocoa, and flowers to the United States.

While Ecuador and the United States sought to deepen economic ties in the early 2000s, extensive negotiations ended amid political and social upheaval in 2006. The two governments did not resume discussions over trade and investment until the administration of President Lenín Moreno (2017-2021). His successor, President Guillermo Lasso, has emphasized the need for Ecuador to deepen trade relations with the United States, with a particular focus on labor rights, intellectual property, gender equality, and environmental sustainability. Indeed, recent developments in both countries—including the elections of new presidents in both countries—offer a unique opportunity to discuss how the two countries might work together to combat the COVID-19 pandemic, spark economic growth, and pursue other priorities.

On June 4, 2021, Global Americans announced the formation of a High-Level Working Group, comprised of seasoned current and former policymakers, foreign service professionals, business leaders, and scholars. In collaboration with Global Americans staff, the Working Group has produced a series of working papers, covering a diverse range of topics central to the United States-Ecuador relationship—and in particular, central to any discussion of deepening commercial and economic relations between the two countries. The High-Level Working Group has served as a forum for nonpartisan and transregional expert analysis, resulting in a series of recommendations regarding the future of United States-Ecuador relations.

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Executive Summary

Traditional knowledge (TK) is an important aspect of modern trade negotiations. The concept shares a close relationship to both Indigenous Peoples’ rights and intellectual property, the topics of previous reports by the Global Americans High-Level Working Group on U.S.-Ecuador Relations. As Chapter 1 explains, TK encompasses knowledge that is “passed on from generation to generation within a community, often forming part of its cultural or spiritual identity.” A particular area of emphasis within TK is genetic material. Certain Indigenous communities have used resources from plants, animals, and microorganisms for many generations, often for medical purposes. Disputes arise when individuals or firms attempt to patent products based in these resources, especially when it is unclear whether a product represents a genuine innovation.

Chapter 2 documents the evolution of international law regarding traditional knowledge. In 1992, the United Nations promulgated the Convention on Biological Diversity (CBD), obligating signatories to respect, preserve, and maintain traditional knowledge. The 2010 Nagoya Protocol went further, providing countries with the option to regulate access to genetic resources and distribute the benefits that arise from their use. All signatories must monitor their own firms for compliance with foreign TK regulations under the Nagoya Protocol. Ecuador is party to both the CBD and Nagoya Protocol. The United States is party to neither agreement.

As Chapter 3 explains, most Latin American countries have domestic laws regulating traditional knowledge, and the region is a pioneer when it comes to including TK provisions in trade agreements. Of the six countries in the world that signed the most trade agreements mentioning genetic material between 2000 and 2015, four were in Latin America (Peru, Colombia, Costa Rica, and Panama). The U.S.-Mexico-Canada Agreement (USMCA), signed in 2020, contained provisions respecting TK for genetic material at the urging of the Canadian and Mexican governments.

Chapter 4 concludes the paper with four recommendations. Policymakers should use trade negotiations as a platform to discuss TK. Ecuadorean leaders should devote attention to TK given the country’s high population of Indigenous Peoples and high biodiversity. Any agreement should emphasis opportunities for holders of TK, not just defensive protections. Finally, the United States should consider enforcing foreign TK protections for its firms that operate abroad, especially in Ecuador.

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1. THE IMPORTANCE OF TRADITIONAL KNOWLEDGE

Traditional knowledge (TK) is a key issue of modern trade agreements, sitting at the intersection of intellectual property and Indigenous Peoples’ rights. Given that Indigenous People comprise a significant share of the population of Ecuador, TK is a particularly relevant topic of discussion as the United States and Ecuador seek to deepen trade relations.

Defining Traditional Knowledge

Indigenous Peoples in Ecuador, the United States, and elsewhere often share certain characteristics, including a collective attachment to ancestral territories and the natural resources of those territories; distinctive customary cultural, economic, social, or political institutions; and a distinct language or dialect. For many Indigenous Peoples, traditional knowledge is closely related to these shared characteristics.

The term “traditional knowledge” can indicate different concepts to different audiences. This paper will adopt the broader definition of the World Intellectual Property Organization (WIPO): “Traditional knowledge (TK) is knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity.”

TK is closely related to traditional cultural expressions, also known as folklore, which may include music, art, designs, symbols, and performances.

TK and Genetic Material

One of the primary topics covered under the concept of traditional knowledge is genetic material. Genetic resources may come from plants, animals, or microorganisms. As such, they are not intellectual property themselves, but they may form the basis for a patentable invention.

Disputes can arise when a product does not represent a genuine innovation, but rather is derivative of existing traditional knowledge.

In many cases, an individual or firm will attempt to patent a genetic resource, or a product derived from a genetic resource, for a specific purpose. Patents aim to incentivize innovation, offsetting the costs of research and development by granting a temporary monopoly to the creator of a new product. If a product represents a genuine innovation based in genetic material, a patent may be an appropriate incentive.

Disputes can arise when a product does not represent a genuine innovation, but is derivative of existing traditional knowledge—for example, an Indigenous community’s use of a plant to treat an illness.

In 1995, two researchers received patents from the U.S. Patent and Trademark Office (PTO) for turmeric powder to treat surgical wounds and ulcers. The Indian Council of Scientific and Industrial Research (CSIR) objected, noting that

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5 See ESS7, supra note 3; see generally, Global Americans, Indigenous Peoples’ Rights, supra note 3.
turmeric, an herb native to India, had been used for centuries as part of the Ayurvedic system of traditional medicine. In 1997, the PTO withdrew the patent following a year-long legal battle.

Sometimes the line between genuine innovation and simply filing a patent for a traditional practice is less clear.

**Ecuador is the 17th most biodiverse country in the world, ranging from the Amazon to the Andes and from the Pacific Coast to the Galapagos.**

In the late 1950s, U.S. pharmaceutical firm Eli Lilly began selling two anti-cancer drugs: vincristine and vinblastine. Both products were derived from the rosy periwinkle, a plant native to Madagascar but that has been cultivated globally for several thousand years. Prior to the 1950s, the Indigenous Peoples of Madagascar and other countries had used the rosy periwinkle for medicinal purposes, including to treat wasp stings, diabetes, and malaria.

Both drugs from Eli Lilly used the rosy periwinkle as a base ingredient for a novel pharmaceutical. They also treated a different illness than had been addressed in traditional medicine. Vinblastine has become a major treatment option for those with Hodgkin’s disease and other types of cancer. Vincristine has contributed to a surge in survival rates for children with leukemia, from around ten to 90 percent of patients.

Eli Lilly’s use of rosy periwinkle has nonetheless created significant controversy. Some NGOs have accused the pharmaceutical company of biopiracy, noting that the firm profited from selling vinblastine and vincristine but that the holders of traditional knowledge never received any compensation, nor did they consent to the use of the rosy periwinkle for medicines.

These concerns, and the responses to them, exemplify the challenge that all countries face in reconciling intellectual property with traditional knowledge.

Ecuador, in particular, is the 17th most biodiverse country in the world, ranging from the Amazon to the Andes and from the Pacific Coast to the Galapagos. Given the country’s high concentration of animals, plants, and microorganisms, particularly in areas that Indigenous People call home, Ecuadorian policymakers must grapple with traditional knowledge as they contemplate deeper trade relations. The next chapter explains how international law has evolved to balance intellectual property with traditional knowledge.

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2. **TK IN INTERNATIONAL LAW**

Traditional knowledge has received greater attention under international law over the last few decades. Indeed, as international law has grown to encompass TK, so too have domestic legislation and trade agreements (see Chapter 3).

**Convention on Biological Diversity**

The first major international agreement to recognize TK was the 1992 Convention on Biological Diversity (CBD), with its preamble noting the positive link between TK and biodiversity.11

Beyond the preamble, the CBD requires that each signatory:

> “respect, preserve, and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations, and practices.”12

As of September 2021, the CBD has 196 parties, including all UN member states except the United States.13

Ten years after the initial signing of the CBD, representatives from 17 countries, including Ecuador, assembled in Cancún to form the Group of Like-Minded Megadiverse Countries.14 The group has since advocated for international protections that favor the interests of biodiverse countries, often including respect for traditional knowledge.

The United Nations also recognized the importance of TK in its 2007 Declaration on the Rights of Indigenous Peoples (UNDRIP).15 Article 31 of the declaration states:

> “Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge, and traditional cultural expressions, as well as the manifestations of their sciences […] They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.”16

**Nagoya Protocol**

International protections for traditional knowledge increased in 2010, as a result of a supplementary agreement to the CBD—the Nagoya Protocol on Access to Genetic Resources Environment.

12 Id., art. 8(j).
14 Group of Like-Minded Megadiverse Countries, South Africa, Department of Forestry, Fisheries, and the
16 Id., art. 31.
and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

**The Nagoya Protocol offers significant latitude to countries to decide how to recognize traditional knowledge, especially on the topic of access and benefit-sharing.**

The Nagoya Protocol focused on the distribution of benefits arising from the use of genetic resources, achieving signatures and ratification from 131 parties as of September 2021. The protocol specifies that signatories may regulate access to genetic resources in their territories and may require a sharing mechanism for the benefits that arise from the exploitation of those genetic resources. These benefits may be monetary or non-monetary (e.g. sharing of research results). Finally, all parties must monitor firms within their territory to ensure compliance with other countries’ access and benefit-sharing (ABS) rules.

In 2016, a few years after the Nagoya Protocol, the Organization of American States reached agreement on the American Declaration on the Rights of Indigenous Peoples. Like the UNDRIP, the American Declaration recognized Indigenous Peoples’ rights to traditional knowledge, traditional cultural expressions, and practices related to biodiversity, seeds, medicinal plants, flora, and fauna.

With the CBD, the UNDRIP, and the American Declaration on the Rights of Indigenous Peoples recognizing TK, there is widespread understanding of the importance of traditional knowledge. The Nagoya Protocol offers significant latitude to countries to decide how to provide access to and share the benefits arising from genetic material. Chapter 3 will cover this topic, examining how different countries in Latin America implement ABS provisions in their domestic legislation and trade deals.

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20 *Id.*, art. 28.
3. TK IN LATIN AMERICA

Latin American countries generally have two options when choosing how to implement international instruments regarding traditional knowledge, such as the CBD or the Nagoya Protocol. One option is to incorporate provisions of international law directly into domestic law. For some countries, this requires implementing legislation. Another option is to include provisions from the CBD or Nagoya Protocol in trade agreements or other types of bilateral or multilateral accords.

The Nagoya Protocol provides policymakers with significant flexibility to choose an ABS system that best fits their country’s context. As such, traditional knowledge provisions differ widely across domestic laws and international agreements, even within the same region.

**TK in Domestic Legislation**

Most countries in Latin America have implemented protections for TK (see Table 1).

Brazil’s TK protections are the most comprehensive in the region. The country first addressed traditional knowledge in its 1998 Law on Copyright and Neighboring Rights. Brazilian leaders then refined the country’s guidelines regarding TK in 2001 with the Genetic Heritage and Traditional Knowledge Provisional Act.

Art 9 of the provisional act states that:

- Third parties that use TK must report the product’s origin and TK status during marketing and distribution.
- Third parties must gain free, prior, and informed consent before using TK or data that arises from traditional knowledge.
- Indigenous Peoples who hold rights to traditional knowledge must receive benefits from the economic use of TK by third parties.

Ecuador’s TK protections are based in the country’s ratification of the CBD and the Nagoya Protocol, as well as Decision 391 of the Andean Community, a trade bloc to which Ecuador belongs. In 2016, Ecuador enacted the Código Orgánico de la Economía Social de los Conocimientos, Creatividad e Innovación, commonly known as the Código Ingenios, to regulate intellectual property. The legislation includes provisions to regulate access and benefit sharing of genetic resources, with an emphasis on free, prior, and informed consent for Indigenous People.

Since the passage of the Código Ingenios, the Ministry of the Environment and Water has worked with Indigenous Peoples in Ecuador to develop community protocols for access to TK. The National Service of Intellectual Law in Ecuador is also developing a confidential registry of traditional knowledge, which can prevent third parties from attempting to patent products that are derivative of existing knowledge and do not represent a genuine innovation.

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23 See generally, Guía para la Construcción de Protocolos Comunitarios Paso a Paso, Ecuador, Ministerio del Ambiente y Agua del Ecuador, 2019.
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<thead>
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<th>Country</th>
<th>Laws or Decrees Regarding TK</th>
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<tr>
<td>Bolivia</td>
<td>Law No. 1322 of April 13, 1992, on Copyright(^25): Article 21</td>
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<td>Chile</td>
<td>Law No. 17.336 on Intellectual Property (as amended by Law No. 20.750 on the Introduction of Digital Terrestrial Television)(^26)</td>
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<td>Law No. 19.039 on Industrial Property (Consolidated Text of January 26, 2007, approved by Decree-Law No. 3)(^27): Article 3</td>
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<td>Colombia</td>
<td>Law No. 23 of January 28, 1982, on Copyright(^28)</td>
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<tr>
<td>Costa Rica</td>
<td>Law No. 7788 of April 30, 1998, on Biodiversity (as amended by Law No. 8686 of November 21, 2008)(^29)</td>
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<tr>
<td>Cuba</td>
<td>Decree-Law No. 290 of November 20, 2011, on Inventions and Industrial Designs(^30)</td>
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<td>Decree-Law No. 291 of November 20, 2011, on the Protection of Plant Varieties(^31)</td>
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<tr>
<td>Dominican</td>
<td>Law No. 65-00 on Copyright(^32)</td>
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<td>Republic</td>
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<tr>
<td>Ecuador</td>
<td>Código Ingenios of December 9, 2016(^33)</td>
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<tr>
<td>Guatemala</td>
<td>Law on Copyright and Related Rights (Decree No. 33-98, as amended up to Decree No. 11-2006 of the Congress of the Republic)(^34)</td>
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<td>Decreto Número 26-97: Ley para la protección del patrimonio cultural de la nación(^35)</td>
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<td></td>
<td>Decreto Número 25-2006(^36)</td>
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\(^24\) This table is a representative list of domestic legislation regarding traditional knowledge in Latin America, but it is not exhaustive.


\(^26\) [https://www.wipo.int/tk/en/databases/tklaws/articles/article_0100.html](https://www.wipo.int/tk/en/databases/tklaws/articles/article_0100.html)


\(^33\) [https://www.wipo.int/edocs/lexdocs/laws/es/ec/ec075es.pdf](https://www.wipo.int/edocs/lexdocs/laws/es/ec/ec075es.pdf)

\(^34\) [https://www.wipo.int/tk/en/databases/tklaws/articles/article_0163.html](https://www.wipo.int/tk/en/databases/tklaws/articles/article_0163.html)

\(^35\) [https://www.wipo.int/edocs/lexdocs/laws/es/gt/gt032es.pdf](https://www.wipo.int/edocs/lexdocs/laws/es/gt/gt032es.pdf)

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<td>Law on Copyright and Related Rights (Decree No. 4-99-E, as amended by Decree No. 16-2006)</td>
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<td>Mexico</td>
<td>Federal Law on Copyright: Articles 157-160</td>
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<td>Nicaragua</td>
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<td>Law No. 27811 on the Introduction of the Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources Law No. 28216 on the Protection of Access to Peruvian Biological Diversity and the Collective Knowledge of Indigenous Peoples</td>
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**TK in International Trade**

While most trade agreements do not include provisions related to genetic resources, Latin America has led the way in incorporating these provisions, and over time they have become more common.

Between 1947 and 2015, the Trade and Environment Database (TREND) reported 684 trade agreements, of which 50 included at least one provision related to genetic resources. The first of these clauses appeared in the early 2000s and largely involved countries in Latin America. Of the six countries that signed the most trade agreements mentioning genetic material prior to 2015, four were in Latin America (Peru, Colombia, Costa Rica, and Panama).

The European Union has also been a key advocate of provisions related to genetic material and TK in trade agreements. In 2013, Peru and Colombia signed a comprehensive trade agreement with the EU, which Ecuador joined in 2017. The agreement

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41 http://www.farmersrights.org/pdf/americas/Panama/Panama-tk00%2001.pdf
46 Morin and Gauquelin, *supra* note 4, at 1.
47 *Id.*, at 5.
included several clauses regarding traditional knowledge.

The United States signed five trade agreements acknowledging genetic material during the same period, falling behind the European Union, China, and several countries in Latin America, but ahead of the rest of the world.48

Of the six countries that signed the most trade agreements mentioning genetic material prior to 2015, four were in Latin America (Peru, Colombia, Costa Rica, and Panama).

During the negotiation of the United States-Mexico-Canada Agreement (USMCA), Canadian negotiators proposed a chapter on trade and Indigenous Peoples, which would have included language referring to the UNDRIP and the protection of traditional Indigenous knowledge. While Mexican negotiators were reportedly open to the proposed section, it failed to gain traction with their U.S. counterparts. The final agreement does not explicitly refer to the UNDRIP. However, it does include several references to traditional knowledge (see Table 2).49

The final text of the USMCA provides duty-free treatment for handmade goods from Indigenous communities, encourages investment in Indigenous communities, and recognizes Indigenous Peoples’ roles in the preservation of the environment, sustainable fisheries, forestry, and biodiversity.

Given that the previous chapters have detailed the role that TK plays in international and domestic law, the final chapter of this report details some policy options that negotiators might consider as they evaluate the U.S.-Ecuador trade relationship.

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<tr>
<td>Chapter 6 (Textiles)</td>
<td>Article 6.2: Handmade, Traditional Folkloric, or Indigenous Handicraft Goods</td>
<td>Indigenous/traditionally made textiles and handicraft goods are eligible for duty-free treatment.</td>
</tr>
<tr>
<td>Chapter 20 (Intellectual Property)</td>
<td>The chapter contains no references to “traditional knowledge” or any synonymous concept.</td>
<td></td>
</tr>
<tr>
<td>Chapter 24 (Environment)</td>
<td>Article 24.15: Trade and Biodiversity</td>
<td>“The Parties recognize the importance of respecting, preserving, and maintaining knowledge and practices of indigenous peoples and local communities embodying traditional lifestyles that contribute to the conservation and sustainable use of biological diversity.”</td>
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48 Id., at 2.

| Chapter 32 (Exceptions and General Provisions) | Article 32.5: Indigenous Peoples Rights | “Provided that such measures are not used as a means of arbitrary or unjustified discrimination against persons of the other Parties or as a disguised restriction on trade in goods, services, and investment, this Agreement does not preclude a Party from adopting or maintaining a measure it deems necessary to fulfill its legal obligations to indigenous peoples.” |
4. RECOMMENDATIONS

Traditional knowledge represents an important element in a modern trade agreement. Both Ecuador and the United States can benefit by addressing the topic during any future negotiation. In this section, we present recommendations to stakeholders in both countries.

1. **Policymakers should consider trade negotiations as a forum to discuss both countries’ laws on traditional knowledge.** Discussions between the United States and Ecuador could result in TK-related provisions in a trade agreement, but they could also result in changes to TK-related law at the domestic level.

2. **Ecuadorean policymakers should place a particular emphasis on traditional knowledge.** As a megadiverse country, Ecuador has an interest in maximizing the benefits derived from its genetic resources and ensuring that some of those benefits are shared domestically. Ecuador’s sizable population of Indigenous Peoples only increases the importance of properly addressing TK.

3. **A potential trade agreement between the United States and Ecuador must emphasize opportunities to maximize the benefits of trade for holders of traditional knowledge.** While defensive protections for holders of traditional knowledge may have a role in trade agreements and domestic legislation, policymakers must also account for the benefits of trade for Indigenous Peoples.

4. **The United States should consider enforcing access and benefit sharing (ABS) provisions on U.S. firms that operate in Ecuador.** The 2010 Nagoya Protocol allows signatories to regulate how third parties access genetic resources in their territory and how they share the benefits derived from those resources. It also requires signatories to enforce these ABS provisions on their own firms. For example, if a German firm operates in Ecuador, the Ecuadorean government can regulate the firm’s access and benefit sharing related to genetic resources, and the German government must ensure that the firm complies with Ecuador’s regulations. While the U.S. is not party to the Nagoya Protocol, the country should consider enforcing compliance, and Ecuadorean negotiators may consider discussing the topic during trade discussions.