

UNIVERSIDAD AUTÓNOMA DE SAN LUIS POTOSÍ
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AND
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**SAFEGUARDING INDIGENOUS TRADITIONAL KNOWLEDGE. THE SUSTAINABLE
COMMERCIALIZATION OF MEDICINAL PLANTS THROUGH BIOTRADE**

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Abstract

Based on the idea of sustainable development, the BioTrade principles and criteria (P&C), based on the idea of sustainable development, have been the essential core guiding the implementation of BioTrade activities since their inception by UNCTAD in 2007. However, after identifying that BioTrade of medicinal plants causes negative impacts on the traditional knowledge related to these plants, the P&C were evaluated in light of the most relevant international agreements that contribute to the safeguarding of this knowledge. The result obtained from the assessment showed that the P&C present many gaps that prevent evaluating the real impact of trade on the traditional knowledge of medicinal plants in Indigenous and local communities. Therefore, in the same framework of the current P&C, the main recommendations contained in the international agreements and the suggestions of specialists in the field have been gathered to create a BioTrade standard that contributes to safeguarding traditional medicinal plant knowledge within a commercial context in any BioTrade initiative where the commercialized product is a sacred or native plant with traditional and cultural value for a community.

Keywords: traditional knowledge • BioTrade • medicinal plants • sacred plants • Indigenous communities

Resumen

Los principios y criterios del BioComercio (P&C), basados en la idea del desarrollo sostenible, han sido el núcleo esencial que guía la implementación de las actividades del BioComercio desde que se establecieron en 2007 por la UNCTAD. Sin embargo, tras identificar que el BioComercio de plantas medicinales causa impactos negativos en el conocimiento tradicional relacionado con estas plantas, los P&C fueron evaluados a la luz de los acuerdos internacionales más relevantes que contribuyen a la salvaguarda de este conocimiento. El resultado obtenido de la evaluación determinó que los P&C presentan muchos vacíos que impiden evaluar el impacto real del comercio sobre el conocimiento tradicional de las plantas medicinales en las comunidades Indígenas y locales. Por lo tanto, en el mismo marco de los actuales P&C, se han recogido las principales recomendaciones contenidas en los acuerdos internacionales y las sugerencias de los especialistas en la materia para crear un

estándar de BioComercio que contribuya a salvaguardar el conocimiento tradicional de las plantas medicinales dentro de un contexto comercial en cualquier iniciativa donde el producto comercializado sea una planta sagrada o nativa que implique un valor tradicional y cultural para una comunidad determinada.

Palabras clave: conocimiento tradicional • BioComercio • plantas medicinales • plantas sagradas • comunidades Indígenas

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Introduction

Over time, the safeguarding of traditional knowledge has increased worldwide. It has been recognized that this body of knowledge plays a vital role in the development of societies. International institutions have challenged establishing agreements and policies that encourage its protection and promote its transmission (United Nations Conference on Trade and Development, 2004).

Therefore, it is considered essential that these international agreements and guidelines are respected at the national level in the diverse activities focused on the economic growth of Indigenous communities in which traditional knowledge could be endangered (United Nations, 1992; UNESCO, 2005; Secretariat of the Convention on Biological Diversity, 2010; World Intellectual Property Organization, 2013).

This research is based on the part of the traditional knowledge related to medicinal plants, or as it will be called here, "Traditional Medicinal Plant Knowledge" (TMPK) (Sajem & Gosai, 2006; Salazar Granara, 2017)

Several studies relate the commercial activity of medicinal plants with the possible adverse effects on the TMPK (Baquero, et al., 2009; Bussmann & Sharon, 2015; Bravo, 2015; González, et al., 2018). It is imperative to regulate the process of cultivation, management, and trade of such plants, to provide economic growth and, at the same time, preserve the intangible heritage of local and Indigenous communities.

Within this context, the United Nations Conference on Trade and Development (UNCTAD) proposed the BioTrade Initiative to contribute to the sustainable use of biological resources, including medicinal plants, and the traditional knowledge related to them (UNCTAD, 2007).

Although the BioTrade Initiative has made a significant input in assessing commercial activity in local communities worldwide regarding environmental, economic, and social sustainability, the importance given to the traditional knowledge that underpins natural resource management and traditional medicine in communities is still not sufficient (United Nations Conference on Trade and Development, 2020).

By reviewing the example of the assessment of BioTrade of guayusa, a medicinal plant from Ecuador with related traditional knowledge, it became evident the current BioTrade principles and criteria do not enable a profound evaluation of the potential impacts that the commercialization of medicinal plants could have on the TMPK (Prefectura del Napo, 2017). This scenario permits us to infer that the BioTrade Initiative's framework is not fully aligned with international agreements supporting the safeguarding of traditional knowledge during the trade process.

Therefore, an in-depth analysis of the policies that support TMPK safeguarding is presented below, followed by a review of BioTrade principles and criteria in the light of these policies. Finally, a proposal will be presented for a BioTrade standard that considers the international recommendations found in the policies and some others obtained from experts in the field.

Objectives

➤ General

To determine how BioTrade principles and criteria can safeguard Indigenous traditional knowledge linked to medicinal plants within a sustainable commercial context.

➤ Specific:

1. To identify the existing international agreements and their principles, objectives, or policies that support the safeguarding of *traditional medicinal plant knowledge* within a BioTrade context.

2. To recognize the BioTrade principles and criteria that are aligned with the safeguarding of *traditional medicinal plant knowledge*.
3. To develop a BioTrade Standard that supports the safeguarding of *traditional medicinal plant knowledge*.

Thus, the following research has five chapters. The first chapter is the reference framework of the study in which the conceptual framework and the antecedents that support the justification are developed. The second chapter is dedicated to detailing the methodology used to collect the necessary information and analyze the obtained results. The third chapter presents the results of the research with their respective analysis and explanation. The fourth chapter is the proposal of a BioTrade standard based on the results obtained, which serves as a recommendation for the study problem. Finally, the fifth and last chapter develops the general discussion of the research study and represents the basis for the conclusions of this report.

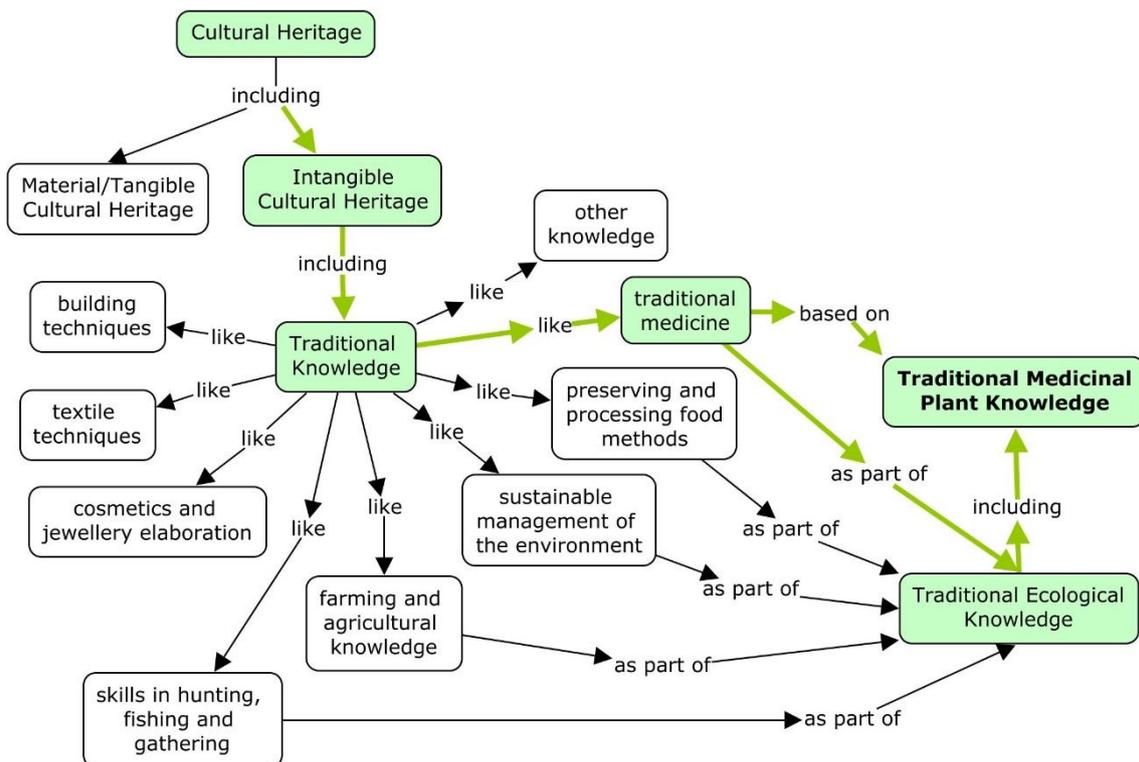
1. THEORETICAL FRAMEWORK

The following section explains essential definitions of relevant concepts to improve the understanding of this study (Lederman & Lederman, 2015). Thus, concepts are presented, which explain the terms that contain the core concept of this study: the traditional medicinal plant knowledge. The concepts developed below are presented from the most general to the most specific to show the relationship among them and how they influence each other. In addition, a second section of this chapter will present and discuss the concept of BioTrade, its principles and criteria.

1.1 Traditional Medicinal Plant Knowledge as Cultural Heritage

According to the Convention for the Safeguarding of Intangible Cultural Heritage (2003), Traditional Medicinal Plant Knowledge (TMPK), being part of Traditional Knowledge (TK), constitutes an Intangible Cultural Heritage (ICH) of communities. Figure 1 represents the concepts and definitions subsequently developed and their interconnections. The arrows in green represent the logical sequence of the concepts explained below.

Figure 1: Theoretical framework explanation



Source: Based on Arjona (1986), Vecco (2010), UNESCO (2003), Berkes (1993), World Health Organization (2019).

1.1.1 Cultural Heritage

According to UNESCO, "*cultural heritage* is, in its broadest sense, both a product and a process, which provides societies with a wealth of resources that are inherited from the past, created in the present and bestowed for the benefit of future generations" (UNESCO, 2014, p. 130).

When years ago, the term *Cultural Heritage (CH)* seemed to be vague due to the inferred meaning imported from anthropology or archaeology without an adequately established theoretical background (Blake, 2000), over time, it has acquired different definitions based on the meaning of *heritage* and *culture* separately, and on their different applications (Rodríguez Temiño, 2010). The concept of *heritage* has acquired a polysemic character; however, when combined with the term *cultural*, it refers to "everything that is socially considered worthy of preservation regardless of its utilitarian interest"¹ (Prats, 1998, p. 115, my translation).

Depending on the context and scientific discipline, the definition of cultural heritage can therefore vary. According to Díaz Cabeza, the primary discipline in this is history since it provides a particular cultural value to the resources and makes them an asset for society (Díaz Cabeza, 2010).

In 1982, the Mexico City Declaration on Cultural Policies adopted by UNESCO mentioned that "the cultural heritage of a people includes the works of its artists, architects, musicians, writers and scientists and also the work of anonymous artists, expressions of the people's spirituality, and the body of values which give meaning to life" (UNESCO, 1982, p. 3).

Therefore, the cultural, material, spiritual, scientific, historical, and artistic value that a community attributes to resources, defining them as distinctive elements, turns these resources into cultural goods (Arjona, 1986). Consequently, resources become a heritage; since "the sum of the cultural goods accumulated voluntarily by a community constitutes its cultural heritage, and the most immediate social

¹ "Todo aquello que se considera digno de conservación independientemente de su interés utilitario" (Prats, 1998, p. 115).

consequence of that is the identification of this group of people with this heterogeneous element ensemble"² (Arjona, 1986, p. 20, my translation).

Some authors consider that cultural heritage is an invention and, at the same time, a social construction, two features that could be contradictory but that, in this particular case, complement each other and comprise the identity of any social group (Prats, 1998; Canclini García, 1999). Cultural heritage construction (and ethnic identity) is regularly based on ideologies, political practices, and, as said before, different scientific disciplines (Zamora Acosta, 2011). It is not a single solid mass. Rather, it is composed of relevant individual tangible or intangible interconnected entities that can be more or less distinguished and described from one another (González & Parceró, 2011).

The growing international relevance of cultural heritage instruments, the widening scope of the term, and the areas in which it is used require a feasible definition of cultural heritage's nature (Blake, 2000). However, over time, this process revealed the many complex issues regarding the nature of cultural heritage and the construction of cultural identity, which would lead to the creation of future international instruments without having arrived at a clear understanding of its meaning (Blake, 2000). For instance, UNESCO (2003) established an extended definition, yet, instead of explaining the intrinsic meaning of what cultural heritage means, it categorizes the several entities individually and mentions:

Cultural Heritage refers to a) monuments: architectural works, works of monumental sculpture and painting, elements or structures of an archaeological nature, inscriptions, cave dwellings and combinations of features which are of outstanding value from the point of view of history, art or science; b) groups of buildings: groups of separate or connected buildings, which because of their architecture, their homogeneity or their place in the landscape, are of outstanding value from the point of view of history, art or science; c) sites: works of man or the combined works of nature and man, and areas including archaeological sites, which are of outstanding value from

² "la suma de los bienes culturales acumulados de modo voluntario por una comunidad conforma su patrimonio cultural, y que la consecuencia social inmediata de ello es la identificación de este conjunto heterogéneo con ese grupo de hombres" (Arjona, 1986, p. 20).

the historical, aesthetic, ethnological or anthropological point of view.
(UNESCO, 2014, p. 134)

It is crucial to understand cultural heritage as the result of the collective memory, which reflects the relationship existing between the relevant past and the present through materializations (tangible) or shared experiences (intangible) with others, and which in turn generates a sense of belonging to a group and a place (Arévalo, 2016). Therefore, cultural heritage is considered a social construction that shapes the collective identity of a group and takes the past's meaning to give significance to the present since it is dynamic and active and therefore subject to change (Hernández, 2003).

Thus, cultural heritage must be viewed as a valuable resource and a living process, not as immutable. Cultural assets, tangible or intangible, are not remnants of a passing time to be preserved in a supposedly perfect model; instead, they are continually auto-recreating, feeding on meanings and manifestations that people remember and recognize as their own (Arévalo, 2016).

Within the context of what is meant by cultural heritage, it is evident that its intangible part is present in every aspect of cultural property since it constitutes the basis of identity, creativity, and cultural diversity, including several expressions of spirituality and ideology (UNESCO, 1982). Also, it represents the historical memory and cultural symbol of any community or social group (Díaz Cabeza, 2009). Vecco (2010) affirms that within the concept of cultural heritage, two dimensions must be considered, perceiving it from both a vertical (logical and objective) and horizontal (creative and non-objective) point of view and consequently, opening the doors to subjectivity which allows understanding the importance of specific intangible goods and elements of a site as a symbol of identity and tradition. In other words, in order to understand the real meaning of cultural heritage, it is crucial to analyse its concept (vertical point of view) as well as all its elements and the interactions between them (horizontal point of view) in indigenous communities.

Hence, it is essential to understand that, although there is a conceptual division between tangible and intangible cultural heritage, this separation only serves analytical purposes; the two are often difficult to distinguish from each other as all

cultural expressions have material and immaterial aspects that are intimately intertwined (Monsalve, 2008). As such, they complement each other, even though the management and treatment are different for each one; for instance, in terms of authenticity, the material cultural heritage is more straightforward to assess than the intangible cultural heritage (Monsalve, 2008). The latter is constituted by several practices and processes that are transmitted among generations, which explains its fragility facing globalization processes and social transformation (UNESCO, 2003).

1.1.2 Intangible Cultural Heritage

Intangible Cultural Heritage (ICH) was born to shape, among societies, the capacity to recognize the past for building the future as part of a whole where the perceptions, communication, and reasoning could act together. Therefore, it is possible to appreciate the different forms of art, rituals, social structures, and collaborative practices and influence politics aimed to achieve its safeguarding (Topete & Amescua, 2013).

Jokilehto (2006) defined intangible cultural heritage as the conception of the cultural identity of a group through its multiple manifestations such as music, traditions, or any intangible element, which represents the essence of its history and culture. These expressions usually constitute part of a spiritual sense of meaning (Kurin, 2004).

Similarly, Lenzerini (2011) refers to intangible cultural heritage as the elements associated with a group or society that constitute an essential part of its identity and diversity; thus, the intangible component is a product of the tradition, knowledge, and dynamism of a group, which shows important aspects of its authenticity (Lenzerini, 2011). Both definitions seem to be in line with the one proposed by the Convention for the Safeguarding of Intangible Cultural Heritage (2003), which says:

The 'Intangible Cultural Heritage' means the practices, representations, expressions, knowledge, skills – as well as the instruments, objects, artifacts and cultural spaces associated therewith – that communities, groups and, in some cases, individuals recognize as part of their cultural heritage. This intangible cultural heritage, transmitted from generation to generation, is constantly recreated by communities and groups in response to their

environment, their interaction with nature and their history, and provides them with a sense of identity and continuity, thus promoting respect for cultural diversity and human creativity. (UNESCO, 2003, p. 5)

Thus, intangible cultural heritage gathers a range of manifestations that only have in common the fact that they cannot be reduced to the tangible without necessarily resembling each other, but that must be embodied in material manifestations that support it (Ministerio de Cultura de España, 2009). Cultures worldwide are in constant change since those who practice them need to adapt to new circumstances creating, combining, and reinventing identities (Topete & Amescua, 2013). Thus, intangible cultural heritage is understood as a set of manifestations that come from the collective memory of a given social group and which could get a material form by incorporating places, objects, and representations that are characteristic of a particular culture (Topete & Amescua, 2013).

After the Convention for the Safeguarding of the Intangible Cultural Heritage (2003), UNESCO determined the following as the four principal characteristics of intangible cultural heritage:

- a. "It is traditional, contemporary, and living since it is about past inherited traditions and contemporary particular rural and urban practices of each cultural group;
 - b. It is inclusive since it contributes to social cohesion, encouraging the identity that allows individuals to feel that they are part of a social group or community;
 - c. It is representative since it is particular and typical of a cultural group and depends on its members' intergenerational transmission;
 - d. It is community-based since it only exists if it is recognized by communities, groups, and individuals that created it, transmitted it, and continue doing this."
- (UNESCO, 2003, pp. 4, 5)

The fact that the traditional repository of intangible cultural heritage is the human mind, and its transmission is oral, is considered to be a significant risk for its safeguarding process (Irigaray Soto, 2013). Consequently, the urgency for safeguarding intangible cultural heritage comes from the speed in the process of loss, transformation, and reinvention of cultural practices and representations

provoked by globalization and environmental changes worldwide (Topete & Amescua, 2013).

In 2003, intending to integrate the different manifestations and expressions of intangible cultural heritage worldwide, UNESCO proposed a framework composed of five domains, each with its categories, which can be adapted or even modified depending on the cultural context of a particular country (UNESCO, 2003). Those domains are:

- a. Oral traditions and expressions
- b. Performing arts
- c. Social practices, rituals, and festive events
- d. Knowledge and practices concerning nature and the universe
- e. Traditional Craftsmanship

The focus of this study will be on the fourth domain since it comprises different categories. One of them is traditional knowledge which is expressed in different ways such as traditional ecological knowledge, traditional healing systems, rituals, beliefs, initiatory rites, cosmologies, shamanism, possession rites, festivals, languages, and others (UNESCO, 2003).

1.1.3 Traditional Knowledge

The term *traditional knowledge (TK)* "is used in a narrower sense to refer to knowledge as such, in particular, the knowledge resulting from intellectual activity in a traditional context, which includes know-how, practices, skills, and innovations" (World Intellectual Property Organization, 2013, p. 4). According to UNESCO, "these sophisticated sets of understandings, interpretations, and meanings are part and parcel of a cultural complex that encompasses language, naming and classification systems, resource use practices, ritual, spirituality and worldviews." (UNESCO & Internal Council of Science, 2002, p. 9)

The Model Law for the Protection of Traditional Knowledge and Expressions of Culture (2002) explains the concept of traditional knowledge with four characteristics (Secretariat of the Pacific Community, Pacific Islands Forum Secretariat, and UNESCO Pacific Regional, 2002):

- a. "It is or has been created, acquired or inspired for traditional, economic, spiritual, ritual, narrative, decorative or recreational purposes;
- b. It is or has been transmitted from generation to generation;
- c. It is regarded as pertaining to a particular traditional group, clan, or community of people;
- d. It is collectively originated and held." (Secretariat of the Pacific Community, Pacific Islands Forum Secretariat, and UNESCO Pacific Regional, 2002, p. 4)

Thus, traditional knowledge is the wisdom that belongs to an ethnic group or community. Generally, it is characterized by its collective intellectual creation, expressed in a particular language and modified over the years; it is indeed the result of the relationship between the people and the original territory to which they consider themselves attached (Cañas, et al., 2008). According to the Indigenous conception, it cannot be individually appropriated unless it is a type of knowledge reserved only for "initiated" people since it is built up with the contribution of ancestors and all community members and is passed on orally to future generations (Unión Mundial para la Naturaleza, 2006). Traditional knowledge changes over time according to the community's needs, and the way it is acquired in each culture is what gives it the character of being traditional, not its antiquity in time (Unión Mundial para la Naturaleza, 2006). Consequently, traditional knowledge tends to be community-owned in forms of beliefs, rituals, languages, stories, proverbs, artistic expressions, songs, cultural manifestations, customary laws, agricultural practices (including the development of plant species and animal breeds), traditional know-how relating to textile and handicraft-making, architecture, fishery, forestry management and health (United Nations, 2005).

1.1.4 Traditional Ecological Knowledge

According to the traditional knowledge definitions reviewed, one of its components is the knowledge related to the environment and biological resources management, called *Traditional Ecological Knowledge (TEK)*.

Despite the novelty and speed in the recent advances of scientific genetics studies, it is crucial to recognize that gaining knowledge about properties and benefits from biological resources is not a modern phenomenon. For centuries, native

communities worldwide have learned, used, and transferred their TEK about local biodiversity management for several purposes that range from nourishment, medicine, and clothes, to the development of abilities and practices related to agriculture and animal husbandry. Thus, within the context of access to and partake in these natural benefits, TEK refers to the wisdom, innovations, and practices of a community related to genetic resources, which have been developed through their own experiences, cultures, and local environments (Secretaria del Convenio sobre la Diversidad Biológica, 2011).

According to Berkes (1993), TEK seemed not to have a universally accepted definition in the literature since he considered both terms, *traditional* and *ecological knowledge*, to be ambiguous. However, based on various meanings and elements brought out in some studies related to this subject, Berkes (1993) established the following definition of TEK:

TEK is a cumulative body of knowledge and beliefs, handed down through generations by cultural transmission, about the relationship of living beings (including humans) with one another and with their environment. Further, TEK is an attribute of societies with historical continuity in resource use practices; by and large, these are non-industrial or less technologically advanced societies, many of them indigenous or tribal (Berkes, 1993, p. 3).

Berkes, Colding, and Folke (2000) stated that TEK is a management structure of the environment's processes and functions that focuses on the responsible and assisted management of the ecological and social system, and which is characterized by being transmitted from generation to generation, helping the coexistence between the environment and the cultural identity (Berkes, et al., 2000). This definition is complemented by Folke (2004), affirming that TEK is a system of knowledge related to the environment, which conceives activities of natural resources management for supporting the sustainability of a group (Folke, 2004). Similarly, Houde (2007) mentions that TEK is a grouping of knowledge about the environment, including the management of resources of the ecological and social system, as a product of a group's culture and identity, and is composed of knowledge imparted and learned over time.

In 2008, Pochettino and Lema established a TEK definition based on the one stated by Berkes in 1993. They maintain that TEK is a cumulative body of knowledge, practices, and beliefs about the relationships between human beings and the plant components of their environment; a body that is modified from processes of selection and transmission of culture among generations and could be affected by the temporal variable (Pochettino & Lema, 2008). In the same way, to other authors, TEK of Indigenous groups is principally qualitative, intuitive, holistic, moral, and spiritual and is based on an empiric observation and facts accumulation that comes from the daily use of natural resources. In their view, this implies a close relationship between society and the environment, which could be the basis of sustainability fomenting a shared worldview (Millán, et al., 2016).

One of the current definitions focuses on the importance of TEK for cultural communities' identity preservation. According to the Mexican National Commission for Biodiversity Knowledge and Use (*Comisión Nacional para el Conocimiento y Uso de la Biodiversidad*, CONABIO):

TEK is the knowledge and practices of indigenous and local communities that are associated with biological resources and integrate the community identity. This knowledge is the base of the relationship with the land and allows the community to satisfy their physical necessities such as food, medicines, construction materials, and also their spiritual and cultural requirements to carry out the ceremonies and rituals linked with their cosmovision. Drawing from their way to understand the world and life (cosmovision), they use the biological resources, identify and conserve them (CONABIO-GIZ, 2017, p. 6, my translation).³

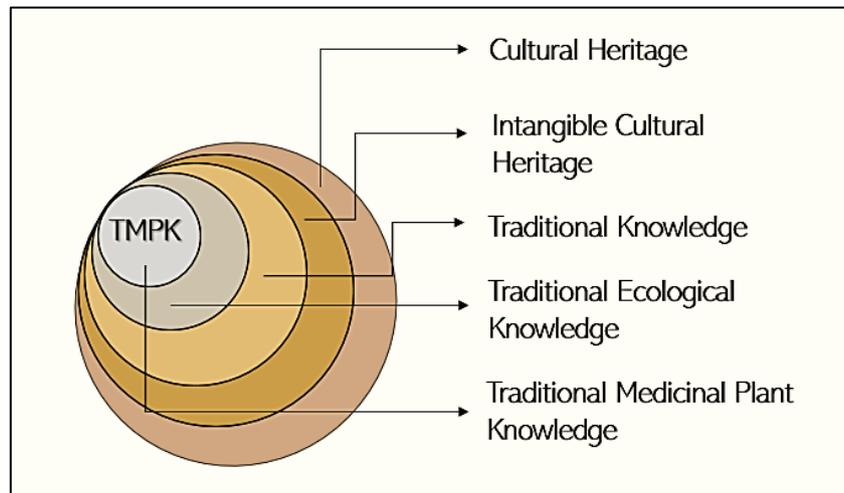
TEK transmission among generations is a complex but fundamental process that is deeply embedded within the socio-cultural structure. This extraordinary complexity stems from the empiric characteristics of the communities that influence this process rather than the biological or physical environment. The curriculum of knowledge

³ “Son los saberes y prácticas de comunidades indígenas y locales asociados a los recursos biológicos e integran parte de la identidad de la comunidad. Estos conocimientos son la base de la relación con el territorio y les permiten satisfacer necesidades como la obtención de alimentos, medicinas, materiales para la construcción, y espirituales o culturales, para la realización de ceremonias o ritos vinculados con su cosmovisión. A partir de su forma de entender el mundo y la vida (cosmovisión), usan los recursos biológicos, los identifican y los conservan”. (CONABIO-GIZ, 2017, p. 6)

transmission is culture itself, which means that it is not random but has a structure, even when their acquisition methods have been primarily empiric or informal, such as individual observation and imitation (Ruddle, 1993).

As explained before, TEK is a far-reaching concept that includes knowledge about the natural resources surrounding a community. For a clearer understanding of TEK, experts in anthropology have categorized this traditional knowledge according to its use in Indigenous or local communities (Millán, et al., 2016). One of these categories is ethnomedicine, which is the science that studies the knowledge related to traditional medicine coming from plants, or in other words, the Traditional Medicinal Plant Knowledge (TMPK) (see Figure 2) (Salazar Granara, 2017).

Figure 2: TMPK as Intangible Cultural Heritage



Source: Own elaboration.

1.1.5 Traditional Medicinal Plant Knowledge

Traditional medicine is cataloged as an essential component of the different cultures' intangible heritage since its information, resources, and practices lead communities to wellbeing and development by preserving cultural and ethnic identity (Jiménez, 2017). Thus, the World Health Organization defines traditional medicine as "the total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness" (World Health Organization, 2019, p. 44).

Thus, traditional medicine is based on cosmological and metaphysical principles expressed in empirical applications, mainly using plant, animal, or mineral resources, although traditional herbal medicine is the best known worldwide (Vadi, 2007) since plants provide healthcare for up to 80% of the world's population (Saslis-Lagoudakis, et al., 2014).

Sajem and Gosai (2006) mention that TMPK is the set of cultural practices focused on using plants from their medicinal folklore to cure various diseases. One of the main ethnobotanical customs is the use of flora and fauna to acquire their properties to benefit people's health (Sajem & Gosai, 2006). This kind of traditional knowledge is established within their cultural-historical process related to cosmology cultural, medicinal, and botanical representation (Sajem & Gosai, 2006). Likewise, other authors mention that TMPK is the traditional use of plants with healing qualities, which are the product of empirical ethnopharmacological knowledge development. This knowledge constitutes an essential part of the practices and cultural expressions of an ethnic group or a specific environment, which is frequently used in pursuit of flora and fauna sustainability (Kunwar, et al., 2013).

Some authors refer to TMPK as the product of the interaction of the subject with the environment, which is understood as the domain of the healing and medicinal properties offered by elements of the environment, considered necessary within its vital process (Gwyneira, et al., 2018). It is called traditional since it is part of the living of the group, its food, its dynamism, and psychological imaginary, representing significant meanings and values, and being part of stories, ceremonies, and other cultural expressions that allow the dissemination of this ecological knowledge, as well as the cultural responsibility for adaptation and biodiversity protection (Gwyneira, et al., 2018). Moreover, other authors mention that TMPK is the understanding and management of agro-systems in the ecological and pharmacological context, in which the medicinal agro-diversity properties are the fundamental basis to ensure the welfare of human beings (Caballero, et al., 2019).

Balasubramanian (1997) mentions that TMPK is transmitted orally among generations as a non-encoded system, primarily based on beliefs, norms, and traditional practices grounded in past experiences of tests, mistakes, successes, and failures in a domestic ambit. That is why they can be called "community's health

culture" (Correa, 2002). However, the level of divulgation of TMPK is different in each community; in some cases, this knowledge is developed by determined individuals without the intervention of any other community member ("individual knowledge"). This is the case of "curanderos" (healers) or "shamanes", selected members that have specific characteristics of wisdom and experience, who also have maintained and maintain most knowledge in secret in specialized areas, such as bone healing, the birth process, and others (Correa, 2002). In other cases, the "curanderos" share some of their knowledge in medical practices, rituals, and ceremonies with few community members, even when they do not realize they are sharing. This sharing is called "distributed knowledge" (Correa, 2002); thus, when a community member is sick, he/she should visit those knowledgeable people and ask for help in order to have access to medicines (Giday, et al., 2009). Moreover, there is also a "common knowledge" distributed to all community members among generations, more often female and elderly people (Correa, 2002). The acquisition of this knowledge is possible through practice and observation and includes the history, origin, names, colors, shapes, uses, and procedures of medicinal plants (CONABIO-GIZ, 2017).

Within this context, studies confirm that in some communities, TMPK transmission occurs in family gardens, which are the spaces where knowledge acquirement is more effective since the medicinal plants used by the family can be found there. Older family members (usually grandparents and parents) are in charge of transmitting their knowledge about uses, sowing, fertilization, irrigation, harvest, and medicine preparation to the younger individuals (Gómez, 2012). Some authors also refer to women as knowledge holders since they are responsible for family care (Sánchez, et al., 2016). Then the question arises: what might happen to TMPK when the community dynamics are influenced by globalizing activities such as trade in medicinal plants?

1.2 Antecedents: Traditional Medicinal Plant Knowledge in a BioTrade context

As mentioned in the previous section, traditional ecological knowledge is linked with biodiversity management and conservation since, in Indigenous and local communities, nature is revered and respected and not seen as a mere productive source (Toledo, 1999).

Over time, Indigenous societies have subsisted by appropriating a wide range of biological resources in their immediate vicinity; thus, the Indigenous peoples' survival is founded more on exchanges with nature than on trade with markets (Salmón, 2000). However, globalization and free-market dynamics have turned biodiversity and the traditional knowledge related to it into a product whose commercialization can generate economic income and improve Indigenous communities' quality of life (Toledo, 1999).

Medicinal plants and their role as biological resources have become a significant commercial product, especially in developing countries. Medicinal plants play a beneficial and affordable role in healthcare worldwide and are still an essential source of preventive and curative medicines (Srivastava, et al., 1996). Therefore, in recent decades, the medicinal plants' trade is already an essential activity to the global economy, which demand is increasing over time even in industrialized countries; however, this rising global interest has meant that the collection and sale of these plants are not always carried out in a regulated manner (Edwards, 1996; Mhame, 2004). Consequently, the uncontrolled commercial activity of one or various medicinal plants could directly affect the TMPK depending on the communities' social, cultural, political, and economic circumstances.

On the one hand, commercialization of medicinal plants can support TMPK conservation when it occurs in local markets, as is the case in some native communities in Brazil (South America) and Dominica (Caribbean), where the small markets, without any external or private interest, help people to maintain their traditions about healing (Monteiro, et al., 2010; Quinlan & Quinlan, 2007). Similarly, research carried out in communities of Tabasco, Mexico, found that the local commercial activity of medicinal plants (more than 100 species) is a result of the conservation of TMPK and its cultural revaluation because of its importance for community health, which drives people to continue growing these plants in their homes (Magaña, et al., 2010).

On the other hand, commercialization as part of the globalization process can cause negative impacts on TMPK. One of these impacts is the decontextualization of this knowledge. Several Indigenous researchers have argued that the scientific perspective of traditional ecological knowledge distorts the very spirit of this

knowledge (Reyes-García, 2009). An example of how this can even end up having negative consequences for the bearers of such knowledge is the case of ayahuasca. Ayahuasca, a tea made from *Banisteriopsis caapi* and *Psychotria viridis*, two plants native to the Amazon, has traditionally been used by native populations of Brazil, Ecuador, and Peru for spiritual uses. In the twentieth century, the use and trade of ayahuasca as a hallucinogenic drug became popular among non-Indigenous populations, leading to drug control policies restricting its use which infringed on the religious freedom of Indigenous peoples (Reyes-García, 2009).

Some research shows the loss of TMPK caused by the extinction of medicinal plants due to their indiscriminate extraction for commercialization. For instance, in Venezuela, in the period between 1991 and 2002, it was necessary to invest 11 million dollars to import medicinal plants (*Matricaria recutita*, *Thea sinensis*, *Cassia senna*, *Salvia officinalis*) since some native medicinal species had extinguished after trade activities and illegal commercialization (Baquero, et al., 2009).

Moreover, some studies argue that such knowledge is lost when Indigenous groups or rural communities are incorporated into the free market economy. This argument is based on the idea that integration into the market economy leads to changes, such as new productive activities, that reduce the time people spend in nature, which in turn interferes with the transmission of cultural knowledge (Reyes-García, 2009). For instance, in Perú, the commerce of medicinal plants (more than 500 species in the northern part of the country) is an activity that threatens TMPK; its contribution to the national economy has caused traditional practices to be replaced by modern industrialized activities, interrupting the transmission of traditional knowledge and increasing the community's indifference to learning it (Bussmann & Sharon, 2015). Likewise, in the community of Xochipala in the Mexican state of Guerrero, family crops used to be grown under TMPK transmission scenarios until they were replaced by monoculture production, causing traditional knowledge gaps in young generations (González, et al., 2018).

Biopiracy activities exacerbate the mentioned adverse effects. To some extent, the misappropriation of TMPK with private interests and the lack of economic recognition for the legitimate owners is evident (Bravo, 2015). For example, scientists and companies have frequently used traditional medicinal plant

knowledge as if it were the common property of humankind, without any intellectual recognition or economic compensation to the groups that generated this knowledge (Reyes-García, 2009). For instance, in Ecuador, Chris Canaday, the husband of a Shuar woman from the Omaere ethnobotanical park in the city of Puyo, commented that foreigners came to learn about the Shuar community's ancestral knowledge of medicinal plants. After a while, they began to market products based on Shuar knowledge without their authorization, which generated great distrust and since then this community has not shared their ancestral knowledge for the production of plant-based products (López, 2021).

Despite the existence in some countries of national regulations that control the use of traditional knowledge related to natural resources, they are minor or not effective in reality (Baquero, et al., 2009). Famous cases of patents granted on processes based on the use of traditional knowledge while ignoring the role and the rights of the communities that created this knowledge include patents on products derived from Neem (*Azadirachta indica*), which were finally revoked in 2005, and patents on medicines for psychiatric illnesses derived from one of the components of ayahuasca (*Banisteriopsis caapi*) (Reyes-García, 2009).

The inherent biodiversity potential to produce new value-added products like food, medicine, cosmetics, and other commercially natural products is evidentially increasing since biological diversity constitutes the basis for development as long as it is used in an ecologically friendly and financially profitable manner (Pushpangadan, et al., 2018). Hence, the idea of BioTrade was born, not as the traditional 'biotrade' concept that is related to the mere activity of biological resources commercialization without considering sustainable processes, but rather as an activity characterized by the respect for environmental, economic, and social dimensions (United Nations Conference on Trade and Development, 2017).

1.3 The concept of BioTrade

The concept of BioTrade was first established as such by the BioTrade Initiative⁴ of the United Nations Conference on Trade and Development (UNCTAD) in 1996 as a support to the Convention on Biological Diversity (CBD) (Ministerio del Ambiente

⁴ It was launched during the third Conference of the Parties (COP3) of the Convention of Biological Diversity in Buenos Aires, Argentina, in November 1996.

de Perú, 2013). The CBD is one of the resolutions of the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro in 1992 and constitutes an important international instrument for sustainable development (Federal Agency for Nature Conservation (BFN), 2021). Thus, the UNCTAD defines BioTrade as: "those activities of collection, production, transformation, and commercialization of goods and services derived from *native biodiversity*⁵ under the criteria of environmental, social, and economic sustainability" (United Nations Conference on Trade and Development, 1996). This definition is based on the understanding that the loss of biodiversity has adverse effects on the functioning of the ecosystem and consequently affects the quality of life of human beings (see Figure 3) (Secretariat of the Convention of Biological Diversity, 2000).

Figure 3: BioTrade process



Source: Adapted from Ministerio del Ambiente de Perú (2013).

With this concept, a particular emphasis on three main aspects of BioTrade is evident (United Nations Conference on Trade and Development, 2006):

- a. It constitutes a tool for the country's sustainable development through the use and conservation of native biodiversity.
- b. It allows strategies and productive activities in areas with high biodiversity value to support sustainable use and conservation.
- c. It promotes the equitable sharing of economic benefits among local and Indigenous communities.

Although the CBD objectives are a fundamental part of the BioTrade Initiative framework to promote biodiversity conservation through sustainable commercial use, the BioTrade principles are also supported by other norms and precepts, such as those established by the Commission on Sustainable Development (CSD), the Millennium Development Goals (SDGs), the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the United Nations

⁵ Species that occur naturally or have existed in a country for many years (UNCTAD, 1996).

Convention to Combat Desertification (UNCCD), and the Ramsar Convention of Wetlands (Hermann, et al., 2014).

Consequently, the main objective of the BioTrade Initiative is to connect trade, biodiversity conservation, and sustainable development in a reciprocally advantageous way at national and international scales (Yupari & Vivas, 2001). It helps to evaluate and contribute to strategies and policies about the trade-biodiversity interaction, it encourages strategic alliances between stakeholders of BioTrade activity, and it is an information source that provides local feedback for international negotiations and vice versa (Yupari & Vivas, 2001).

Thus, the principles of BioTrade can be applied considering four different approaches, which increase the possibility of analyzing and understanding the BioTrade process and activities in different contexts and for various purposes. The mentioned approaches are:

1. Value-chain approach: the enhancement of value chains is an indispensable element in promoting sustainable use and conservation of biodiversity and facilitating the fair distribution of environmental, social, and economic benefits among the actors involved in the value chain (United Nations Conference on Trade and Development, 2007).
2. Adaptive management approach: it contributes to the establishment of sustainable practices (plans and tools), recognizing impacts on ecosystems and species, and constantly enhancing BioTrade practices among organizations, suppliers, and authorities (United Nations Conference on Trade and Development, 2007).
3. Ecosystem approach: it is based on a holistic perspective integrating ecological and social dimensions and the dynamics of the interactions and processes implied in the production system; it ensures that any BioTrade initiative will be environmentally and socially responsible regarding the impact on species, habitats, ecosystems and local communities (United Nations Conference on Trade and Development, 2007).
4. Sustainable Livelihoods approach: improves the awareness and implementation of sustainable livelihood activities, especially for the disadvantaged and marginalized population (United Nations Conference on Trade and Development, 2020).

Within this context, the BioTrade principles and criteria are regularly updated to ensure that they reflect evolving legal and policy frameworks and expand lessons learned and experiences of BioTrade partners in more than 65 countries (see Table 1) (United Nations Conference on Trade and Development, 2020).

Table 1: Current Principles and Criteria of BioTrade

Principle	Description	Criteria
1. Conservation of biodiversity	It focuses on preserving the wealth of species, ecosystems, and genetic diversity; and looks at protecting biodiversity and restoring and enhancing it.	1.1 Activities contribute to maintaining, restoring, or enhancing biodiversity, including ecosystems, ecological processes, natural habitats, and species, particularly threatened or endangered species.
		1.2 Genetic variability of flora, fauna, and microorganisms (for use and conservation) is maintained, restored, or promoted.
2. Sustainable Use of Biodiversity	It requires to base BioTrade activities on adaptive management practices and measures to prevent or mitigate adverse environmental impacts.	2.1 The use of biodiversity is sustainable, based on adaptive management practices that advance the long-term viability of the biological resources used and supported by workers' and producers' training on the good collection, harvesting, cultivation, breeding, or sustainable tourism practices.
		2.2 Measures are taken to prevent or mitigate negative environmental impacts of the activities, including flora and fauna; soil, air, and water quality; the global climate, agrochemicals; pollution and waste disposal; and energy consumption.

		2.3 Activities contribute to measures that strengthen resilience and species and ecosystems' adaptive capacity to climate-related hazards and natural disasters.
3. Fair and equitable sharing of benefits derived from the use of biodiversity	It requires to involve BioTrade activities in long-term partnerships along supply chains, fair prices, and contributions to local sustainable development, as well as compliance with rules and agreements on access and benefit-sharing.	3.1 Activities are agreed upon and undertaken based on transparency, dialogue, and long-term partnerships between all organizations involved in the supply chain.
		3.2 Prices take into account the costs of value chain activities (e.g., production, investment, research and development, marketing, commercialization, etc.) according to these Principles and Criteria and allow for a profit margin.
		3.3 Activities contribute to sustainable local development, as defined by producers and their local communities.
		3.4 Activities comply with applicable legal requirements and/or relevant contractual arrangements on access to biodiversity, including biological and genetic resources, their derivatives and associated traditional knowledge, and on the fair and equitable sharing of benefits derived from their utilization.
		3.5 In cases without applicable legal requirements, utilization of

		genetic resources and associated traditional knowledge takes place with prior informed consent and mutually agreed terms.
4. Socio-economic sustainability	It requires involving organizations in BioTrade activities to have solid businesses, procedures, and practices in line with industry and market conditions.	4.1 The organization demonstrates the integration of these Principles and Criteria in its business and supply chain management.
		4.2 The organization has a quality management system in line with its market requirements
		4.3 A system is in place to allow for supply chain traceability up to the country of origin and/or the place of collection, harvesting and/or cultivation.
5. Compliance with national and international legislation	It requires the legal compliance of the leading international agreements and relevant types of national and local laws.	5.1 The organization complies with applicable legal and administrative requirements at local, national, and regional levels. If measures required by local, national or regional legislation are less strict than those required by these Principles and Criteria, the organization meets the stricter requirements.
		5.2 Activities respect the principles and obligations of relevant international agreements and instruments, such as the CBD, the Nagoya Protocol, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), Convention on

		<p>International Trade in Endangered Species of Wild Fauna and Flora (CITES), Bonn Convention on Migratory Species (CMS), the International Labour Organization (ILO) Conventions, the United Nations Declaration on the Rights of Indigenous Peoples, and the United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas</p>
		<p>5.3 When dealing with marine and coastal biodiversity, activities respect the principles and obligations established under the United Nations Convention on Law of the Sea (UNCLOS), United Nations Fish Stocks Agreement (UNFSA), and any subsequent instrument on biodiversity in areas beyond national jurisdiction, as well as relevant conventions and instruments adopted under the United Nations Conference on Trade and Development, (UNCTAD), Food and Agricultural Organization of the United Nations (FAO), UN Environment, International Maritime Organization (IMO) and International Labour Organization (ILO).</p>
		<p>5.4 The organization gathers and maintains information and records required to ensure the legality of</p>

		access to and use of biodiversity, such as the country of origin, geographical location of capture or introduction from the sea, the existence of applicable laws or regulations, and relevant permits and certificates.
6. Respect for the rights of actors involved in BioTrade activities	It is directed to promote and protect these actors' rights, including their fundamental human rights, their rights as workers and employees, and their rights as part of vulnerable groups.	6.1 The organization respects fundamental human rights in keeping with the United Nations Guiding Principles on Business and Human Rights and relevant International Labour Organization Conventions.
		6.2 The organization respects worker rights, provides adequate working conditions, and prevents any negative impacts on workers' health and safety, in accordance with national legislation.
		6.3 The organization respects the rights of Indigenous peoples and local communities, women, children, and other vulnerable groups involved in BioTrade activities in accordance with national legislation and the United Nations Declaration on the Rights of Indigenous Peoples.
7. Clarity on the right to use and access to	It seeks to ensure that BioTrade activities respect land tenure and rights to	7.1 The organization uses natural resources in compliance with all relevant laws and regulations and preventing any negative impacts on

natural resources	use and access natural resources and the associated traditional knowledge of communities.	the health, safety, and wellbeing of surrounding populations.
		7.2 In cases where required by international, national, local, or customary law, as well as Criteria 3.5, the organization accesses natural resources and associated traditional knowledge with the prior informed consent of, and subject to mutually agreed terms with, the party that provides them.
		7.3 The organization respects Indigenous peoples and local communities' rights over land, natural resources, and associated traditional knowledge following national legislation and the United Nations Declaration on the Rights of Indigenous Peoples.
		7.4 The organization does not threaten the food diversity or food security of producers and their local communities

Source: Based on United Nations Conference on Trade and Development (2020).

According to the above, the BioTrade Initiative seems to be an excellent option to promote the sustainable and endogenous development of local communities in different parts of the world by increasing the value of products, sharing economic benefits with producers, promoting partnerships with non-governmental organizations, controlling illegal trade and through other different forms (Reid, 1996; Murillo & Arias, 2008; Guzmán & González, 2004). However, it has also caused different impacts in the communities where it has been applied depending on their particular economic, social, and environmental context. Thus, although BioTrade objectives achieve equity and ecological sustainability, in some cases it has materialized in a succession of unintended consequences in some cases. Some of

those are, for instance, marginalization of Indigenous groups, replacement of customary laws with those of local or national governance (which are often confusing or unfair), illegal cultivation and commercialization of products, and misuse or misappropriation of traditional knowledge (Wynberg, et al., 2015). Therefore, BioTrade principles and criteria should be applied depending on the communities' context and all actors/stakeholders involved in the commercialization process of a given product.

Thus, in the case of trade in plants with related traditional knowledge, the principles and criteria mentioned above may have many gaps that hinder identifying the true impact of this activity on TMPK. The case of guayusa BioTrade in Kichwa Ecuadorian communities is a clear illustration of this.

1.3.1 Guayusa in BioTrade

Guayusa (*Ilex guayusa*) is a plant native to the Amazon region of Ecuador (Crespo Coello, 2013). It is cultivated and grows well, especially in the Amazonian foothills from the south of Colombia to the north of Peru; however, guayusa thrives and grows better in the upper Ecuadorian Amazon, especially in the province of Napo (Crespo Coello, 2013), where it is known mainly by Kichwas communities for its medicinal applications and ritual uses (Dueñas, et al., 2016).

The Amazonian Kichwas cultivate guayusa in their horticultural plots called *chakras*; many Kichwas consume a tea-like herbal beverage using guayusa leaves almost daily (Dueñas, et al., 2016). This ethnic group recognizes several beneficial qualities of guayusa leaves, including increasing fertility, preventing insect bites, and avoiding body aches and pains after long working hours (Kramer, 2017). Dueñas affirms that "while the Kichwa people use the infusion of the leaves primarily as a stimulant, they also employ guayusa as a stomach tonic, diuretic, and flu remedy, usually in some combination of ginger, lime juice, *chuchuwasu*⁶ and/or sugarcane liquor." (Dueñas, et al., 2016, p. 88)

Several ethnobotanical studies demonstrate the significance of guayusa within the traditional knowledge system due to its stimulant and purgative properties (Bennett,

⁶ Amazonian root used in infusions or medicines (Salazar, 2014).

1992; Shoemaker, 2014; Bennett & Alarcón, 2015). Among the Kichwa, guayusa consumption plays a central role in promoting community life (Overing & Passes, 2000) since several activities are performed while drinking guayusa. Thus, some Kichwa adults weave fishing nets, traps, and bags; play music, and tell stories, while some elders interpret dreams or give advice to young people, and others drink guayusa to be able to dream and make wise decisions (Dueñas, et al., 2016; Villacís-Chiriboga, 2017).

For a little over a decade, guayusa has been formally commercialized by different enterprises that work together with the Kichwa communities to cultivate this plant (Crespo Coello, 2013). This new economic activity has attracted the attention of various researchers to continue with pharmacological studies about guayusa (Wise & Santander, 2018) and to evaluate from different perspectives the possible impacts that its commercialization has on Indigenous communities. The most significant studies nowadays have been related to the impact that guayusa trade has on the social (Jarrett, 2019), economic (Jarrett, 2019; Wood, 2013), and environmental (Krause & Ness, 2017) dimensions of the communities. However, the only tool used so far for assessing the impact of that guayusa trade has on traditional knowledge has been the BioTrade principles and criteria, the results of which unfortunately do not provide factual information that could promote possible prevention, mitigation, or compensation strategies for impacts on TMPK (see Tables 2 and 3).

Table 2 explains the scoring according to compliance with BioTrade principles and criteria. Table 3 shows the scores obtained by the guayusa value chain concerning the BioTrade principles and criteria and the reasons why this score has been awarded.

Table 2: BioTrade principles and criteria compliance assessment score

Points	Levels
1 a 3	1.- total breach
	2.- serious breach
	3.- insufficient compliance
4 a 7	4.- minimum compliance
	5.- medium compliance
	6.- regular compliance
	7.- good compliance
8 a 10	8.- excellent compliance
	9.- optimal compliance
	10.- total compliance

Source: Summarised from Prefectura del Napo (2017).

The compliance assessment was carried out by a team of evaluators selected to include academic consultants and civil servants with third and fourth-level training in different areas of knowledge. The rating was based on a joint evaluation of the information obtained in workshop reports, publications, books and technical reports, direct and indirect experiences, and other written means (Prefectura del Napo, 2017).

Table 3 shows that the impact of BioTrade on traditional knowledge related to guayusa is considered in principles 6 and 7; criteria 6.3, 6.4, and 7.3 are directly related to this issue, while criteria 6.1, 6.2, and 7.2 are indirectly related. According to these criteria, current guayusa trade impacts traditional knowledge since its management is not appropriate. However, the assessment results do not allow for an accurate evaluation of all aspects of traditional knowledge related to guayusa that may be affected by the commercial activity of this plant.

By reviewing the results in Table 3, it is noted that principles 2 and 4 have average compliance of 8 points, which translates as "excellent compliance". Principles 1 and 6 have average compliance of 7 points, which translates as "good compliance". However, the individual score for criterion 6.3, which is directly related to TK, is 6 points, which means "regular compliance". Principles 5 and 7 show average compliance of 5 points, which translates as "medium compliance"; however, the individual score for criterion 7.3, directly related to TK, is 4 points translated as "minimum compliance" (See table 2).

Table 3: Assessment of BioTrade principles and criteria (in effect in 2017) in the guayusa value chain

Principle	Criterion	Guayusa Value Chain	
		Points	Explanation
1. Biodiversity Conservation	1.1 Maintaining the characteristics of ecosystems and habitats	7	Guayusa monoculture is replacing the traditional system called chakra.
	1.2 Maintenance of genetic variability of flora, fauna and microorganisms (for use and conservation)	7	Green guayusa is used for trade because red or purple guayusa does not have good productivity.
	1.3 Maintenance of ecological processes	7	Monoculture presence.
	1.4 Activities should be framed in management plans, whether in protected areas or not, in coordination with the competent authorities and stakeholders.	6	Mobilization and operation planning is required
	PARTIAL AVERAGE	7	
2. Sustainable use of biodiversity	2.1 Biodiversity utilization should be based on a sustainable management document, including elements such as a harvest rate lower than the regeneration rate, monitoring systems (population status) and yield indices.	7	There is information on the management of farm-grown guayusa but not of wild-grown guayusa.
	2.2 The use of agrobiodiversity should include agricultural practices that contribute to biodiversity conservation.	7	Most crops are grown in traditional "chakras" together with other food plants.
	2.3 Compliance with technical standards for the development of environmental services initiatives.	8	If the "chakra" system is considered, the technical standards are fulfilled.
	2.4 Generation of information and documentation of the organization's experiences as a contribution to contribution to biodiversity knowledge.	8	The Runa Company and its foundation have generated information about it.
	PARTIAL AVERAGE	8	
3. Fair and equitable distribution of benefits derived from the use of biodiversity.	3.1 Interaction and inclusion of as many value chain actors as possible in the framework of BioTrade activities.	3	Poor socialization of information from companies to producers.
	3.2 Value generation must take place throughout the chain, under conditions of transparency, thus contributing to the positioning of value-added products in the markets.	3	The main company does not distribute the value added.
	3.3 Information and knowledge of the markets.	4	The level of feedback between private enterprise and producers is low.
	PARTIAL AVERAGE	3	
4. Socioeconomic sustainability (management, productive, financial and market sustainability)	4.1 Existence of market potential.	8	There is a potential growth in the market, especially in the EU, where samples have been sent to generate commercial relations.
	4.2 Financial profitability	8	There is financial profitability due to the added value generated, especially in the final processing of the products on hangers.
	4.3 Generation of employment and improvement of quality of life.	8	The sale of guayusa is an important source of employment for the community.
	4.4 Prevention of possible negative impacts on local productive and cultural practices that could, for example, affect food diversification and food security.	7	The "chakra" system prevents negative impacts. The mass production of guayusa has caused many people to prefer to sell it rather than consume it.
	4.5 Organizational and management capacity	7	Guayusa-producing communities have a great organizational capacity, but their management capacity is not as good.
	PARTIAL AVERAGE	8	

5. Compliance with national and international legislation	5.1 Knowledge of and compliance with applicable national and local legislation for the use of biodiversity and the trade of its products and services (wildlife management, labor, phytosanitary and commercial legislation, environmental impact studies, etc.).	6	There is knowledge about the regulations, but many communities do not have access to them due to lack of internet. Compliance with regulations is not always optimal.
	5.2 Knowledge of and compliance with applicable applicable international legislation for the use of biodiversity and trade of its products and services. derived products and services.	4	Producers have poor knowledge of international legislation.
	PARTIAL AVERAGE	5	
6. Respect for the rights of actors involved in BioTrade.	6.1 Respect for human rights, generational and gender rights	7	There is no report or complaint about activities that violate rights. However, in some cases the prices paid to producers are not fair.
	6.2 Respect for intellectual property rights	6	A private company obtained a patent on some components of guayusa and the benefits and information obtained have not yet been socialized.
	6.3 Respect for the rights of local communities and indigenous peoples (territory, culture, knowledge, practices).	6	Producers think that there is appropriation of knowledge, but on the other hand, thanks to private enterprise, the guayusa business exists.
	6.4 Maintenance and rescue of traditional knowledge and traditional practices.	7	There was a rescue and diffusion of ancestral knowledge through the use of guayusa.
	6.5 Occupational safety and proper working conditions	8	There are no cases of adverse labor conditions in the production of guayusa.
	PARTIAL AVERAGE	7	
7. Clarity on land tenure, use and access to natural resources and knowledge.	7.1 Land tenure in accordance with the corresponding regulations.	6	Conflicts exist, especially over the communal use of certain plots of land.
	7.2 Access to biological and genetic resources for sustainable use with prior informed and on the basis of mutually agreed terms	5	There were raw material purchase contracts that did not comply with reciprocity procedures.
	7.3 Access to traditional knowledge is with prior informed consent	4	There is no prior and informed consent. This is one of the most questionable practices of private companies working in the territory.
	PARTIAL AVERAGE	5	
	TOTAL AVERAGE	6	

Source: Summarised from Prefectura del Napo (2017).

Taking these results as a starting point, it shows that the principles and criteria of BioTrade applied to medicinal plants with related traditional knowledge, are not an effective tool to evaluate the true impact of trade on TMPK.

The fact that respect for intellectual property and the rights of indigenous communities has a score of 6 (criteria 6.2 and 6.3) shows that the TMPK could be threatened by BioTrade if it is not properly regulated. According to the guayusa management plan (2017), the Kichwa community claimed the misappropriation of traditional knowledge by the private company and the unfair distribution of the benefits acquired from the use of this knowledge. Moreover, the low score observed in criterion 7.3 shows that access to traditional knowledge is free and no measure

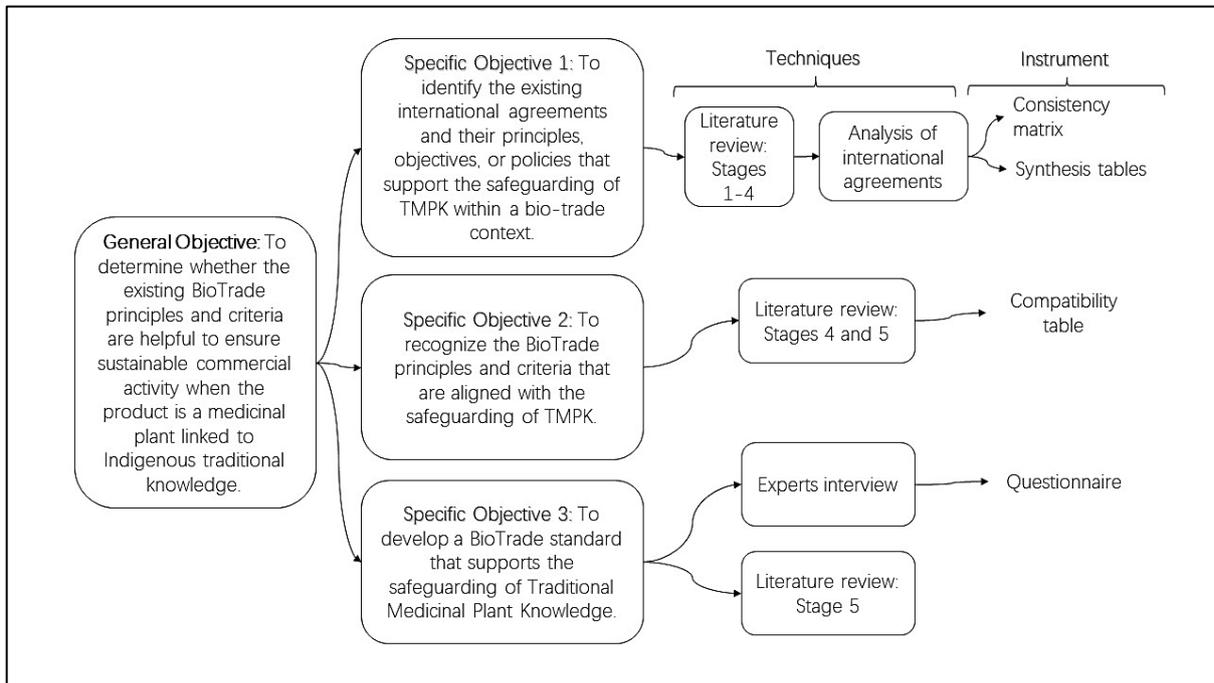
considers requesting permission from its holders for its use. This may result in the distortion of traditional knowledge and its subsequent erosion or loss.

Thus, after having reviewed in this section both the main concepts and the background of this research, it is necessary to present the methodology used to achieve the objectives of this study. Therefore, the following section shows in detail the steps followed and instruments used, both in data collection, analysis, and subsequent improvement proposals for the mentioned principles and criteria.

2. METHODOLOGY

The research design includes different techniques and methods to meet each specific objective. Figure 4 shows the objectives of the study and explains in detail the methodology that is followed.

Figure 4: Research objectives with their respective techniques and instruments



Source: Own elaboration.

A mixed-method with an explanatory research design is proposed as the framework of this approach. The methodology is presented and justified below, showing the different steps and methods of the research process.

2.1 Research Framework

The research was carried out using two primary research approaches. Considering the study's expected depth, it is explanatory research; and regarding the type of data to be analyzed, it is mixed research, as explained below.

2.1.1 Explanatory research

This kind of research is used to study aspects in a detailed manner where the researcher has a general idea or hypothesis that needs to be studied in-depth; its primary purposes are getting conclusive evidence to gain a better and efficient

understanding of the problem and reaching useful conclusions to solve it (Cazau, 2006; Jiménez Paneque, 1998).

Taking as a starting point the results of BioTrade principles and criteria in the particular case of guayusa in Ecuador, the present study aims to test the idea that the existing principles and criteria do not help ensure sustainable commercial activity regarding TMPK safeguarding when a medicinal plant linked to Indigenous traditional knowledge is commercialized. Literature and international agreements' review were the core tool to propose a BioTrade Standard with new criteria and indicators that, when applied to specific study cases, provide accurate information about the real impact that BioTrade activities have on traditional medicinal plant knowledge in Indigenous communities.

2.1.2 Mixed research

The mixed-methods represent several systematic, empiric, and critical research processes that imply collecting and analyzing quantitative and qualitative data and integrating them within a more extensive discussion of the posed problem (Hernández Sampieri, 2014). The mixed-method also helps to combine paradigms with some data (images, stories, and others.) that can be considered evidence for giving sense to the numerical data and supporting a better comprehension of phenomena (Pereira Pérez, 2011).

Although the research is, indeed, primarily qualitative, quantitative data are also crucial to explain the problem. To achieve the first specific objective, which refers to the analysis of international agreements, qualitative data from the literature review was used, which for better analysis was converted into quantitative data using the coding and categorization method. In this way, a systematic and logical analysis of the information was achieved.

On another note, only qualitative data (from literature and expert interviews) was used to achieve specific objective 2 which refers to the analysis of BioTrade principles and criteria, and specific objective 3 which refers to the proposal of a new standard to supporting TMPK safeguarding.

2.1.2.1 Qualitative research

Qualitative research is a form of social science that focuses on understanding and interpreting experiences to comprehend individuals' social realities. It uses interviews, case studies, literary criticism, and other techniques to elicit, analyze and interpret data from textual materials or oral stories (Haradhan, 2018).

In the present study, data collected from the literature review is crucial to explain the problem's background and understand the main concepts. On the other hand, qualitative data obtained from interviews and international agreements analysis was the guideline to establish the new criteria and indicators for supporting TMPK safeguarding in a BioTrade context.

2.1.2.2 Quantitative research

Quantitative research comprises a series of systematic research methods related to investigating social phenomena using statistical or numerical data. Thus, quantitative research implies measurement and supposes that the phenomena studied can be quantified. It aims to examine data to pursue trends and patterns and confirm the results of the measurements obtained (Watson, 2014).

In this research, the analysis of the international agreements provided numerical data from comparison matrices to be interpreted to better understand the qualitative results.

2.2 Techniques

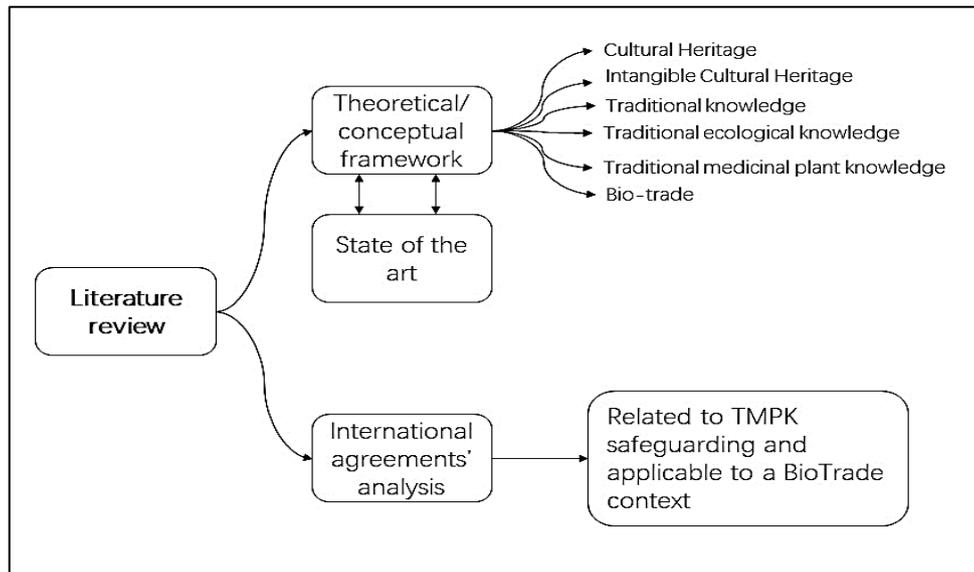
2.2.1 Literature review

This process implies detecting sources to consult relevant information needed to develop a conceptual framework for the research; it is vital to select the most relevant sources according to the proposed objectives (Hernández Sampieri, 2014).

In general, in qualitative research, the literature review should be done in three crucial moments: a) in the introduction of the study to create the context of the problem, b) in the theoretical framework where the main concepts and state of the art are explained, c) in the discussion to contrast and compare the obtained results (Arnau & Sala, 2020).

For the present research, the literature review was a technique used for the theoretical framework and state of the art and during the whole research process to provide information that sustains the subsequent analysis of international agreements (see Figure 5).

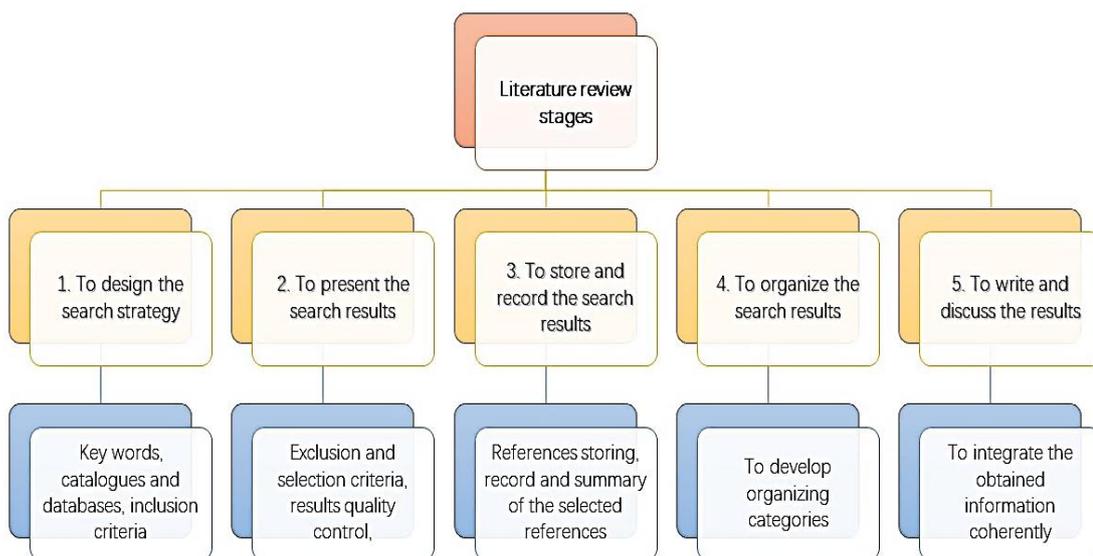
Figure 5: Literature review proposal for the present research



Source: Own elaboration.

Within this context, it is essential to consider that this process should be critical and systematic, following some stages as explained in Figure 6.

Figure 6: Literature review stages



Source: Own elaboration based on Arnau & Sala (2020).

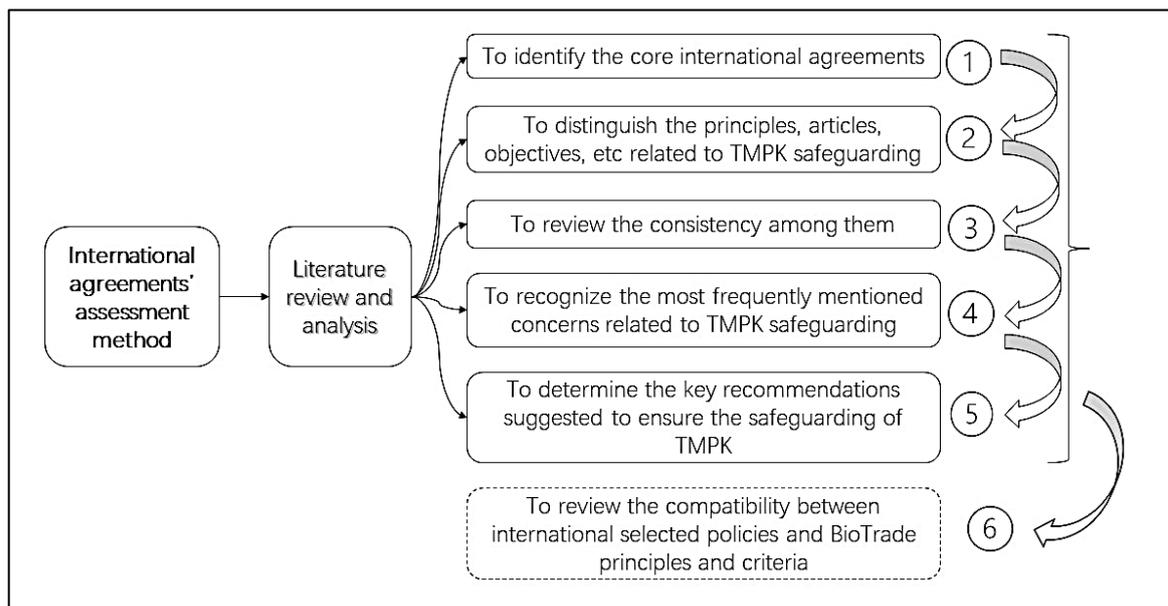
2.2.1.1 International agreements analysis

According to Meny and Thoenig (1992) cited in Muller, (2006), public policies should have at least five main characteristics to be considered as such: a) they should be a set of concrete measures, b) should be formed by decisions of resource allocation, c) must be registered in a general framework of action, d) should have an audience and aim to serve affected individuals, groups or organizations, and e) they should seek to achieve a set of defined goals and objectives (Muller, 2006).

In the present study, an analysis of international agreements and public policies is crucial to understanding current concerns and recommendations that could be applied to safeguarding TMPK within a Bio-trade context.

Figure 7 describes in detail the method that was used to review and analyze the public policies in the present research.

Figure 7: Public policies assessment method



Source: Own proposal and elaboration.

2.2.3 Experts' interviews

This technique is used to triangulate the information obtained from the literature and the analysis of international agreements for the elaboration of new criteria and indicators to ensure that BioTrade is an activity that supports the safeguarding of TMPK. Therefore, persons selected to be interviewed must be experts who have worked on the same research problem or similar phenomena. Their experience can

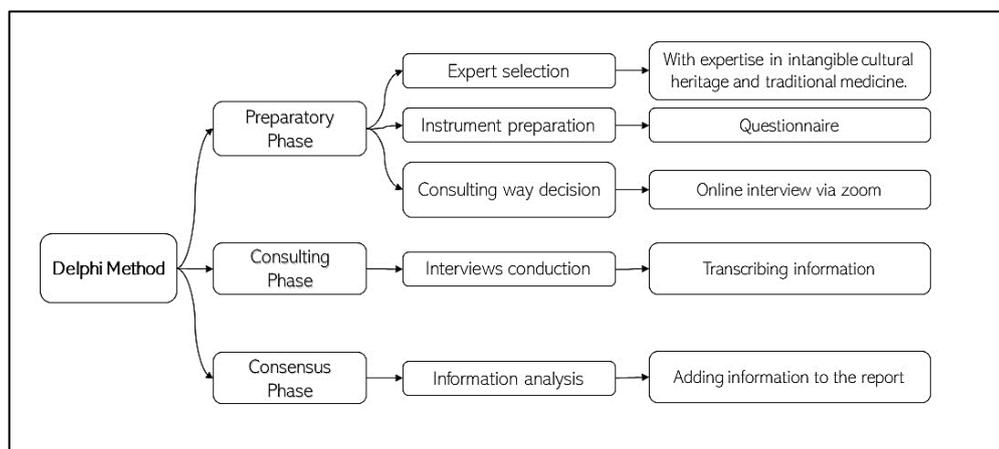
give detailed and in-depth information about the study subject and grant certainty (Galicia, et al., 2017).

For the purposes of this research, two experts were interviewed virtually. The experts interviewed were Dr. Miguel Ángel Hernández, an expert on issues related to the protection of intangible heritage in Latin America, and Dr. Jesús López Villada, an expert on issues related to traditional knowledge and medicinal plants in Ecuador.

The topics covered in both interviews were selected based on the gaps found in the literature review. In addition, their experience and opinion regarding the current situation of the BioTrade of medicinal plants and its possible impacts on the TMPK were appealed to (see Annexes). In this way, it was identified that in practice, it is very necessary to have a standard that facilitates the evaluation of the impact of BioTrade on the TMPK. Thus, the information obtained in the interviews served as support for several criteria and indicators presented in the proposal (see table 23).

In the present study, the Delphi method guided the experts' interview design following the phases presented in Figure 8.

Figure 8: Delphi Method for Experts Interview



Source: Adapted and translated from García & Suárez (2013).

2.3 Proposal

After obtaining the information from literature review, international agreements analysis, and interviews with experts about what would be the expected scenario for the adequate safeguarding of TMPK within a BioTrade context, it is necessary

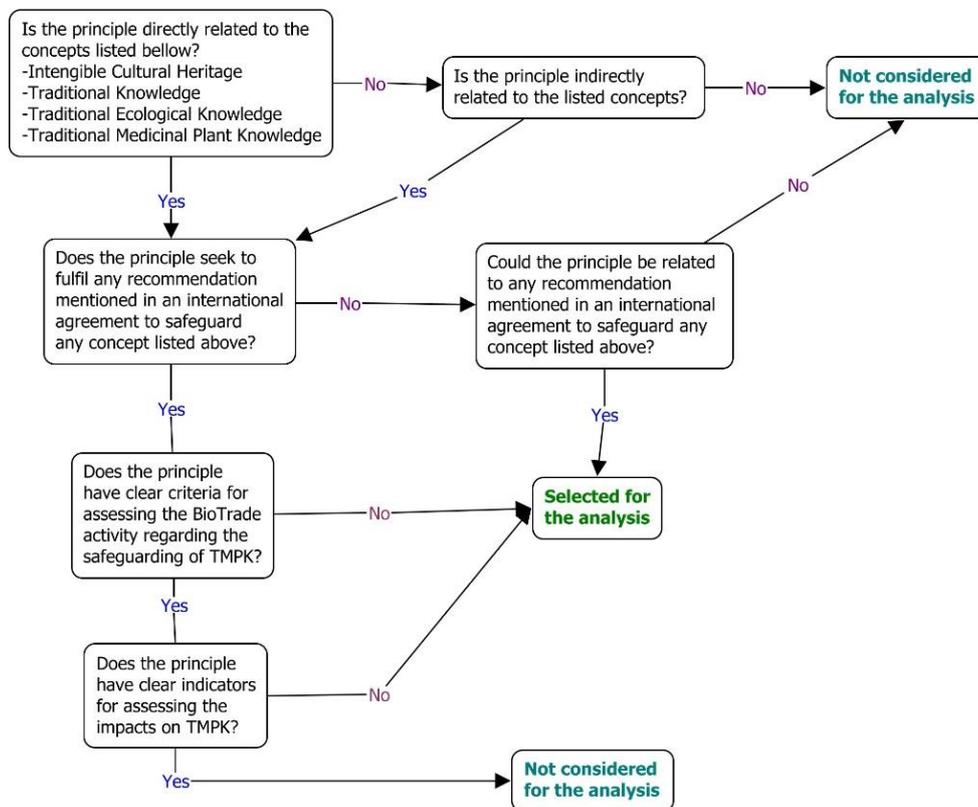
to assess the existing BioTrade principles to find the possible gaps and subsequently try to fill them with the recommendations found in the previous data collection and analysis process.

Therefore, the assessment of BioTrade principles follows three main stages: 1) screening and scoping; 2) assessing, and 3) proposing.

2.3.1 Screening and Scoping

In this stage, the seven principles of bio-trade were assessed to define which of them are more closely related to TMPK safeguarding and further focus, considering the following flowchart (see Figure 9).

Figure 9: Screening and Scoping Flowchart



Source: Own elaboration.

2.3.2 Assessing

In this stage, the selected principles were assessed in terms of compatibility with international recommendations for the safeguarding of TMPK within a BioTrade context found in the previous analysis. Table 4 shows the matrix that was used during this stage of the study.

Table 4: Compatibility matrix

Actions for the Safeguarding of Traditional Medicinal Plant Knowledge	Principle 1	Policy Code	Principle 2	Policy Code	Principle 3	Policy Code	Principle 4	Policy Code	Principle 5	Policy Code	Principle 6	Policy Code	Principle 7	Policy Code
Existing														
Gaps														

Source: Adapted from Grenier (2011).

2.3.3 Proposing

2.3.3.1 BioTrade standard proposal

After analyzing the compatibility between BioTrade principles selected and each of the elements (policies, principles, objectives, etc.) found in the international agreements, the current BioTrade principles were restructured, and new criteria and indicators were proposed. This proposal is aimed at improving the existing criteria that support the TMPK safeguarding and filling the discovered gaps. Thus, the final output of the research is a BioTrade Standard that supports the TMPK safeguarding within the trade of medicinal plants.

According to the Business and Biodiversity Offsets Programme (2012) “principles are the fundamental statements about a desired outcome. Criteria are the conditions that need to be met in order to comply with a principle. Indicators are the measurable states which allow the assessment of whether or not a particular criterion has been met” (p. 1). Thus, the main goals for the creation of indicators are a) to generate helpful information for the decision-making process, b) to monitor the fulfillment of international agreements, c) to quantify changes in a problematic situation, and d) to correct timely plans, programs, and projects (DANE, 2008).

Table 5 explains in detail what principle, criterion, and indicator mean in the particular case of the new standard.

Table 5: Structure of the BioTrade standard for the TMPK safeguarding

	Description
Principles	Norms that guide and regulate commercial activity in order to achieve the safeguarding of the TMPK. These principles are based on the UNCTAD BioTrade Initiative Principles
Criteria	Actions to guide compliance with the principles. These criteria is focused on the TMPK safeguarding
Indicators	Quantitative or qualitative parameters that can be assessed in relation to criteria. Indicators have different levels of importance in this standard (see below)

Source: Based on Union for Ethical BioTrade (2020).

The guideline for creating the new BioTrade standard was the current BioTrade principles and criteria (UNCTAD, 2020) and the Ethical BioTrade Standard (The Union for Ethical BioTrade, 2020). Both documents contributed to the structure of the proposal. However, the new criteria and indicators were established based on the main recommendations identified in the international agreements' analysis and expert interviews.

Therefore, it was necessary to modify the current BioTrade principles, adapt current criteria and propose new ones, and formulate indicators for evaluating the real impact that commercialization of medicinal plants has on TMPK.

3. RESULTS. Analysis of BioTrade Initiative concerning TMPK safeguarding

Local and Indigenous communities have been using traditional knowledge for centuries. This knowledge covers everything from agriculture, animal husbandry, and food storage to construction, medicine, and the preservation of biological resources and the environment. Customary law and cultural taboos of these communities have long helped preserve this knowledge and control its use. However, the increasing commercial use of these resources beyond the traditional context makes them increasingly vulnerable to misuse and misappropriation by third parties, leading to the decontextualization and potential loss of traditional knowledge; this is why many traditional knowledge holders and many international policymakers call for new policies and legislation in this area (Ouma, 2017).

Over time, the idea of protecting traditional knowledge from possible threats caused by globalization has increased. Several international bodies have signed agreements to encourage its safeguarding and continuity. However, in many countries, especially developing ones, the lack of interest of new generations in maintaining their history and cultural identity may be one of the threats to traditional knowledge that is difficult to control (Jewel, 2017).

This chapter will identify and analyze the main international agreements⁷ that relate to the protection of traditional knowledge in a possible context of trade in medicinal plants; to further discuss whether the regulations of this commercial activity, known as "BioTrade Initiative" contribute to the safeguarding of traditional knowledge or, on the contrary, need to be modified to meet this objective. In addition, the results of the interviews conducted with experts will be presented to complement the information obtained from secondary sources.

⁷ My translation: "international agreements are instrument containing dispositions freely agreed between two or more subjects of International Law with the purpose of creating, modifying or extinguishing obligations and rights" (Linares, 1992, p. 61).

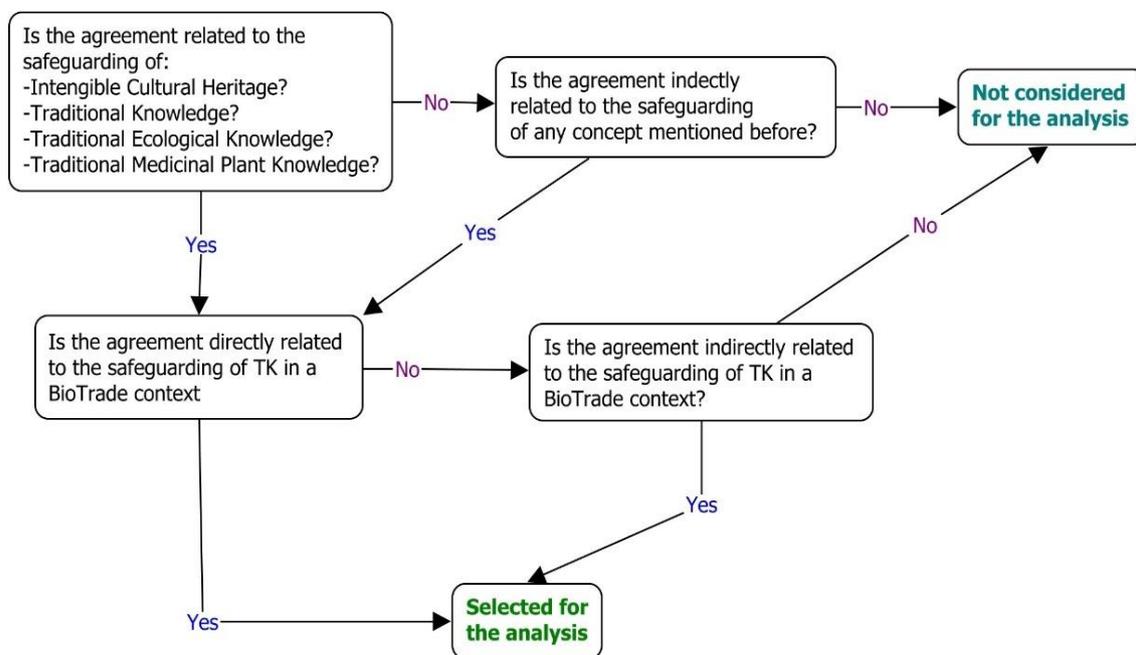
3.1 Analysis of BioTrade principles and criteria in the light of international agreements supporting the safeguarding of TMPK

The six steps mentioned in the methodology will be followed for this analysis (see Figure 7). The results of each step will be analyzed and discussed before moving on to the next step to better understand the method employed.

3.1.1 Step 1: To identify the core international agreements for the safeguarding of traditional knowledge

To identify the most relevant international agreements on the safeguarding of traditional knowledge in a possible context of the commercialization of medicinal plants, the flowchart detailed in Figure 10 was followed.

Figure 10: Flowchart to identify the core agreements for the study



Source: Own elaboration.

As a result, it was determined that the primary efforts in the context of the international legal protection of traditional knowledge and traditional cultural expressions became significant after it was recognized that culture, as an intangible element of peoples, is influenced by the ways of life of modernity and industrialized economic activities. Thus, several measures are undertaken within the framework of different international organizations such as the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Intellectual Property

of the population, including the protection of their identity, language, and religion, as they constitute a significant contribution to cultural diversity and social and ecological harmony (International Labour Organization, 1989).

Based on the ILO initiative, UNESCO contributed to the safeguarding of traditional knowledge by promoting the protection of the intangible cultural heritage of peoples. This effort started in 1989 with the *Recommendation on Safeguarding of Traditional Culture and Folklore*. In this act, the term "traditional knowledge" was not yet used as such, but, after reviewing the different definitions of TK, it can be inferred that in this agreement, TK is included within the various expressions of folklore related to oral traditions or that are transmitted from generation to generation (UNESCO, 1989). Thus, by this date, UNESCO already recognized the cultural, social, economic, and political relevance of these expressions due to their significance in the history of peoples and their role in contemporary culture; it also understood the fragility of folklore as it is subject to constant changes due to external influences and therefore established a series of recommendations to guarantee its protection (UNESCO, 1989).

In 2003, the *Convention for the Safeguarding of the Intangible Cultural Heritage* was signed, recognizing the invaluable role of intangible cultural heritage for sustainable development and its importance for maintaining communities' collective identity and cultural diversity. Noting further that no binding multilateral instrument as yet existed, it was considered essential to create an instrument that protected intangible cultural heritage from threats caused by globalization and social transformation, which could lead to the deterioration, destruction, or disappearance of intangible cultural heritage, and which over time have generated lesser interest in the younger generations concerning its practice and transmission (UNESCO, 2003).

In 2005, the *Convention of the Protection and Promotion of the Diversity of Cultural Expressions* was adopted by the UNESCO General Conference. It recognizes the importance of protecting cultural diversity and its expressions as a means of fostering collective identity; it admits that traditional knowledge is a source of cultural wealth and that, in particular, the knowledge systems of Indigenous groups constitute a significant contribution to sustainable development, and are therefore subject to protection and promotion (UNESCO, 2005). Moreover, in the same year,

UNESCO established the *Universal Declaration on Bioethics and Human Rights*, addressing ethical issues related to medicine, life sciences, and associated technologies as applied to human beings. It considers the social, legal, and environmental dimensions, highlighting the respect and protection of traditional knowledge as a crucial contribution to biodiversity conservation since it still constitutes the primary source for medicine production (UNESCO, 2005).

For its part, the United Nations member states signed the *Convention on Biological Diversity (CBD)* in 1992 to protect traditional knowledge associated with genetic resources and guarantee the equitable sharing of the benefits acquired from using this knowledge with its legitimate owners. The member states recognized that traditional knowledge is the basis for the sustainable development of communities and plays a significant role in the conservation of biodiversity, as well as being a contribution to the progress of scientific knowledge (United Nations, 1992). Thus, the CBD was the base for the *Global Strategy for Plant Conservation* proposed in 2002 (updated in 2011), after understanding that human life and the functioning of the planet is possible because of the presence of plant diversity and that this diversity should be protected, preventing flora species extinction and the loss of traditional knowledge related to them as a result of commercial and research projects (United Nations, 2012). Similarly, in 2010, the *Nagoya Protocol* was adopted. Among its core considerations, it recognizes the importance of traditional knowledge for the conservation of biological resources and, therefore, for the sustainable development of Indigenous communities (Secretariat of the Convention on Biological Diversity, 2010). It establishes that access to this knowledge must be informed and consented to by its legitimate owners, following the norms and protocols established by each community and guaranteeing an equitable sharing of the benefits acquired by using this knowledge (supporting what is established by the CBD) (Secretariat of the Convention on Biological Diversity, 2010).

From another point of view, in 2007, the United Nations adopted the *Declaration on the Rights of Indigenous Peoples*, in which they recognized that Indigenous peoples and communities have the right to maintain, control, protect and develop their cultural heritage, including traditional knowledge and the diverse manifestations related to it, such as customary medicinal practices, traditional technologies and the management of natural resources (United Nations, 2007).

Since 1994, when the World Trade Organization (WTO) established *the Agreement on Trade-Related Aspects of Intellectual Property Rights*, the relevance of the intellectual property of knowledge related to traditional medicine processes began to be considered. This topic was expanded in 2006 when the council elaborated a document for the protection of traditional knowledge and folklore in commercialization processes to support the idea of the protection of traditional knowledge, the possibility of patenting it, and the equitable distribution of the benefits acquired by its use. Likewise, the World Intellectual Property Organization (WIPO) has tried to develop an international instrument to preserve traditional knowledge and cultural expressions in the industrial processing of genetic resources obtained from local and Indigenous communities (Sharifullova Gazizova, 2020). Therefore, in 2000 the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was created and has developed several drafts on how to combat misappropriation and misuse of traditional knowledge, ensuring the mutual advantage of stakeholders, providers, and users of TK; the most recent is *The Protection of Traditional Cultural Expressions* elaborated in 2019 (Intergovernmental Committee on Intellectual Property and Genetic Resources, 2019). However, it is still under discussion whether the document should be considered internationally binding (as developing countries expect) or flexible and non-binding (which is the wish of several industrialized countries) (Intergovernmental Committee on Intellectual Property and Genetic Resources, 2019).

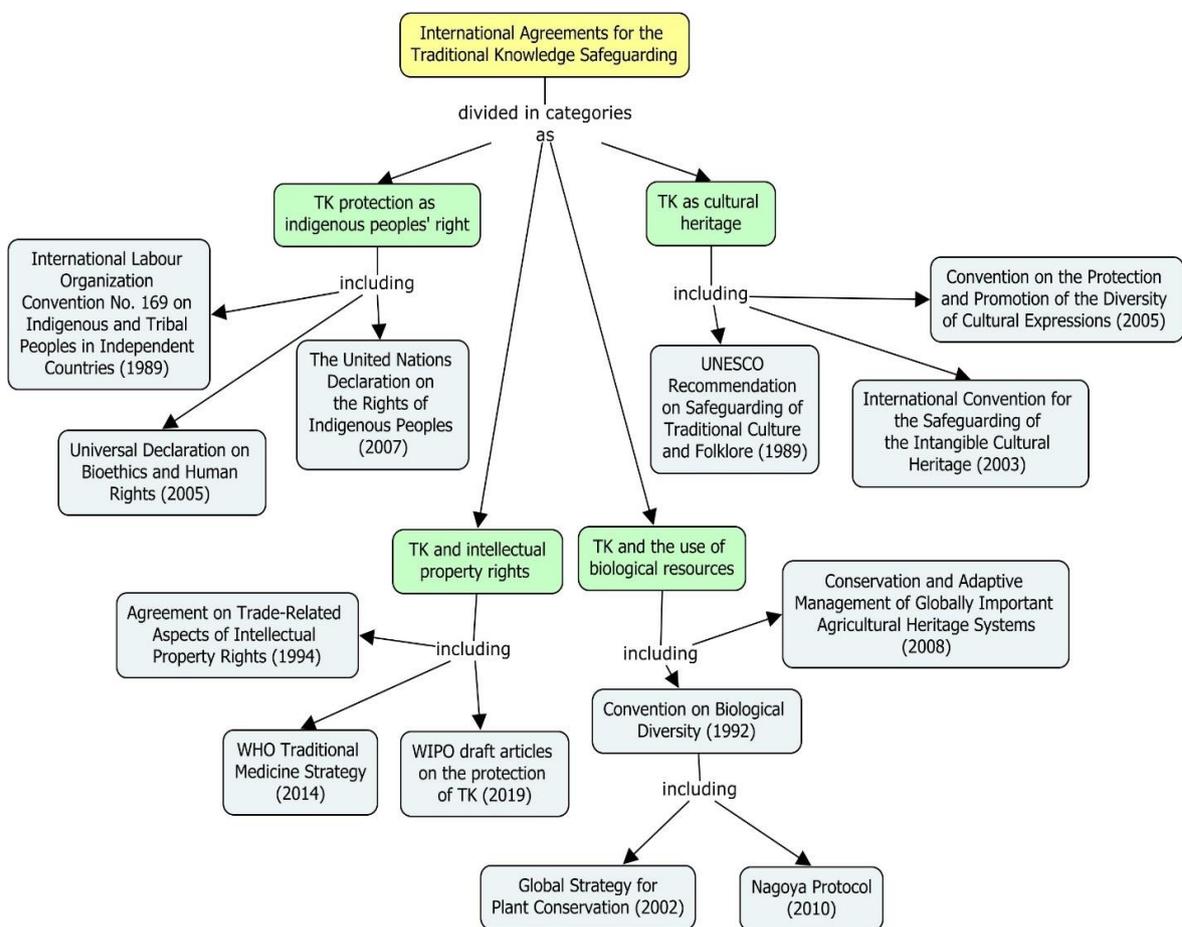
Furthermore, the question arises whether the protection of this knowledge should be considered within the intellectual property protection system or whether it would be better to approach it from a human rights perspective by applying a sui generis safeguard system (Intergovernmental Committee on Intellectual Property and Genetic Resources, 2019). In the same way, the WHO proposed the *Traditional Medicine Strategy* in 2014. This strategy constitutes an effort to safeguard traditional knowledge related to customary medicine practices in Indigenous communities, as it constitutes a significant contribution to public health and the advances of modern medicine in general (World Health Organization, 2014).

In 2008, the FAO implemented the *Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems* project to valorise Indigenous and traditional agricultural patrimony. It recommended this knowledge as part of the primary education at the local level after recognizing that modernization and the lack of interest of young generations are the main threats to traditional agricultural practices and traditional knowledge (Food and Agricultural Organization, 2008).

After the former explanation, it is evident that the protection of traditional knowledge in international agreements has been addressed in different contexts and from different perspectives. Three categories have therefore been established for the analysis to be discussed in the following section (see Figure 12) (Neale, 2016):

1. TK protection as Indigenous peoples' right
2. TK and intellectual property rights
3. TK and the use of biological resources
4. TK as cultural heritage

Figure 12: Categories of international agreements for the TK safeguarding



Source: Own elaboration.

3.1.2 Step 2: To distinguish the principles, articles, and objectives related to TMPK safeguarding in a BioTrade context

After selecting the main international agreements, it was necessary to read them carefully to find the principles, articles, and objectives related to the TMPK safeguarding within a BioTrade context. Each item was assigned a code for subsequent analysis.

Table 6 shows the articles of the agreements that are part of the first category under analysis: TK protection as Indigenous peoples' right. Thus, the following agreements will be analyzed: the Indigenous and Tribal Peoples Convention (1989), the Universal Declaration on Bioethics and Human Rights (2005), and the United Nations Declaration on the Rights of Indigenous Peoples (2007).

The first category refers that the protection of TK is considered a right of Indigenous or tribal peoples. Therefore, it is essential to mention that for this analysis, these people are those who distinguish themselves from the national community by being governed by their own customs, are descendants of native populations of a given place, and are fully aware of their Indigenous or tribal identity (United Nations, 2013).

Table 6 also shows that TKIPO08 and TKIPO09 refer literally to TMPK safeguarding. In comparison, the other policies of this category refer to different concepts that indirectly include the concept of TMPK according to the information reviewed in the theoretical framework and supported by some other authors, as mentioned below.

- TKIPO01: TMPK is part of the *cultural identity*. (Akhagba, 2017).
- TKIPO01 & TKIPO07: TMPK is a *custom or/and a tradition*. (Eyssartier, et al., 2008).
- TKIPO02: TMPK is a *cultural practice*. (Verma, et al., 2010).
- TKIPO03 & TKIPO04: TMPK is part of the communities' *culture*. (Qiu, 2007).
- TKIPO05: TMPK is part of *traditional knowledge and technologies*. (Zhang, 2004).
- TKIPO06: TMPK is part of *traditional ecological knowledge*. (La Torre-Cuadros & Islebe, 2003).

Table 6: Policies related to the protection of TK as an Indigenous right

Traditional Knowledge Protection as Indigenous Peoples` Right			
Agreement		Statement	Code
Indigenous and Tribal Peoples Convention	Art. 2(b)	Promoting the full realisation of the social, economic and cultural rights of these peoples with respect for their social and cultural identity, their customs and traditions and their institutions.	TKIP01
	Art. 5 (a)	The social, cultural, religious and spiritual values and practices of these peoples shall be recognised and protected, and due account shall be taken of the nature of the problems which face them both as groups and as individuals.	TKIP02
	Art. 7 (1)	The peoples concerned shall have the right to decide their own priorities for the process of development as it affects their lives, beliefs, institutions and spiritual well-being and the lands they occupy or otherwise use, and to exercise control, to the extent possible, over their own economic, social and cultural development. In addition, they shall participate in the formulation, implementation and evaluation of plans and programmes for national and regional development which may affect them directly.	TKIP03
	Art.7 (3)	Governments shall ensure that, whenever appropriate, studies are carried out, in co-operation with the peoples concerned, to assess the social, spiritual, cultural and environmental impact on them of planned development activities. The results of these studies shall be considered as fundamental criteria for the implementation of these activities.	TKIP04
	Art. 27 (1)	Education programmes and services for the peoples concerned shall be developed and implemented in co-operation with them to address their special needs, and shall incorporate their histories, their knowledge and technologies, their value systems and their further social, economic and cultural aspirations.	TKIP05
Universal Declaration on Bioethics and Human Rights	Art. 17	Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.	TKIP06
United Nations Declaration on the Rights of Indigenous Peoples	Art.11 (1)	Indigenous peoples have the right to practise and revitalize their cultural traditions and customs. This includes the right to maintain, protect and develop the past, present and future manifestations of their cultures, such as archaeological and historical sites, artefacts, designs, ceremonies, technologies and visual and performing arts and literature.	TKIP07
	Art. 24 (1)	Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, to all social and health services.	TKIP08
	Art. 31 (1)	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, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.	TKIP09

Source: Own elaboration.

Table 7 shows some articles and one strategy of the agreements that are part of the second category under analysis: TK and intellectual property rights. Thus, the following agreements will be analyzed: the Agreement on Trade Related-Aspects of Intellectual Property Rights (1994), the WHO Traditional Medicine Strategy (2014), and the Draft Articles of WIPO for the Protection of Traditional Knowledge (2019). For this analysis, it is necessary to mention that intellectual property rights refer to the legal rights granted to the creator or inventor of ideas, expressions, or knowledge so that he/she may have total control over it (Nath Saha & Bhattacharya, 2011). The case of traditional knowledge includes laws to prevent its misuse or misappropriation by third parties beyond the community circle (World Intellectual Property Organization, 2015).

Table 7 shows that TKIPRO03 refers directly to TMPK safeguarding since the agreement to which it corresponds is related to traditional medicine. In comparison, the other policies of this category refer to different concepts or ideas that indirectly include the concept of TMPK according to the information reviewed in the theoretical framework and supported by some other authors, as mentioned below.

- TKIPRO01 & TKIPRO02: TMPK can generate *processes or products for the industry*. (Fokunang, et al., 2011).
- TKIPRO04, TKIPRO05, TKIPRO06, TKIPRO07 & TKIPRO08: TMPK is a *traditional cultural expression*. (Antons, 2009; Abbott, 2014).

Table 8 shows some articles and objectives of the third category agreements under analysis: TK and the use of biological resources. Thus, the agreements that will be analyzed within this context are the Convention on Biological Diversity (1992), the Global Strategy for Plant Conservation (2002), the Nagoya Protocol (2010), and the Conservation and Adaptive Management Agreement of Globally Important Agricultural Heritage Systems (2008). It should be stated that this final agreement was selected for this study due to the fact that the TMPK is closely related to agroecology. The traditional agricultural systems used to cultivate medicinal plants are the most suitable for controlling pests and maintaining the genetic diversity of these plants; protecting them safeguards the traditional knowledge related to them (Shahrajabian, et al., 2019).

Table 7: Policies related to the protection of TK through the intellectual property rights system

Traditional Knowledge and Intellectual Property Rights			
Agreement		Statement	Code
Agreement on Trade Related-Aspects of Intellectual Property Rights - according to Issues Raised and Points Made: The Protection of Traditional Knowledge and Folklore, The Relationship between TRIPS Agreement and CBD	Art.27 (1)	Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. ⁵ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.	TKIPRO1
	Art. 27 (3b)	Members may also exclude from patentability: plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.	TKIPRO2
WHO Traditional Medicine Strategy	Strategic objective 1, strategic direction 1.2	Strengthen the knowledge base, build evidence and sustain resources	TKIPRO3
WIPO The Protection of Traditional Cultural Expressions: Draft Articles	Art. 2, Alt 3, a	The objective of this instrument is to support the appropriate use and protection of traditional cultural expressions within the intellectual property system, in accordance with national law, respecting the interests of indigenous peoples and local communities to: prevent the misappropriation, misuse, and unauthorized use of their traditional cultural expressions, while making the most of the existing intellectual property system	TKIPRO4
	Art. 2, Alt 3, d	The objective of this instrument is to support the appropriate use and protection of traditional cultural expressions within the intellectual property system, in accordance with national law, respecting the interests of indigenous peoples and local communities to: promote the appropriate use of traditional cultural expression for sustainable, community-based development where so desired by indigenous peoples and local communities.	TKIPRO5
	Art. 5, Alt 2. 5.1, a, i	Member States [should/shall] take legislative, administrative and/or policy measures, as appropriate, in accordance with national law, in a reasonable and balanced manner, and in a manner consistent with Article 14, with the aim of ensuring that: Where with reference to the customary laws and practices of indigenous [peoples] and local communities/beneficiaries, access to traditional cultural expressions is restricted, including where the traditional cultural expressions are secret or sacred: Beneficiaries have the exclusive and collective right to maintain, control, use, develop, authorize or prevent access to and use/utilization of their traditional cultural expressions; and receive a fair and equitable share of benefits arising from their use.	TKIPRO6
	Art. 5, Alt 3, 5.1, b, iii	Where the [protected] traditional cultural expression is [sacred], [secret] or [otherwise known only] [closely held] within indigenous [peoples] or local communities, Member States should/shall: encourage users [to]: use/utilize the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the [inalienable, indivisible and imprescriptible] nature of the moral rights associated with the [protected] traditional cultural expressions.	TKIPRO7
	Art. 5, Alt 3, 5.2, c	Where the [protected] traditional cultural expression is still [held], [maintained], used [and]/[or] developed by indigenous [peoples] or local communities, and is/are publicly available [but neither widely known, [sacred], nor [secret], Member States should/shall encourage that users]/[provide legal, policy and/or administrative measures, as appropriate and in accordance with national law to encourage users [to]: use/utilize the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the [inalienable, indivisible and imprescriptible nature of the moral rights associated with the [protected] traditional cultural expressions	TKIPRO8

Source: Own elaboration.

Table 8 shows that TKBRU03 and TKBRU04 refer directly to TMPK safeguarding since the agreement to which they correspond is linked to the knowledge related to plants use. In comparison, the other policies of this category refer to different concepts or ideas that indirectly include the concept of TMPK according to the information reviewed in the theoretical framework and supported by some other authors, as mentioned below.

- TKBRU01: TMPK is *knowledge related to the use of biological diversity*. (Pretty, et al., 2009).
- TKBRU02: TMPK is a *cultural practice*. (Verma, et al., 2010).
- TKBRU05-TKBRU08: TMPK is *knowledge related to the use of genetic resources*. (Rajendran, et al., 2000).
- TKBRU09: TMPK is related to *agricultural heritage systems*. (Arnés García, et al., 2020).

Table 9 concerns the articles and recommendations of the fourth category agreements under analysis: TK as cultural heritage. Thus, the following agreements will be analyzed: the UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore (1989), the Convention for the Safeguarding of the Intangible Cultural Heritage (2003), and the Convention on the Protection and Promotion of the Diversity of Cultural Expressions (2005). Table 9 shows that the policies of this category refer to different concepts or ideas that indirectly include the concept of TMPK according to the information reviewed in the theoretical framework and supported by some other authors, as mentioned below.

- TKCH01 & TKCH02: TMPK is a *folk tradition* (Chandra Prasad, et al., 2008).
- TKCH03 & TKCH04: TMPK is part of *folklore* (Mukherjee, 2001).
- TKCH05-TKCH11, TKCH13, TKCH14: TMPK is part of the *intangible cultural heritage* (Vadi, 2007).
- TKCH12: TMPL is part of the *heritage* (di Sarsina, et al., 2011).
- TKCH15, TKCH16, TKCH21-TKCH24: TMPK is a *traditional cultural expression* (Antons, 2009; Abbott, 2014).
- TKCH17, TKCH19, TKCH20 & TKCH25: TMPK as part of the *culture links with development* (Ali Arazeem, 2011).
- TKCH18: TMPK is a *cultural activity (practice)* (Verma, et al., 2010).

Table 8: Policies related to the protection of TK in the process of biological resources use

Traditional Knowledge and the Use of Biological Resources			
Agreement		Statement	Code
Convention on Biological Diversity	Art. 8 (j)	Subject to its national legislation, 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.	TKBRU01
	Art. 10 (c)	Each Contracting Party shall, as far as possible and as appropriate: protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.	TKBRU02
Global Strategy for Plant Conservation	Objective 2, Target 9	70 per cent of the genetic diversity of crops including their wild relatives and other socio-economically valuable plant species conserved, while respecting, preserving and maintaining associated indigenous and local knowledge.	TKBRU03
	Objective 3, Target 13	Indigenous and local knowledge, innovations and practices associated with plant resources, maintained or increased, as appropriate, to support customary use, sustainable livelihoods, local food security and health care.	TKBRU04
Nagoya Protocol	Art. 7	In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.	TKBRU05
	Art. 12 (2)	Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.	TKBRU06
	Art. 16 (1)	Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.	TKBRU07
	Art.21	Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues.	TKBRU08
Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems	Goal	The overall goal of the project is to identify and safeguard Globally Important Agricultural Heritage Systems and their associated landscapes, agricultural biodiversity and knowledge systems through mobilising global and national recognition and support for such systems and enhancing global, national and local benefits derived through their dynamic conservation, sustainable management and enhanced viability.	TKBRU09

Source: Own elaboration.

Table 9: Policies related to the protection of TK as part of the cultural heritage

Traditional Knowledge as Cultural Heritage			
Agreement		Statement	Code
UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore	Recommendation C Conservation of Folklore	Conservation is concerned with documentation regarding folk traditions and its object is, in the event of the non-utilization or evolution of such traditions, to give researchers and tradition-bearers access to data enabling them to understand the process through which tradition changes. While living folklore, owing to its evolving character, cannot always be directly protected, folklore that has been fixed in a tangible form should be effectively protected.	TKCH01
	Recommendation D - Preservation of Folklore	Preservation is concerned with protection of folk traditions and those who are the transmitters, having regard to the fact that each people has a right to its own culture and that its adherence to that culture is often eroded by the impact of the industrialized culture purveyed by the mass media. Measures must be taken to guarantee the status of and economic support for folk traditions both in the communities which produce them and beyond.	TKCH02
	Recommendation E Dissemination of Folklore	The attention of people should be drawn to the importance of folklore as an ingredient of cultural identity. It is essential for the items that make up this cultural heritage to be widely disseminated so that the value of folklore and the need to preserve it can be recognized. However, distortion during dissemination should be avoided so that the integrity of the traditions can be safeguarded.	TKCH03
	Recommendation F Protection of Folklore	In so far as folklore constitutes manifestations of intellectual creativity whether it be individual or collective, it deserves to be protected in a manner inspired by the protection provided for intellectual productions. Such protection of folklore has become indispensable as a means of promoting further development, maintenance and dissemination of those expressions, both within and outside the country, without prejudice to related legitimate interests.	TKCH04
The Convention for the Safeguarding of the Intangible Cultural Heritage	Part II, Art. 11 (a)	Each State Party shall: take the necessary measures to ensure the safeguarding of the intangible cultural heritage present in its territory.	TKCH05
	Part II, Art. 11 (b)	Each State Party shall: identify and define the various elements of the intangible cultural heritage present in its territory, with the participation of communities, groups and relevant nongovernmental organizations.	TKCH06
	Part II, Art. 12 (1)	To ensure identification with a view to safeguarding, each State Party shall draw up, in a manner geared to its own situation, one or more inventories of the intangible cultural heritage present in its territory. These inventories shall be regularly updated.	TKCH07
	Part II, Art. 13 (a)	Each State Party shall: adopt a general policy aimed at promoting the function of the intangible cultural heritage in society, and at integrating the safeguarding of such heritage into planning programmes.	TKCH08
	Part II, Art. 13 (b)	Each State Party shall: designate or establish one or more competent bodies for the safeguarding of the intangible cultural heritage present in its territory.	TKCH09
	Part II, Art. 13 (c)	Each State Party shall: foster scientific, technical and artistic studies, as well as research methodologies, with a view to effective safeguarding of the intangible cultural heritage, in particular the intangible cultural heritage in danger.	TKCH10
	Part II, Art. 14 (a)	Each State Party shall to: ensure recognition of, respect for, and enhancement of the intangible cultural heritage in society, in particular through: (i) educational, awareness-raising and information programmes, aimed at the general public, in particular young people; (ii) specific educational and training programmes within the communities and groups concerned; (iii) capacity-building activities for the safeguarding of the intangible cultural heritage, in particular management and scientific research; and (iv) non-formal means of transmitting knowledge.	TKCH11
	Part II, Art. 14 (b)	Each State Party shall to: keep the public informed of the dangers threatening such heritage, and of the activities carried out in pursuance of this Convention.	TKCH12

The Convention for the Safeguarding of the Intangible Cultural Heritage	Part II, Art. 14 (c)	Each State Party shall to: promote education for the protection of natural spaces and places of memory whose existence is necessary for expressing the intangible cultural heritage.	TKCH13
	Part II, Art. 15	Within the framework of its safeguarding activities of the intangible cultural heritage, each State Party shall endeavour to ensure the widest possible participation of communities, groups and, where appropriate, individuals that create, maintain and transmit such heritage, and to involve them actively in its management.	TKCH14
Convention on the Protection and Promotion of the Diversity of Cultural Expressions	Art. 1 (a)	One objective is: to protect and promote the diversity of cultural expressions.	TKCH15
	Art. 1 (e)	One objective is: to promote respect for the diversity of cultural expressions and raise awareness of its value at the local, national and international levels.	TKCH16
	Art. 1 (f)	One objective is: to reaffirm the importance of the link between culture and development for all countries, particularly for developing countries, and to support actions undertaken nationally and internationally to secure recognition of the true value of this link.	TKCH17
	Art. 1 (g)	One objective is: to give recognition to the distinctive nature of cultural activities, goods and services as vehicles of identity, values and meaning.	TKCH18
	Art.2 (principle 5)	Principle of the complementarity of economic and cultural aspects of development.- since culture is one of the mainsprings of development, the cultural aspects of development are as important as its economic aspects, which individuals and peoples have the fundamental right to participate in and enjoy.	TKCH19
	Art.2 (principle 6)	Principle of sustainable development.- cultural diversity is a rich asset for individuals and societies. The protection, promotion and maintenance of cultural diversity are an essential requirement for sustainable development for the benefit of present and future generations.	TKCH20
	Art. 7 (1a)	Parties shall endeavour to create in their territory an environment which encourages individuals and social groups: to create, produce, disseminate, distribute and have access to their own cultural expressions, paying due attention to the special circumstances and needs of women as well as various social groups, including persons belonging to minorities and indigenous peoples.	TKCH21
	Art. 8 (1)	Without prejudice to the provisions of Articles 5 and 6, a Party may determine the existence of special situations where cultural expressions on its territory are at risk of extinction, under serious threat, or otherwise in need of urgent safeguarding.	TKCH22
	Art. 8 (2)	Parties may take all appropriate measures to protect and preserve cultural expressions in situations referred to in paragraph 1 in a manner consistent with the provisions of this Convention.	TKCH23
	Art. 10 (a)	Parties shall encourage and promote understanding of the importance of the protection and promotion of the diversity of cultural expressions, inter alia, through educational and greater public awareness programmes.	TKCH24
	Art. 13	Parties shall endeavour to integrate culture in their development policies at all levels for the creation of conditions conducive to sustainable development and, within this framework, foster aspects relating to the protection and promotion of the diversity of cultural expressions.	TKCH25

Source: Own elaboration.

3.1.3 Step 3: To review the consistency among the selected policies

The following matrices show the consistency between each objective, principle, and article (from now on referred to as policies) selected for this analysis (see Tables 11, 12, 13). First, table 10 explains the consistency keys used for this analysis, where the dark green colour identifies a high consistency, the light green is a standard consistency, and the yellow determines a neutral relation. Figure 11 shows that all the agreements selected for the study are directly or indirectly interconnected. Hence, the matrices do not show the “no link” option.

As this is a qualitative evaluation, the results depend on the assessment criteria established by the researcher (Hernández Sampieri, 2014). Therefore, for the purposes of this assessment, two policies have been determined to be very consistent when, in context, both pursue the same aim, or one pursues an aim that directly influences the pursuit of the other. On the other hand, two policies are consistent when one pursues an end that could indirectly influence the achievement of the other; and finally, two policies are considered neutral when the end of one policy does not directly influence the other, or could indirectly influence the other, but it is not clear how.

Table 10: Consistency keys used for the analysis

Consistency keys	
Very Consistent	++
Consistent	+
Neutral	o
No link	--

Source: Own elaboration.

The results obtained from the matrices' evaluation are presented in Tables 14, 15, 16, and 17. These tables present the number of coincidences per consistency key (very consistent, consistent, and neutral) for each of the policies grouped into the four categories established. The totals were then converted to percentages, and finally, averages were calculated by consistency key for both totals and percentages.

Table 11: Consistency analysis between category 1 “TK as Indigenous peoples’ right” and categories 2, 3, 4 (Matrix 1)

Code	TKIPRO1	TKIPRO2	TKIPRO3	TKIPRO4	TKIPRO5	TKIPRO6	TKIPRO7	TKIPRO8		TKBRU01	TKBRU02	TKBRU03	TKBRU04	TKBRU05	TKBRU06	TKBRU07	TKBRU08	TKBRU09		TKCH01	TKCH02	TKCH03	TKCH04	TKCH05	TKCH06	TKCH07	TKCH08	TKCH09	TKCH10	TKCH11	TKCH12	TKCH13	TKCH14	TKCH15	TKCH16	TKCH17	TKCH18	TKCH19	TKCH20	TKCH21	TKCH22	TKCH23	TKCH24	TKCH25
TKIPO1	+	o	o	+	++	+	++	+		+	+	+	+	+	+	+	++	+		+	++	++	+	+	+	o	++	+	+	+	o	+	++	++	++	+	+	++	++	++	o	+	+	++
TKIPO2	+	+	+	+	+	+	++	+		+	+	+	+	+	+	+	+	++		+	++	+	++	+	++	++	+	+	++	++	+	+	+	++	++	o	++	+	+	++	++	+	+	+
TKIPO3	++	++	+	++	++	++	++	++		+	+	o	+	++	++	++	+	+		o	+	o	+	+	++	o	+	o	o	+	o	o	++	+	+	o	+	+	+	o	o	o	o	o
TKIPO4	o	o	o	+	+	+	o	o		o	o	o	o	++	+	++	+	o		o	+	o	o	o	o	o	o	+	o	++	o	++	o	++	+	+	o	+	+	o	++	o	o	
TKIPO5	o	o	+	o	+	o	+	+		+	+	o	o	o	+	o	++	+		++	++	++	+	+	o	o	++	o	+	++	+	++	+	+	+	+	o	o	+	o	+	++	+	
TKIPO6	++	++	+	++	++	++	++	++		++	++	++	++	++	++	++	++	+		+	o	+	+	+	o	o	+	o	+	+	o	o	+	+	+	+	+	o	o	+	o	+	++	+
TKIPO7	+	+	++	++	++	++	++	++		+	+	+	+	+	+	+	o	++		++	++	++	++	++	+	+	++	++	++	++	+	++	++	++	++	o	+	o	++	++	+	++	++	++
TKIPO8	o	o	+	o	o	+	o	+		+	++	++	++	+	+	+	+	o		+	++	+	+	+	+	+	+	+	+	o	+	+	+	+	+	+	+	o	o	+	o	+	+	
TKIPO9	++	++	++	++	++	++	++	++		++	++	++	++	+	+	++	++			+	++	++	++	++	++	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Source: Own elaboration.

Table 12: Consistency analysis between category 2 “TK and Intellectual Property Rights” and categories 3, 4 (Matrix 2)

Code	TKBRU01	TKBRU02	TKBRU03	TKBRU04	TKBRU05	TKBRU06	TKBRU07	TKBRU08	TKBRU09		TKCH01	TKCH02	TKCH03	TKCH04	TKCH05	TKCH06	TKCH07	TKCH08	TKCH09	TKCH10	TKCH11	TKCH12	TKCH13	TKCH14	TKCH15	TKCH16	TKCH17	TKCH18	TKCH19	TKCH20	TKCH21	TKCH22	TKCH23	TKCH24	TKCH25						
TKIPRO1	+	+	+	o	+	+	+	+	o		o	+	o	+	+	o	o	+	o	+	o	o	o	o	+	+	o	+	o	o	o	o	o	+	o	+	o	+	+		
TKIPRO2	+	+	+	o	+	+	+	+	o		o	+	o	+	+	o	o	+	o	+	o	o	o	o	+	+	o	+	o	o	o	o	o	+	o	+	o	+	+		
TKIPRO3	++	++	++	++	+	+	+	++	+		+	+	+	++	++	+	+	+	+	+	+	+	+	+	+	o	o	+	o	+	++	+	+	+	+	+	+	+	+	+	
TKIPRO4	++	+	+	+	++	++	++	+	+		+	+	o	++	++	+	o	+	+	+	o	o	+	+	+	+	+	o	o	o	o	+	+	+	+	+	+	+	+	+	+
TKIPRO5	++	++	+	++	+	++	++	+	++		o	o	o	+	+	o	o	+	o	o	o	o	o	o	o	+	+	++	o	++	++	+	o	+	+	+	o	+	+	++	
TKIPRO6	++	+	+	+	+	++	++	++	o		o	+	o	+	+	o	o	o	o	o	o	o	o	o	o	+	+	o	o	+	+	o	o	o	o	o	+	+	+	+	+
TKIPRO7	++	+	+	+	+	+	++	+	o		o	+	o	+	+	o	o	+	o	o	o	o	o	+	+	o	+	o	o	+	o	+	o	+	+	+	+	+	+	+	+
TKIPRO8	++	+	+	+	+	+	++	+	o		o	+	o	+	+	o	o	+	o	o	o	o	+	+	o	+	+	o	o	+	o	+	o	+	+	+	+	+	+	+	+

Source: Own elaboration.

Table 13: Consistency analysis between categories 3 “TK and the use of biological resources” and 4 “TK as cultural heritage” (Matrix 3)

Code	TKCH01	TKCH02	TKCH03	TKCH04	TKCH05	TKCH06	TKCH07	TKCH08	TKCH09	TKCH10	TKCH11	TKCH12	TKCH13	TKCH14	TKCH15	TKCH16	TKCH17	TKCH18	TKCH19	TKCH20	TKCH21	TKCH22	TKCH23	TKCH24	TKCH25
TKBRU01	+	++	++	++	++	+	+	++	+	o	+	o	+	++	+	+	+	+	++	+	+	o	+	+	++
TKBRU02	+	+	o	o	o	o	o	o	o	o	+	o	++	+	+	+	o	o	+	+	o	o	o	+	+
TKBRU03	o	+	+	+	+	o	o	o	o	+	+	o	+	+	+	+	o	+	o	+	o	o	o	+	+
TKBRU04	o	+	+	+	+	o	o	o	o	+	+	+	+	+	+	+	+	o	o	+	+	o	+	+	+
TKBRU05	o	++	o	+	+	o	o	o	o	+	o	o	o	+	o	+	o	o	+	o	o	o	+	o	+
TKBRU06	o	+	o	+	+	o	o	+	o	+	o	o	o	++	+	+	o	o	+	o	+	o	+	+	+
TKBRU07	o	+	o	+	+	o	o	+	+	+	o	o	o	++	+	+	o	o	o	+	o	o	+	+	+
TKBRU08	+	o	+	o	o	o	o	o	o	o	+	o	+	o	+	++	o	+	+	o	+	o	o	++	o
TKBRU09	++	+	++	++	+	+	o	o	o	o	o	+	+	o	+	++	+	++	+	++	+	o	+	o	+

Source: Own elaboration.

Table 14: Consistency results of category 1 “TK as Indigenous peoples’ rights” with the other three categories

Code	++	+	o	%	%	%
TKIP01	13	24	5	31	57	12
TKIP02	13	28	1	31	67	2.4
TKIP03	12	17	13	29	40	31
TKIP04	7	11	24	17	26	57
TKIP05	9	19	14	21	45	33
TKIP06	15	18	9	36	43	21
TKIP07	25	14	3	60	33	7.1
TKIP08	4	26	12	9.5	62	29
TKIP09	24	16	2	57	38	4.8
<i>Average</i>	14	19	9	32	46	22

Source: Own elaboration.

Table 14 shows the consistency between each policy of category 1 and the policies of the other three categories. According to the averages, the highest number of matches that category 1 has with the other three categories is found in the “consistent” key with 46%. It means that, in general, the policies related to TK protection as an Indigenous right are “consistent” with the rest of the policies selected for the analysis. The numbers highlighted in blue represent the top three policies that are “consistent” of category 1 (TKIP02, TKIP08, and TKIP01). The colour blue is darker in the number one “consistent” policy of the whole category (TKIP02).

Table 14 also shows that 32% of the policies mentioned in category 1 are “very consistent” with those of the other three categories. The numbers highlighted in pink represent the top three policies that are “very consistent” of category 1 (TKIP07, TKIP09, and TKIP06). The pink colour is darker in the policy that obtained the highest score for the parameter “very consistent” (TKIP07).

Table 15: Consistency results of category 2 “TK and Intellectual Property Rights” with the other three categories

Code	++	+	o	%	%	%
TKIPRO1	3	20	20	7	47	47
TKIPRO2	3	19	21	7	44	49
TKIPRO3	10	28	5	23	65	12
TKIPRO4	10	23	10	23	53	23
TKIPRO5	15	14	14	35	33	33
TKIPRO6	8	15	20	19	35	47
TKIPRO7	8	19	16	19	44	37
TKIPRO8	6	22	15	14	51	35
<i>Average</i>	8	20	15	18	47	35

Source: Own elaboration.

Table 15 shows the consistency between each policy of category 2 and the policies of the other three categories. According to the averages, the highest number of matches

that category 2 has with the other three categories is found in the “consistent” key with 47%. It means that, in general, the policies related to TK and intellectual property rights are “consistent” with the rest of the policies selected for the analysis. The numbers highlighted in blue represent the top three policies that are “consistent” of category 2 (TKIPR03, TKIPR04, and TKIPR08). The colour blue is darker in the number one “consistent” policy of the whole category (TKIPR03).

Table 15 also shows that 35% of policies mentioned in category 2 are “neutral” concerning the other three categories. On the other hand, just 18% of them are “very consistent.” The numbers highlighted in pink represent the top three policies that are “very consistent” of category 2 (TKIPR05, TKIPR03/TKIPR04, and TKIPR06/TKIPR07). The pink colour is darker in the policy that obtained the highest score for the parameter “very consistent” (TKIPR05).

Table 16: Consistency results of category 3 “TK and the use of biological resources” with the other three categories

Code	++	+	o		%	%	%
TKBRU01	16	22	4		38	52	9.5
TKBRU02	6	21	15		14	50	36
TKBRU03	4	24	14		9.5	57	33
TKBRU04	5	25	12		12	60	29
TKBRU05	5	20	17		12	48	40
TKBRU06	6	24	12		14	57	29
TKBRU07	10	19	13		24	45	31
TKBRU08	7	19	16		17	45	38
TKBRU09	10	17	15		24	40	36
<i>Average</i>	8	21	13		18	51	31

Source: Own elaboration.

Table 16 shows the consistency between each policy of category 3 and the policies of the other three categories. According to the averages, the highest number of matches that category 3 has with the other three categories is found in the “consistent” key with 51%. It means that, in general, the policies related to TK and the use of biological resources are “consistent” with the rest of the policies selected for the analysis. The numbers highlighted in blue represent the top three policies that are “consistent” of category 3 (TKBRU04, TKBRU03/TKBRU06, and TKBRU01). The colour blue is darker in the number one “consistent” policy of the whole category (TKBRU04).

Table 16 also shows that 31% of policies mentioned in category 3 are “neutral” concerning the other three categories. On the other hand, just 18% is “very consistent”. The numbers highlighted in pink represent the top three policies that are “very consistent” of category 3 (TKBRU01, TKBRU07/TKBRU09, and TKBRU08). The pink colour is darker in the policy that obtained the highest score for the parameter “very consistent” (TKBRU01).

Table 17: Consistency results of category 4 “TK as cultural heritage” with the other three categories

Code	++	+	o	%	%	%
TKCH01	3	10	13	12	38	50
TKCH02	8	15	3	31	58	12
TKCH03	6	7	13	23	27	50
TKCH04	7	16	3	27	62	12
TKCH05	5	18	3	19	69	12
TKCH06	3	7	16	12	27	62
TKCH07	1	5	20	3.8	19	77
TKCH08	4	15	7	15	58	27
TKCH09	1	8	17	3.8	31	65
TKCH10	3	14	9	12	54	35
TKCH11	3	11	12	12	42	46
TKCH12	1	6	19	3.8	23	73
TKCH13	3	13	10	12	50	38
TKCH14	8	12	6	31	46	23
TKCH15	4	17	5	15	65	19
TKCH16	7	17	2	27	65	7.7
TKCH17	1	8	17	3.8	31	65
TKCH18	2	12	12	7.7	46	46
TKCH19	3	13	10	12	50	38
TKCH20	4	11	11	15	42	42
TKCH21	5	12	9	19	46	35
TKCH22	2	4	20	7.7	15	77
TKCH23	2	19	5	7.7	73	19
TKCH24	4	15	7	15	58	27
TKCH25	4	19	3	15	73	12
<i>Average</i>	4	12	10	14	47	39

Source: Own elaboration.

Table 17 shows the consistency between each policy of category 4 and the policies of the other three categories. According to the averages, the highest number of matches that category 4 has with the other three categories is found in the “consistent” key with 47%. It means that, in general, the policies related to TK as cultural heritage are “consistent” with the rest of the policies selected for the analysis. The numbers highlighted in blue represent the top three policies that are “consistent” of category 4

(TKCH23/TKCH25, TKCH05, and TKCH15/TKCH16). The colour blue is darker in the number one “consistent” policies of the whole category (TKCH23/TKCH25).

Table 17 also shows that 39% of policies mentioned in category 4 are “neutral” concerning the other three categories. On the other hand, just 14% of them are “very consistent.” The numbers highlighted in pink represent the top three policies that are “very consistent” of category 3 (TKCH02/TKCH14, TKCH04/TKCH16, and TKCH03). The pink colour is darker in the policy that obtained the highest score for the parameter “very consistent” (TKCH02/TKCH14).

After carrying out this third step of the analysis, it can be concluded that the methodology used was sufficiently helpful to identify the consistency between each of the selected policies. Thus, it can be observed that category 1 “TK as Indigenous peoples’ rights”, since it contains general policies on TK safeguarding, is the one that had more coincidences in the “very consistent” parameter. In contrast, since they are related to a specific topic, the other three categories are not “very consistent” but are nonetheless “consistent” among themselves.

3.1.4 Step 4: To recognize the most frequently mentioned concerns related to TMPK safeguarding

The results obtained in the previous step (Tables 14, 15, 16, and 17) were combined in a single table to complete this step. The first column of Table 18 shows the policies in descending order according to the “very consistent” parameter. According to the approach of this study, the best scored in the “very consistent” parameter contains the most internationally mentioned concerns about safeguarding traditional knowledge in a potential BioTrade context.

The second column of Table 18 shows the principal subjects of safeguarding (those related to TMPK). It should be mentioned that, as explained in Step 2, most are synonyms of the term “traditional knowledge” or, on the other hand, terms that somehow contain the “traditional knowledge” and “traditional medicinal plant knowledge” concepts (see Figure 14). In green can be seen the subjects that are directly related to TMPK. Thus, the TMPK safeguarding is stated in three of the top 5 international concerns.

In column 3, all actions were gathered, which, in one way or another, contribute to the safeguarding of TK to identify the ones most required in international agreements; many of them can be interpreted as synonyms. However, it is essential to understand their meaning in the context of the present research.

Thus, the meaning of the mentioned verbs are as follows:

- To recognize: to accept something officially (Cambridge University, 2013).
- To respect: to pay attention to something (Cambridge University, 2013).
- To maintain/preserve: to keep something in good condition (Cambridge University, 2013).
- To protect/conservate: to prevent the harm or destruction of something (Cambridge University, 2013).
- To develop: to convert to a new purpose or make other use of it (Cambridge University, 2013).
- To control/manage: to be in charge of something (Cambridge University, 2013).
- To promote/foment: to support or actively encourage the progress of something (Cambridge University, 2013).

Table 18: Most frequently mentioned concerns related to TMPK, subjects of safeguarding, and core recommendations

Code	++	Issues Raised and Points Made related to Traditional Knowledge				To Safeguard					Recommendations		
		Subjects				to recognize	to respect	to maintain / preserve	to protect / conserve	to develop		to control / manage	to promote / foment
TKIP07	60	cultural traditions and customs		ceremonies				x	x	x			Indigenous peoples rights
TKIP09	57	cultural heritage	traditional knowledge	traditional medicine	genetic resources			x	x	x	x		Intellectual property rights
TKBRU01	38	indigenous knowledge	indigenous practices	innovations	biological diversity			x	x				National legislation, knowledge holders involvement, equitable benefits sharing
TKIP06	36	traditional knowledge		biological and genetic resources			x				x		Policies for access and use
TKIPR05	35	traditional cultural expressions					x		x			x	National legislation, intellectual property system
TKIP01	31	socio-cultural identity		cultural traditions and customs			x					x	
TKIP02		social, cultural, religious and spiritual values and practices				x			x				Recognizing the problems of indigenous groups and individuals
TKCH02		folk traditions		transmitters					x				Measures to guarantee the status and economic support
TKCH14		intangible cultural heritage						x		x		x	Involving communities in management
TKIP03		29	spirituality and beliefs									x	
TKCH04	27	manifestations of intellectual creativity						x	x	x		x	Intellectual property rights
TKCH16		diversity and value of cultural expressions					x					x	
TKBRU07	24	traditional knowledge associated with genetic resources							x		x		Legislative, administrative or policy measures
TKBRU09		agricultural heritage systems	agricultural knowledge	landscape	biodiversity	x			x		x	x	Enhancing viability and benefits
TKIPR03	23	medicinal knowledge		medicinal resources					x			x	Researching
TKIPR04		traditional cultural expressions									x		Intellectual property system
TKCH03		folklore	cultural identity	cultural heritage		x			x			x	Avoiding distortion during dissemination
TKIP05	21	traditional knowledge	traditional technologies	cultural aspirations		x				x		x	Education programmes
TKIPR06	19	customary laws and practices		traditional cultural expressions				x	x	x	x		Legislative, administrative or policy measures, equitable benefits' sharing
TKIPR07		sacred and secret traditional cultural expressions					x		x		x		
TKCH05		intangible cultural heritage				x	x	x	x	x	x	x	National measures
TKCH21		indigenous cultural expressions								x	x	x	Paying attention to the needs of indigenous peoples
TKIP04	17	social, spiritual, cultural and environmental aspects				x							Researching in cooperation with communities, identifying impacts
TKBRU08		traditional knowledge associated with genetic resources							x		x		Measures to access and benefit sharing

TKCH08	15	intangible cultural heritage			x	x	x	x	x	x	Planning programmes	
TKCH15		cultural expressions						x		x		
TKCH20		cultural diversity					x	x			x	Thinking about present and future generations (sustainable development)
TKCH24		diversity of cultural expressions						x			x	Education and public awareness programmes
TKCH25		diversity of cultural expressions						x			x	Integrating culture in development policies
TKIPR08	14	traditional knowledge	cultural norms and practices	moral rights	traditional cultural expressions		x	x	x		x	National legal, policy and/or administrative measures
TKBRU02		customary use of biological resources		traditional cultural practices				x	x		x	Measures for sustainability
TKBRU06		traditional knowledge associated with genetic resources									x	Mechanisms to inform potential users about their obligations, equitable benefits' sharing, community participation
TKBRU04		indigenous and local knowledge	health care/food security	innovations and practices associated with plant resources				x		x		
TKBRU05	traditional knowledge associated with genetic resources									x	Measures in domestic law	
TKCH01	12	folk traditions			x		x					Documenting traditions
TKCH06		elements of intangible cultural heritage			x							Communities and nongovernmental organizations working together
TKCH10		intangible cultural heritage			x	x	x	x	x	x	x	Fostering scientific, technical and artistic studies, as well as research methodologies
TKCH11		intangible cultural heritage			x	x			x			Education programmes
TKCH13		natural spaces and places of memory needed for expressing intangible cultural heritage						x			x	Education programmes
TKCH19		cultural aspects					x				x	Recognizing their importance for development
TKIP08		traditional medicine		health practices/procedures				x	x		x	Indigenous peoples rights
TKBRU03	indigenous and local knowledge related to plants and genetic diversity of crops					x	x	x			Conservation programs for plants	
TKCH18	8	cultural activities, goods and services as means of identity			x							Establishing values and meanings
TKCH22		cultural expressions			x			x				Defining those under risk of extinction
TKCH23		cultural expressions						x				Appropriate measures
TKIPR01		technologies or products locally developed for industry						x				Patents
TKIPR02	7	processes for the production of plants		plants varieties				x			Patents/sui generis system	
TKCH07	4	intangible cultural heritage			x							Generating inventories
TKCH09		intangible cultural heritage			x	x	x	x	x	x		Establishing a competent governmental body
TKCH12		intangible cultural heritage			x			x				Provide information of the dangers and threats
TKCH17		culture									x	Promoting the importance of culture for development

Source: Own elaboration based on ILO (1989), UN (1992, 2002, 2007), WTO (1994), UNESCO (1989, 2003, 2005), FAO (2008), WHO (2014), WIPO (2019).

After conducting step 4 of this analysis, it can be concluded that safeguarding TMPK is a primary international concern, which underpins this research. Moreover, although all the selected policies contribute to safeguarding TMPK, the suggested actions (expressed as verbs) to achieving this goal are different and should have an accurate interpretation to be effective in reality.

3.1.5 Step 5: To determine the key recommendations suggested ensuring the safeguarding of TMPK

For this step, it was necessary to identify the recommendation that each of the policies selected for analysis proposes safeguarding the TK and, consequently, the TMPK. According to the context of each policy, some of the observed recommendations tend to be very general, which means that in reality, they could be challenging to achieve without a specific program to implement and monitor them (Mayntz, 1983; Attai, et al., 2012).

The last column of Table 18 shows the different recommendations highlighted with specific colors to group those related or similar recommendations in Table 19. Thus, seven key recommendations were found, and since they could be applied in different contexts where TK is threatened or in danger, for this research, they were explicitly contextualized for the safeguarding of TMPK and categorized according to their application into general and specific (see Table 19).

At the outset of the analysis, four categories of international agreements were established, as it was inferred that each category would propose clear recommendations on a specific topic (see Figure 12). However, upon reviewing each policy in-depth, it was identified that these are not specialized policies, as could be presumed from reading the agreement's title. Several policies of different categories propose similar recommendations but use different terms (see Table 18).

Table 19: Key recommendations summarised from Table 18 and contextualized in terms of TMPK

Key Recommendations			
Code	General	Code	Specific
TKIP06 TKIPR05 TKIPR06 TKIPR08 TKBRU01 TKBRU02 TKBRU05 TKBRU06 TKBRU07 TKBRU08 TKBRU09 TKCH02 TKCH05 TKCH08 TKCH09 TKCH23 TKCH25	1. Establishing a governmental body, national legislations, policies and measures to protect TMPK and control its use for sustainable development	TKIP04 TKIPR03 TKCH01 TKCH07 TKCH10 TKCH18 TKCH22	2. Implementing scientific research programs and methodologies to identify the TMPK present in a community and the impacts that external activities have on it.
TKIP02 TKCH21 TKIP07 TKIP08	3. Recognizing the protection of the TMPK as an indigenous peoples' right	TKIP09 TKIPR01 TKIPR02 TKCH04 TKBRU03	4. Implementing conservation programmes for plants and establishing the protection of the TMPK as an intellectual property right
TKCH17 TKCH19 TKCH20	5. Recognizing the importance of TMPK for communities' development	TKIP03 TKCH06 TKCH14 TKIP05 TKCH03 TKCH11 TKCH12 TKCH13 TKCH24	6. Involving and empowering communities in TMPK management for development 7. Implementing education and public awareness programs to promote TMPK safeguarding avoiding the distortion of this knowledge.

Source: Own elaboration.

After obtaining the results of this step, it can be concluded that international agreements related to the safeguarding of traditional knowledge need to standardize the terms and concepts used in their recommendations and that these should be more focused. As mentioned before, this will allow their implementation at the plans/programmes level to be more effective.

It is precisely for this reason that this study has attempted to standardize both the concepts and the recommendations in order to be able, in the next step, to contrast the selected policies with the principles and criteria of the BioTrade program proposed by UNCTAD and further on to achieve the last specific objective of this research: the proposal of new criteria and indicators for BioTrade Principles.

3.1.6 Step 6: To review the compatibility between international selected policies and BioTrade principles and criteria

As mentioned in the theoretical framework, the BioTrade Initiative is a programme proposed by the United Nations Conference on Trade and Development that supports sustainable development through trade and investment in biological resources (UNCTAD, 2005).

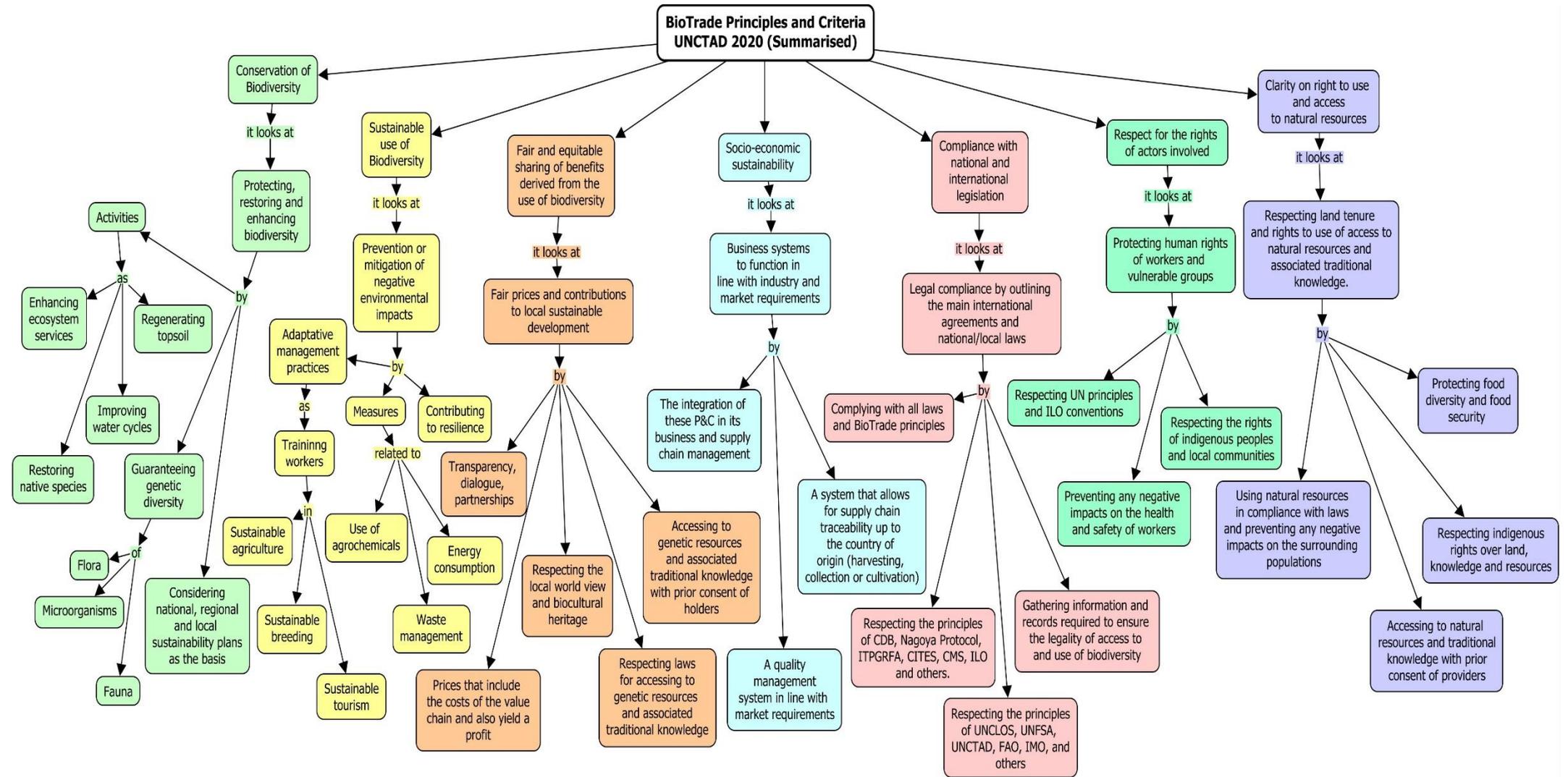
Companies, governments, and other interested parties apply the principles to conduct the provisioning, production, and trade of goods and services derived from native biodiversity (ecosystems, species, and genetic resources) in accordance with environmental, economic, and social sustainability criteria (UNCTAD, 2020). These criteria, known as the BioTrade Principles and Criteria (P&C), formed the core basis guiding the implementation of UNCTAD's BioTrade Initiative activities, programs, and other related actions since its launch in 2007 (UNCTAD, 2020).

Figure 13 is a graphical summary of the seven current BioTrade principles and their respective evaluation criteria. The intention is to simplify the information presented in the theoretical framework (see Table 1) to better understand Table 20.

Table 20 shows the existing relationship between BioTrade P&C and the policies selected for the analysis. This comparison intends to identify possible gaps that hinder BioTrade P&C from being a tool to facilitate the assessment of the impact of trade on TMPKs.

It should be mentioned that BioTrade principles that were analyzed in Table 20 were selected according to the screening and scoping process represented in Figure 9. Thus, the only principle that was not considered for the comparison was principle number 4 "Socio-economic sustainability" due to the fact that it has no direct or indirect relationship with TMPK.

Figure 13: Summary of BioTrade principles and criteria



Source: Own elaboration based on UNCTAD 2020 (see Table 1).

Table 20: A review of the compatibility between international policies for the safeguarding of TMPK and BioTrade principles and criteria

Actions for the Safeguarding of Traditional Medicinal Plant Knowledge	BioTrade Principles 2020													
	1. Conservation of biodiversity	Code	2. Sustainable use of biodiversity	Code	3. Fair and equitable sharing of benefits derived from the use of biodiversity	Code	4. Socio-economic sustainability	5. Compliance with national and international legislation	Code	6. Respect for the rights of actors involved in BioTrade activities	Code	7. Clarity on right to use and access to natural resources	Code	
Existing	Criterion 1.2: Genetic variability of flora is maintained, restored and promoted	TKIPO9 TKBRU01 TKBRU03	Criterion 2.1: Adaptive management practices, supported by training producers and workers in sustainable processes (agriculture, tourism)	TKBRU09	Criterion 3.3: Activities contribute to sustainable local development, as defined by producers and their local communities (respecting world view).	TKIPO3 TKIPRO8 TKCH17	not applicable	Criterion 5.2: Activities respect the principles and obligations of relevant international agreements and instruments such as the CBD, the Nagoya Protocol, the International Labour Organization (ILO) Conventions, the United Nations Declaration on the Rights of Indigenous Peoples.	TKIPO1 TKIPO2 TKIPO3 TKIPO4 TKIPO5 TKIPO7 TKIPO8 TKIPO9 TKBRU01 TKBRU02 TKBRU05 TKBRU06 TKBRU07 TKBRU08	Criterion 6.3: The organization respects the rights of indigenous peoples and local communities.	TKIPO1 TKIPO2 TKIPO3 TKIPO4 TKIPO5 TKIPO7 TKIPO8 TKIPO9	Criterion 7.2: In cases where required the organization accesses natural resources and associated traditional knowledge with prior informed consent of, and subject to mutually agreed terms with, the party that provides them.	TKIP06 TKIPRO6 TKBRU02 TKBRU05 TKBRU06 TKBRU07 TKBRU08 TKCH19	
					Criterion 3.4: Respecting laws for accessing to genetic resources and associated traditional knowledge.	TKIPO6 TKIPRO6 TKBRU02 TKBRU05 TKBRU06 TKBRU07 TKBRU08 TKCH19						Criterion 7.3: The organization respects the rights of indigenous peoples and local communities over land, natural resources, and associated traditional knowledge in accordance with national legislation and the United Nations Declaration on the Rights of Indigenous Peoples	TKIP01 TKIP02 TKIP03 TKIP04 TKIP05 TKIP07 TKIP08 TKIP09	
					Criterion 3.5: Accessing to genetic resources and associated traditional knowledge with prior consent of holders.									
Gaps	1. Inventory of medicinal plants and the traditional knowledge related to them (involving communities and NGOs).	TKIPO4 TKCHO1 TKCHO6 TKCHO7	1. Generating educational programmes to producers and workers about the traditional knowledge, values, technologies and uses related to medicinal plants and their production.	TKIPO5 TKBRU02 TKBRU06 TKBRU09 TKCHO8 TKCH11 TKCH24	not applicable	1. Respecting other international agreements such as the Universal Declaration on Bioethics and Human Rights, the Agreement on Trade Related-Aspects of Intellectual Property Rights; the WHO Traditional Medicine Strategy; the WIPO Draft Articles about the Protection of Traditional Cultural Expressions; the Global Strategy for Plant Conservation; the Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems agreement; the UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore; the Convention on the Protection and Promotion of the Diversity of Cultural Expressions and the Convention for the Safeguarding of the Intangible Cultural Heritage.	TKIPO6 TKIPRO1 TKIPRO2 TKIPRO3 TKIPRO4 TKIPRO5 TKIPRO6 TKIPRO7 TKIPRO8 TKBRU03 TKBRU04 TKBRU09 TKCH01 to TKCH25							
	2. Categorising native, sacred and endangered medicinal plants (endangered TMPK).	TKIPO4 TKCH18 TKCH22	2. Fostering intergenerational transmission of traditional medicinal plant knowledge (values, technologies and uses) among the community.	TKCHO3 TKCH11 TKCH13										
	3. Fostering scientific research to support traditional medicinal uses.	TKIPRO3 TKCH10	3. Establishing education and training programmes for using native, sacred and endangered medicinal plants species.	TKIPO6 TKBRU04										

Source: Own elaboration based on (UNCTAD, 2020).

In Table 20, BioTrade P&C are represented with colors (the same colors used in Figure 13). Each principle and its corresponding criteria related to TMPK safeguarding were compared with the recommendations observed in Table 17. In this way, the current contribution of the P&C to the safeguarding of TMPK was identified as well as the existing gaps that need to be addressed for the purposes of this research. Thus, the policies supporting the existing contributions, as well as those suggesting the existence of gaps, have been represented with the codes stipulated in Tables 6, 7, 8 and 9.

The main findings of Step 6 are described below and explained according to each principle:

- Principle 1: Conservation of Biodiversity

The criterion that contributes to the safeguarding of the TMPK is number 1.2: *Genetic variability of flora is maintained, restored, and promoted*. The policies that support this criterion are TKIP09, TKBRU01, TKBRU03.

The fact that the mentioned policies support criterion 2.1 allows concluding that there is a clear contribution to safeguarding the TMPK. In this case, the contribution is indirect. It does not focus on the knowledge but instead on flora conservation. Thus, by ensuring the conservation of medicinal plants, the traditional knowledge related to them is also safeguarded (Panda, 2015).

However, it is necessary to know in depth the subject to be conserved when talking about conservation. Therefore, the analyzed policies suggest:

1. To draw up an inventory of medicinal plants and the traditional knowledge related to these (supported by TKCH07, TKCH01, TKIP04, TKCH06).
2. To establish categories to prioritize the care of certain species (native, sacred, or in danger of extinction) (supported by TKCH22, TKCH18, TKIP04).
3. To promote scientific research to verify the current TMPK (supported by TKCH10, TKIPR03).

- Principle 2: Sustainable Use of Biodiversity

The criterion that contributes to the safeguarding of the TMPK is number 2.1: *Adaptative management practices, supported by training producers and workers in sustainable processes*. The policy supporting this criterion is TKBRU09, which mainly focuses on agriculture systems and indirectly on agrotourism, two activities related to the commercialization of medicinal plants. Therefore, this criterion's contribution for TMPK safeguarding is to ensure that both producers and all workers involved in the trade of medicinal plants are aware of the importance of these and use the proper agricultural and medicinal plant management practices for their diversity conservation and protection (Shahrajabian, et al., 2019).

Although it is important to educate about sustainable practices, the reasons why the biological and genetic diversity of medicinal plants should be conserved is also a matter to consider (Gomez-Flores & Tamez-Guerra, 2011). In addition, the community should be included in these initiatives, as it is also a stakeholder in the process of commercialization of medicinal plants (Calvano, 2008). Therefore, the analyzed policies suggest:

1. To educate producers and workers involved in the medicinal plant trade about the traditional knowledge, values, uses, and technologies related to the medicinal plants being traded (supported by TKIP05, TKCH08, TKCH24, TKCH11, TKBRU09, TKBRU02, TKBRU06).
2. To foster the intergenerational transmission of traditional medicinal plant knowledge (values, technologies, and uses) among the community members (supported by TKCH03, TKCH13, TKCH11).
3. To establish education and training programmes to promote the sustainable use of native, sacred, and endangered medicinal plant species (supported by TKIP06, TKBRU04).

- Principle 3: Fair and equitable sharing of benefits derived from the use of biodiversity

The criteria that contribute to the safeguarding of the TMPK are number 3.3: *Activities contribute to sustainable local development, as defined by producers and their local communities (respecting world view)* (supported by TKIP03, TKIPR08, TKCH17); number 3.4: *Respecting laws for accessing to genetic resources and*

associated traditional knowledge and number 3.5: *Accessing to genetic resources and associated traditional knowledge with the prior consent of holders*. (both supported by TKIP06, TKBRU07, TKIPR06, TKBRU08, TKBRU02, TKBRU06, TKBRU05, TKCH19).

The contribution that criterion 3.3 has for TMPK safeguarding is that it promotes respect for cultural beliefs and communities' worldview in trade practices, which means that the trade of medicinal plants should consider and respect the knowledge related to them. On the other hand, criteria 3.4 and 3.5 contribute by encouraging the regulation when accessing and using traditional knowledge related to genetic resources, including medicinal plants and, therefore, TMPK. Moreover, both criteria promote equitable sharing with communities of benefits derived from biological resource use (medicinal plant trade).

It is relevant to note that this principle (number 3) is the one that contributes the most to the safeguarding of the TMPK since it refers directly to the impact that the trade of biological resources may have on traditional knowledge. In addition, the analysis showed that it complies with international recommendations, and no gaps were found.

- Principle 5: Compliance with international and national legislation

The criterion that contributes to the safeguarding of the TMPK is number 5.2: *Activities respect the principles and obligations of relevant international agreements and instruments such as the CBD, the Nagoya Protocol, the International Labour Organization (ILO) Conventions, the United Nations Declaration on the Rights of Indigenous Peoples*. The policies supporting this criterion are TKIP01, TKIP02, TKIP03, TKIP04, TKIP05, TKIP07, TKIP08, TKIP09, TKBRU01, TKBRU02, TKBRU05, TKBRU06, TKBRU07, and TKBRU08, which are policies taken precisely from the international agreements mentioned in criterion 5.2.

For the purposes of this research, this criterion is the most significant since it is the basis for the analysis, and it is therefore essential that the international agreements are duly contextualized and complied with at the local level. Moreover, although the analysis shows that many of these agreements are complied with to evaluate trade

in biological resources in general, there are still some other international treaties to consider when dealing with trade in traditional medicinal plants.

Consequently, it is suggested that in order to safeguard the TMPK in a BioTrade context, the following international agreements (in addition to those mentioned in the criterion) should be respected: the Universal Declaration on Bioethics and Human Rights, the Agreement on Trade Related-Aspects of Intellectual Property Rights; the WHO Traditional Medicine Strategy; the WIPO Draft Articles about the Protection of Traditional Cultural Expressions; the Global Strategy for Plant Conservation; the Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems agreement; the UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore; the Convention on the Protection and Promotion of the Diversity of Cultural Expressions and the Convention for the Safeguarding of the Intangible Cultural Heritage. It is, therefore, necessary to generate a tool that establishes the specific standards taken from the aforementioned international agreements and that allows constant monitoring of this compliance.

- Principle 6: Respect for the rights of actors involved

The criterion that contributes to the safeguarding of the TMPK is number 6.3: *The organization respects the rights of Indigenous peoples and local communities*. The policies supporting this criterion are TKIP01, TKIP02, TKIP03, TKIP04, TKIP05, TKIP07, TKIP08, and TKIP09, which are policies taken precisely from the international agreements related to Indigenous peoples' rights since, according to this research, they are the principal stakeholders within the BioTrade of traditional medicinal plants.

This criterion (6.3) contributes to the TMPK safeguarding since, according to the analysis previously developed, the protection of traditional knowledge related to biological resources is an inalienable right of Indigenous peoples and communities. However, the same analysis showed that compliance with all the international agreements discussed in this research (and mentioned in principle 5) are directly or indirectly related to the rights of Indigenous communities, and therefore should also be considered and compliant.

- Principle 7: Clarity on the right to use and access to natural resources

The criteria that contribute to the safeguarding of the TMPK are number 7.2: *In cases where required the organization accesses natural resources and associated traditional knowledge with the prior informed consent of, and subject to mutually agreed terms with, the party that provides them* (supported by TKIP06, TKBRU07, TKIPR06, TKBRU08, TKBRU02, TKBRU06, TKBRU05, and TKCH19); and number 7.3: *The organization respects the rights of Indigenous peoples and local communities over land, natural resources, and associated traditional knowledge in accordance with national legislation and the United Nations Declaration on the Rights of Indigenous Peoples* (TKIP01 TKIP02 TKIP03 TKIP04 TKIP05 TKIP07 TKIP08 TKIP09).

The contribution that criterion 7.2 has for TMPK safeguarding is related to that of criteria 3.3, 3.4, and 3.5 since they all relate directly to the control of access and use of traditional knowledge related to biological resources. On the other hand, the contribution of criterion 7.3 relates to that of criterion 6.3 since both emphasize respect for Indigenous rights, although, in the case of criterion 7.3, care for traditional knowledge is literally mentioned as a right of these groups.

It is relevant to note that since these criteria (7.2 and 7.3) are very similar to others previously analyzed, therefore, they do not present additional contributions or gaps that have not been previously identified.

After contrasting the BioTrade principles and criteria with the selected policies, it was found that, in general, there is some contribution to safeguarding the TMPK in the criteria already established even when, in some cases, they lack clarity, and it is evident that they are repetitive in different principles. The unclear content of the current criteria that were analyzed, and the gaps found in the six principles studied, are solid reasons to consider the need to develop a standard for the BioTrade of medicinal plants that allows the safeguarding of TMPK.

3.2 Analysis of the current situation of TMPK and the impact that BioTrade has on it according to expert opinion

During the interviews with the experts, various topics were discussed, especially those related to the current situation of TMPK in real community contexts, to complement the information obtained in the literature review. The following are the most relevant topics for the research (the complete information can be found in the annexes).

3.2.1 TMPK is a significant resource for the sustainable development of Indigenous communities.

TMPK is the basis of the communities' identity, but it is also their own pharmacy. The use of medicinal plants allows not only the health care of the community but also the opening of markets and the development of pharmaceutical products that constitute economic income to improve the lifestyle of these communities. However, both empowerment of the community and protection measures for the TMPK are required to make the commercial use of this knowledge sustainable (Hernández, 2021; López, 2021).

3.2.2 Importance of safeguarding the TMPK as part of intangible cultural heritage from a public policies approach.

The TMPK as part of the intangible cultural heritage is of paramount importance in the political environment, especially in recent times when the great vulnerability of Indigenous peoples has become evident. Unfortunately, not all countries have public policies or legislative measures that control its use or promote its safeguarding (Hernández, 2021; López, 2021).

In the case of Peru, there is a law in force (No. 27811) that seeks the protection of traditional knowledge related to biological resources and although a strategy for the safeguarding of traditional knowledge has been formulated at the national level, it has not yet been implemented (Hernández, 2021).

On the other hand, in the particular case of Ecuador, several efforts have been made to improve public policies related to the rights of Indigenous peoples, however, there

is no specific law to safeguard TMPK, and although there are some codes of ethics to control pharmaceutical products based on medicinal plants, some of them favor transnationals more than Indigenous communities (López, 2021).

3.2.3 The need for an instrument that contributes to the safeguard of TMPK in a BioTrade context.

The necessity of controlling the commercial activity of medicinal plants is urgent. In the absence of other instruments that can assess the impacts of BioTrade on TMPK, it is urgent to implement a measure, both national and international, that goes hand in hand with the participation and empowerment of Indigenous peoples in commercial projects (Hernández, 2021).

However, other aspects that may influence the maintenance of traditional knowledge should also be considered and other cultural measures should be applied holistically. In other words, it is essential to standardize the BioTrade of medicinal plants, but this standard must be applied in an integrated manner with other instruments that can protect important cultural aspects such as the Indigenous language since this is the basis for the transmission of traditional knowledge among community members (Hernández, 2021; López, 2021).

3.2.4 The values required to promote the safeguarding of the TMPK in the relationship between the private company and the Indigenous community.

The most important value is transparency, the fact of being able to communicate satisfactorily the international and national agreements related to the safeguarding of traditional knowledge, since this empowers the communities to manage such knowledge (Hernández, 2021).

In addition, respect is fundamental. It is vital to respect the sovereignty that the communities have over their traditional knowledge. This implies that the trade of medicinal plants with related traditional knowledge should be an initiative of the community itself and seeking first of all a community benefit (López, 2021).

3.2.5 Impacts of BioTrade on TMPK. Real cases.

There are several cases where BioTrade has caused impacts on TMPK, especially when the plants have a special or sacred value for communities. In the case of Ecuador, a patent was established for ayahuasca (*Banisteriopsis caapi*) and the benefits acquired from its use were not shared with the community, so much distrust was generated concerning new commercial projects in the area (López, 2021).

Another well-known case is that of guayusa in the city of Napo, a plant that was the basis for academic research and later generated a business idea to export its leaves to various countries worldwide. However, this situation provoked intellectual property conflicts, economic benefit sharing inequality, and a lack of community recognition in academic environments (López, 2021).

Thus, there are several other cases, where the main problem is the use of traditional knowledge without the permission of the community and the enrichment of private companies without adequate economic benefit-sharing to the communities from which they acquire the knowledge (López, 2021).

3.2.6 Recommendations to avoid impacts of BioTrade on TMPK.

One of the principal recommendations is that there should be clearly established national measures for the safeguarding of traditional knowledge, considering that this is an inalienable right of indigenous and native peoples worldwide. These measures should be monitored by a specialized state body, but they should also be communicated to civil society to encourage civic responsibility. On the other hand, measures regulating the intellectual property of indigenous traditional knowledge must be holistic, in other words, they must include other aspects such as cultural heritage or the relationship between traditional knowledge and the sustainability of biological resources.

Respect for the communities' customary laws is also an aspect to be considered. In the absence of established national measures, the ad hoc procedures of the communities on the use of traditional knowledge must be respected. In this way, access to this knowledge and its misuse can be controlled. In addition, it is suggested the implementation of consents by the community, in which an

agreement on the distribution of economic benefits for the use of traditional knowledge acquired for commercial purposes is established.

Finally, consideration should be given to the idea of including traditional knowledge in the formal education of the indigenous communities. In this way, the communities can be empowered in aspects related to natural resource management, economics, and trade; consequently, communities can have a little more economic independence from private enterprise.

4. PROPOSAL. BioTrade Standard for the Safeguarding of Traditional Medicinal Plant Knowledge

After the analysis presented in the previous section of this research and:

- Affirming that TMPK safeguarding is an Indigenous and tribal people's right supporting their social and cultural identity and community development (International Labour Organization, 1989; UNESCO, 2005; United Nations, 2007);
- Recognizing that TMPK access and use should be controlled and regulated as a prevention measure against its misappropriation and misuse (World Trade Organization, 2006; World Health Organization, 2014);
- Taking into account the importance of the equitable sharing of the benefits arising from the utilization of TMPK (World Intellectual Property Organization, 2019; United Nations, 1992; Secretariat of the Convention on Biological Diversity, 2010);
- Conscious of the relationship between the protection of traditional agricultural systems and the conservation of medicinal plants, and emphasizing the significance of their conservation for the safeguarding of traditional knowledge related to them (United Nations, 2012; FAO, 2008);
- Recognizing that TMPK as part of the intangible cultural heritage of Indigenous and local communities should be documented, preserved, and promoted (UNESCO, 2003; UNESCO, 2005);
- Reaffirming that TMPK is a rich asset for sustainable development and therefore needs appropriate legislative, administrative, or policy measures to guarantee its safeguarding (UNESCO, 2005) (Hernández, 2021);
- Being aware that the commercial trade of medicinal plants often harms the traditional knowledge related to them (Toledo, 1999; Reyes-García, 2009);

Baquero, et al., 2009; Bussmann & Sharon, 2015; Bravo, 2015; González, et al., 2018);

- Conscious that although the current BioTrade principles and criteria are the only regulatory tool for trade in medicinal plants for sustainable purposes, they are not 100% effective in guaranteeing the safeguarding of traditional knowledge related to these plants (see Table 20).

It is pertinent to propose a *BioTrade Standard for the Safeguarding of TMPK*.

The BioTrade standard described in this research establishes practices that contribute to the safeguarding of TMPK in the way medicinal plants are cultivated, collected, processed, and commercialized. The main goal of the Biotrade Standard is to promote such practices in the operations of companies and other organizations that work together with Indigenous and local communities in the trade of medicinal plants.

In order to ensure the compliance of the mentioned practices, the BioTrade principles established by UNCTAD in 2020 have been reorganized, and new criteria and indicators have been proposed to identify the real impact that the commercialization of medicinal plants has on the traditional knowledge related to them. Thus, to avoid repetition, principles 3, 5, and 6 of the UNCTAD BioTrade Initiative are gathered in principle 1 of this proposal (since it is considered as the base for the other three principles proposed).

4.1 Structure

The standard is structured in principles, criteria, and indicators (see Table 5).

4.2 Scope

- **Type of Product**

The standard applies to the commercial activity of medicinal plants or their parts (e.g., flowers, leaves, roots, stems, fruits, or bark). However, it is oriented towards especially those related to significant traditional knowledge.

- **Geographical Scope**

The standard can be applied around the globe and does not have any geographical restrictions.

- **Production System**

The standard applies to the commercialization system, which includes processes of cultivation, harvesting, packaging, and distribution of medicinal plants or their parts nationally or internationally.

4.3 Uses

The standard can be used for different purposes, all of them focused on safeguarding the TMPK, such as the following:

- Guide for the evaluation of existing BioTrade initiatives.
- Guide for the creation of new BioTrade proposals.
- Tool for monitoring the impact of BioTrade initiatives on the TMPK

4.4 Values

For the effective use of the standard proposed below, specific values must exist in the relationship between the private company and the Indigenous or local communities involved in the commercial process of medicinal plants. Those values are:

- **Respect:** There must be respect for all stakeholders in the commercial activity as each may have different needs or aspirations. Therefore, private enterprises must respect the local culture and reach mutually beneficial agreements by accepting that some local stakeholders may not be interested in engaging or developing partnerships, considering the biocultural context of local partners, and complying with jointly established commitments (International Labour Organization, 1989; UNESCO, 2005; Union for Ethical BioTrade, 2014; Hernández, 2021).
- **Trust:** Considering that building trust requires time and effort on the part of the actors involved in the business activity, it is necessary to have transparency, authenticity, and commitment. Therefore, the private company should invest

time and effort to maintain communication with the local community and implement procedures to distribute benefits equitably and manage conflicts (United Nations, 1992; Secretariat of the Convention on Biological Diversity, 2010; World Intellectual Property Organization, 2019; Union for Ethical BioTrade, 2014; Hernández, 2021).

- **Participation:** Companies should involve Indigenous or local communities in discussions and decision-making in the business process. Therefore, they should empower communities for their own sustainable development by granting them the right to manage the medicinal plants present in their territory and the traditional knowledge related to them (International Labour Organization, 1989; UNESCO, 2003; Union for Ethical BioTrade, 2014; Hernández, 2021).
- **Information Sharing:** Companies should generate inventories and research on the medicinal plants they wish to commercialize. This research can be empirical (with the help of the community) in which traditional knowledge will be identified, or it can be scientific, whose results must, in turn, be shared with the members of the community (International Labour Organization, 1989; UNESCO, 1989; UNESCO, 2003; World Health Organization, 2014).

4.5 Indicators

Table 21 explains the different levels of importance of the indicators for the safeguarding of TMPK. The three levels mean differing expectations as to whether and when compliance is required, as described below.

Table 21: Indicator's importance levels

Importance	explanation
Minimum requirement	Compliance is always required to avoid irreversible impacts on TMPK (complete loss)
Critical	Compliance is considered essential to avoid negative impacts on TMPK
Regular	Compliance is necessary to promote positive impacts on TMPK leading to cultural sustainability

Source: Based on Union for Ethical BioTrade (2020).

Table 22 shows the scoring system according the compliance of each indicator, which allows to have a final quantitative result.

Table 22: Scoring system for assessing the indicators

Score	Name	Description
N.A.	Not applicable	The indicator is not applicable to the specific situation.
0	Not fulfilled	Measures required by the indicator are not complied. Improvements are needed.
1	Insufficient	Measures required by te indicator are yet partially fulfilled and not sufficient for compliance. Improvements are needed.
2	Sufficient	Measures required by te indicator are yet partially fulfilled and enough to find compliance. Improvements are recommended.
3	Fulfilled	Measures required by te indicator are fully complied.

Source: Based on Union for Ethical BioTrade (2020).

4.6 The BioTrade Standard for TMPK Safeguarding

The proposal of the following principles, criteria, and indicators is based on the results obtained from the analysis of both international agreements and current BioTrade principles and criteria. In addition, recommendations obtained by two experts in the field of cultural heritage and traditional knowledge have been included.

The principles described below were adapted based on the same BioTrade principles proposed by UNCTAD (2020). Table 23 explains in detail the information on which the criteria and indicators were based.

Table 23: Sources of information for criteria and indicators

Principle	Criteria	Indicators	Based on:			
			Policies	Key Recommendations	Expert opinion	
1	1.1	1.1.1	TKIP06, TKIPR05, TKIPR06, TKIPR08, TKBRU01, TKBRU02, TKBRU05, TKBRU06, TKBRU07, TKBRU08, TKBRU09, TKCH02, TKCH05, TKCH08, TKCH09, TKCH23, TKCH25.	1	Hernández (2021), López (2021)	
		1.1.2				
		1.1.3				
	1.2	1.2.1			Hernández (2021), López (2021)	
		1.2.2				
	1.3	1.3.1	TKIP01-TKIP05	3		
		1.3.2	TKIP06	1		
		1.3.3	TKIP07-TKIP09	2, 3, 7		
	1.4	1.4.1	TKIPR04-TKIPR08	1		
		1.4.2	TKBRU01, TKBRU02			
		1.4.3	TKBRU05-TKBRU08			
	1.5	1.5.1	TKIPR01, TKIPR02	4		
		1.5.2	TKCH01-TKCH04	1, 2, 3		
		1.5.3	TKCH05-TKCH14	1, 2, 6, 7		
		1.5.4	TKCH15-TKCH25	1, 2, 3, 5, 7		
		1.5.5	TKBRU03, TKBRU04	4		
		1.5.6	TKIPR03	2		
1.5.7		TKBRU09	1			
2	2.1	2.1.1	TKIP04, TKIPR03, TKCH01, TKCH07, TKCH10, TKCH18, TKCH22.	2	Hernández (2021)	
		2.1.2			López (2021)	
		2.1.3				
	2.2	2.2.1	TKIP06, TKBRU03, TKBRU05, TKBRU07.	1, 4		
		2.2.2				
		2.2.3	TKBRU09		1	
3	3.1	3.1.1	TKIP05, TKCH03, TKCH11, TKCH12, TKCH13, TKCH24.	7		
		3.1.2			Hernández (2021), López (2021)	
		3.1.3				
		3.1.4			López (2021)	
4	4.1	4.1.1			Hernández (2021)	
		4.1.2				
	4.2	4.2.1	TKIP03, TKCH06, TKCH14.	6		
		4.2.2				
		4.2.3				López (2021)

Source: Own elaboration.

Table 24: Summary of the policies with a focus on the safeguarding of TMPK

Agreement	Code	Action to safeguard TMPK in the context of BioTrade
Indigenous and Tribal Peoples Convention	TKIP01	To respect and promote the socio-cultural identity of communities through the traditional medicine practices.
	TKIP02	To recognise the problems of indigenous groups related to TMPK in order to protect it.
	TKIP03	To empower communities with the control and management of their TMPK.
	TKIP04	To research about the main impacts on TMPK in cooperation with communities.
	TKIP05	To recognise, develop and promote TMPK through education programmes.
Universal Declaration on Bioethics and Human Rights	TKIP06	To respect and control TMPK access and use by complying national policies.
United Nations Declaration on the Rights of Indigenous Peoples	TKIP07	To maintain, protect and develop TMPK as an indigenous people's custom.
	TKIP08	To maintain and protect TMPK and health practices/procedures as an indigenous people's right.
	TKIP09	To maintain, protect, develop and control TMPK through intellectual property rights' system.
Agreement on Trade Related-Aspects of Intellectual Property Rights	TKIPR01	To protect through patents the technologies and products related to TMPK that are locally developed.
	TKIPR02	To protect the processes for the production of medicinal plants through patents or sui generis systems.
WHO Traditional Medicine Strategy	TKIPR03	To encourage research on TMPK in order to protect and promote it.
WIPO The Protection of Traditional Cultural Expressions: Draft Articles	TKIPR04	To control/manage TMPK as a cultural expression through intellectual property system.
	TKIPR05	To respect, control and promote TMPK as a cultural expression by complying the national legislation and intellectual property system.
	TKIPR06	To maintain, protect, develop and control TMPK by complying with the national legislative, administrative or policy measures that ensure the equitable sharing of benefits derived by its use.
	TKIPR07	To respect, protect and control sacred and secret TMPK.
	TKIPR08	To respect, maintain, protect and control TMPK as a cultural practice and expression by complying with the national legislative, administrative or policy measures.
Convention on Biological Diversity	TKBRU01	To maintain and protect TMPK by complying with national legislation that involves the holders of this knowledge and guarantees the equitable sharing of the benefits derived from its use.
	TKBRU02	To maintain, protect, control and promote the customary use of medicinal plants (TMPK) by complying national sustainable measures.
Global Strategy for Plant Conservation	TKBRU03	To maintain, respect and protect TMPK by establishing conservation programmes.
	TKBRU04	To maintain and develop TMPK including the innovations and practices.
Nagoya Protocol	TKBRU05	To control TMPK by complying with measures in domestic law.
	TKBRU06	To control TMPK by establishing mechanisms with community participation to inform potential users about their obligations and equitable benefits' sharing.
	TKBRU07	To protect and control TMPK by complying national legislative, administrative or policy measures.
	TKBRU08	To protect and control TMPK by complying national measures to access and equitable benefit sharing.
Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems	TKBRU09	To recognize, protect, control and promote TMPK by encouraging the use of agricultural heritage systems as means of medicinal plant diversity safeguard.
UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore	TKCH01	To recognize and maintain TMPK by documenting it.
	TKCH02	To protect TMPK by complying with measures that guarantee its status and economic support.
	TKCH03	To recognize, protect and promote TMPK avoiding its distortion during dissemination.
	TKCH04	To maintain, protect, develop and promote TMPK by complying with the intellectual property rights.
The Convention for the Safeguarding of the Intangible Cultural Heritage	TKCH05	To safeguard TMPK by complying with national measures related to intangible cultural heritage.
	TKCH06	To recognize TMPK by encouraging the cooperative work between communities and nongovernmental organizations.
	TKCH07	To recognize TMPK by implementing inventories of it.
	TKCH08	To safeguard TMPK as part of the intangible cultural heritage by establishing planning programmes.
	TKCH09	To recognize, respect, maintain, protect, develop and control TMPK by complying the measures established by the national governmental competent body.
	TKCH10	To safeguard TMPK fostering scientific, technical and artistic studies, as well as research methodologies.
	TKCH11	To recognize, respect and develop TMPK as part of intangible cultural heritage by establishing education programmes.
	TKCH12	To recognize and protect TMPK by identifying its dangers and threats.
	TKCH13	To protect and promote natural spaces and places of memory needed for expressing TMPK by establishing education programmes.
	TKCH14	To maintain, develop and promote TMPK by involving communities in its management.
Convention on the Protection and Promotion of the Diversity of Cultural Expressions	TKCH15	To protect and promote TMPK as a cultural expression
	TKCH16	To respect and promote TMPK as part of cultural expressions diversity.
	TKCH17	To control TMPK by promoting its important for development.
	TKCH18	To recognize TMPK by identifying its value and meaning.
	TKCH19	To maintain and control TMPK since it is important for development.
	TKCH20	To maintain, protect and promote TMPK as a value for community sustainable development.
	TKCH21	To develop, control and promote TMPK by paying attention to the needs of indigenous people.
	TKCH22	To recognize and protect TMPK by identifying its risks of extinction.
	TKCH23	To protect TMPK by complying with national appropriate measures.
	TKCH24	To protect and promote TMPK through education and public awareness programmes.
	TKCH25	To protect and promote TMPK by complying development policies that integrate culture.

Source: Own elaboration.

- **Principle 1:** *Compliance with national and international legislation*

This principle encourages and promotes compliance with national regulations and international agreements that contribute to the safeguarding of TMPK in a BioTrade context, i.e., during the cultivation, harvesting, research, processing, and commercialization of medicinal plants (United Nations Conference on Trade and Development, 2020). Table 24 summarizes the different policies of the international agreements that must be complied with in order to achieve the purpose of this standard.

Criterion 1.1: BioTrade activities respect current national laws and regulations that support the safeguarding of TMPK (Hernández, 2021; López, 2021).

Indicators: in this case, the indicators will vary according to the country in which the standard is applied. Each indicator shall assess individual compliance with national regulations established to safeguard the TMPK according to the scoring system. There is no maximum number of national regulations considered for the indicators, but at least three should be addressed.

1.1.1 *Minimum requirement:* BioTrade activities comply with the regulations of the national regulation “A.”

1.1.2 *Minimum requirement:* BioTrade activities comply with the regulations of the national regulation “B.”

1.1.3 *Minimum requirement:* BioTrade activities comply with the regulations of the national regulation “C.”

Criterion 1.2: In case there is no national legislation for the TMPK safeguarding in force. BioTrade activities respect the customary laws of Indigenous and local communities related to TMPK safeguarding. In case there are national and local laws and they clash, customary law should always be considered first. (Hernández, 2021; López, 2021).

Indicators: in this case, the indicators will vary according to the country and community in which the standard is intended to be applied.

1.2.1 *Minimum requirement:* The private company in charge of the BioTrade initiative has identified the customary laws of the partner community.

1.2.2 *Minimum requirement:* BioTrade activities comply with the identified customary laws.

Criterion 1.3: BioTrade activities comply with current international agreements that support the respect for the rights of actors involved in BioTrade activities. One of these rights is the safeguarding of TMPK (see Table 24).

Indicators:

1.3.1 *Minimum requirement:* BioTrade activities comply with the Indigenous and Tribal Peoples Convention.

1.3.2 *Minimum requirement:* BioTrade activities comply with the Universal Declaration on Bioethics and Human Rights.

1.3.3 *Minimum requirement:* BioTrade activities comply with the United Nations Declaration on the Rights of Indigenous Peoples.

Criterion 1.4: BioTrade activities respect current international agreements that support the fair and equitable sharing of benefits derived from the use of medicinal plants and related traditional knowledge (TMPK) (see Table 24).

Indicators:

1.4.1 *Minimum requirement:* BioTrade activities comply with the World Intellectual Property Organization agreement “The Protection of Traditional Cultural Expressions: Draft Articles.”

1.4.2 *Minimum requirement:* BioTrade activities comply with the Convention on Biological Diversity.

1.4.3 *Minimum requirement:* BioTrade activities comply with the Nagoya Protocol.

Criterion 1.5: BioTrade activities respect current international agreements that support the safeguarding of TMPK in general (see Table 24).

Indicators:

1.5.1 *Minimum requirement:* BioTrade activities comply with the Agreement on Trade Related-Aspects of Intellectual Property Rights - according to Issues Raised and Points Made: The Protection of Traditional Knowledge and Folklore.

1.5.2 *Minimum requirement:* BioTrade activities comply with the UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore.

1.5.3 *Minimum requirement*: BioTrade activities comply with the Convention for the Safeguarding of the Intangible Cultural Heritage.

1.5.4 *Minimum requirement*: BioTrade activities comply with the Convention on the Protection and Promotion of the Diversity of Cultural Expressions.

1.5.5 *Critical*: BioTrade activities comply with the Global Strategy for Plant Conservation.

1.5.6 *Regular*: BioTrade activities comply with the WHO Traditional Medicine Strategy.

1.5.7 *Regular*: BioTrade activities comply with the Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems.

- **Principle 2: *Conservation of biodiversity***

This principle establishes a framework for practices to maintain, regenerate and enhance biodiversity, and therefore the diversity of medicinal plants, taking into account that this safeguards the traditional knowledge related to them. Principle 2 requires evaluating the local context and adapting practices to local circumstances and strategies.

Criterion 2.1: Information on medicinal plants and their related traditional knowledge is collected (Hernández, 2021; López, 2021).

Indicators:

2.1.1 *Minimum requirement*: An inventory of medicinal plants and their related traditional knowledge has been made. The inventory is elaborated with community participation, and the identified medicinal plants have been categorized as sacred, native, or endangered.

2.1.2 *Minimum requirement*: relevant information has been collected about the commercialized medicinal plant and the traditional knowledge about its uses and practices.

2.1.3 *Regular*: scientific studies have been generated on the commercialized medicinal plant initiative to corroborate its pharmacological properties.

Criterion 2.2: Concrete actions are taken to maintain, restore, and promote the genetic variability of medicinal plants.

Indicators:

2.2.1 *Minimum requirement:* BioTrade actions are not resulting in the extinction of the commercialized medicinal plant.

2.2.2 *Critical:* BioTrade actions do not cause damage to the ecosystems and habitats of the commercialized medicinal plant.

2.2.3 *Regular:* BioTrade actions include scientific research and sustainable agricultural practices.

- **Principle 3:** *Sustainable use of biodiversity*

This principle encourages biodiversity sustainability. Thus, it promotes natural regenerative processes within medicinal plant cultivation and harvesting practices. Principle 3 requires evaluating the local context and adapting practices to local circumstances and strategies.

Criterion 3.1: Concrete actions are taken to foment sustainable practices in the use of medicinal plants (Hernández, 2021; López, 2021).

Indicators:

3.1.1 *Minimum requirement:* Producers and workers are trained in sustainable agricultural and touristic practices that support TMPK safeguarding.

3.1.2 *Minimum requirement:* If the commercialized plant has been categorized as sacred, native, or endangered (see indicator 2.1.1), producers, workers, and the community are informed through educational programs about its appropriate uses and management.

3.1.3 *Critical:* Educational programs have been implemented for producers and workers, teaching them about the traditional knowledge related to the commercialized medicinal plant, its cultural values, and traditional production technologies.

3.1.4 *Critical:* BioTrade activities enable and/or encourage the intergenerational transmission of TMPK among the community.

- **Principle 4:** *Clarity on the right to use and have access to natural resources*

This principle contributes to strengthening the relationship between producers and private enterprises. The main intention of this principle is to promote transparency in the process of commercialization of medicinal plants, seeking agreements for mutual benefit.

Criterion 4.1: Conflicts over the ownership of medicinal plants or related traditional knowledge are appropriately addressed (Hernández, 2021).

Indicators:

4.1.1 *Minimum requirement:* Information is collected on the legal or customary rights of ownership of the commercialized medicinal plant and/or the traditional knowledge related to it.

4.1.2 *Minimum requirement:* In case of disputes over the ownership of the commercialized medicinal plant or its related traditional knowledge, an attempt is made to resolve them until an agreement is reached with the community.

Criterion 4.2: Consensual agreement between the community and the private company in the commercialization of medicinal plants and the use of TMPK (López, 2021).

Indicators:

4.2.1 *Minimum requirement:* BioTrade of the medicinal plant (or parts thereof) and the use of related traditional knowledge for commercial purposes is undertaken with the community's consent.

4.2.2 *Critical:* New knowledge generated for commercial purposes by scientific research based on traditional knowledge must be socialized with the community.

4.2.3 *Regular:* The providers of traditional knowledge for scientific-commercial research should be recognized if new knowledge is generated for academia.

➤ **Monitoring and evaluating**

Results-based monitoring and evaluation is an effective tool that helps policymakers and decision-makers to follow a process and demonstrate the impact of a given initiative (Kusek & Rist, 2004). In this case, the monitoring and evaluating tool will

help track the medicinal plant BioTrade process and, thus, identify the impact that this activity has on the TMPK.

Since the information to apply the standard should be obtained through dialogue between the private company and the community (considering both realities), it is concluded that the best monitoring and evaluation method should be participatory.

Participatory monitoring and evaluation (PM&E) is a collaborative process that involves stakeholders in the monitoring or evaluation of a given project. In a cooperative and consultative manner, stakeholders define the scope, methodologies, and results of the monitoring and evaluation efforts (Union for Ethical BioTrade, 2014).

Since this way of assessing is inclusive, it responds to the needs and expectations of those who are most affected (communities). Therefore, it seeks to prove the effectiveness of the standard itself and empower communities to create accountability and transparent measures for improving the situation (Union for Ethical BioTrade, 2014).

Although it is suggested to establish a particular monitoring system for each community in which the mentioned standard can be applied, the following scenarios serve as a guide for evaluating the results obtained by applying the standard.

- ***The Optimistic Scenario***

Assuming that all indicators are applicable, and the priority is to fully comply with those that are “minimum required” (see Table 21), it is possible to conclude that the scenarios shown in Tables 25 and 26 are the most optimal for the BioTrade activity to continue since it is evident that safeguarding the TMPK is considered a higher value.

Table 25 shows the best scenario with 99 points. Unfortunately, this best scenario is not always possible in real life. Therefore, Table 26 shows the most optimistic scenario with 79 points, where all indicators that are “minimum required” are fully

complied, the “critical” ones sufficiently comply, which means that “regular” indicators may or may not be met.

Table 25: Optimistic scenario 1

Indicator	Importance level	Score
1.1.1	Minimum requirement	3
1.1.2	Minimum requirement	3
1.1.3	Minimum requirement	3
1.2.1	Minimum requirement	3
1.2.2	Minimum requirement	3
1.3.1	Minimum requirement	3
1.3.2	Minimum requirement	3
1.3.3	Minimum requirement	3
1.4.1	Minimum requirement	3
1.4.2	Minimum requirement	3
1.4.3	Minimum requirement	3
1.5.1	Minimum requirement	3
1.5.2	Minimum requirement	3
1.5.3	Minimum requirement	3
1.5.4	Minimum requirement	3
1.5.5	Critical	3
1.5.6	Regular	3
1.5.7	Regular	3
2.1.1	Minimum requirement	3
2.1.2	Minimum requirement	3
2.1.3	Regular	3
2.2.1	Minimum requirement	3
2.2.2	Critical	3
2.2.3	Regular	3
3.1.1	Minimum requirement	3
3.1.2	Minimum requirement	3
3.1.3	Critical	3
3.1.4	Critical	3
4.1.1	Minimum requirement	3
4.1.2	Minimum requirement	3
4.2.1	Minimum requirement	3
4.2.2	Critical	3
4.2.3	Regular	3
	Total	99

Source: Own elaboration.

Table 26: Optimistic scenario 2

Indicator	Importance level	Score
1.1.1	Minimum requirement	3
1.1.2	Minimum requirement	3
1.1.3	Minimum requirement	3
1.2.1	Minimum requirement	3
1.2.2	Minimum requirement	3
1.3.1	Minimum requirement	3
1.3.2	Minimum requirement	3
1.3.3	Minimum requirement	3
1.4.1	Minimum requirement	3
1.4.2	Minimum requirement	3
1.4.3	Minimum requirement	3
1.5.1	Minimum requirement	3
1.5.2	Minimum requirement	3
1.5.3	Minimum requirement	3
1.5.4	Minimum requirement	3
1.5.5	Critical	2
1.5.6	Regular	0
1.5.7	Regular	0
2.1.1	Minimum requirement	3
2.1.2	Minimum requirement	3
2.1.3	Regular	0
2.2.1	Minimum requirement	3
2.2.2	Critical	2
2.2.3	Regular	0
3.1.1	Minimum requirement	3
3.1.2	Minimum requirement	3
3.1.3	Critical	2
3.1.4	Critical	2
4.1.1	Minimum requirement	3
4.1.2	Minimum requirement	3
4.2.1	Minimum requirement	3
4.2.2	Critical	2
4.2.3	Regular	0
	Total	79

Source: Own elaboration.

- **The Stable Scenario**

Assuming that all indicators are applicable, and the priority is to comply with those that are “minimum required” at least in a “sufficient” way (see Table 21), Table 27 shows the most stable scenario for BioTrade activities, where all indicators are sufficiently complied reaching a score of 66 points. Whereas Table 28 shows a stable scenario with 51 points, where the indicators that are “minimum required” are

sufficiently complied, the “critical” ones insufficiently comply, and “regular” indicators may or may not be met.

Table 27: Stable scenario 1

Indicator	Importance level	Score
1.1.1	Minimum requirement	2
1.1.2	Minimum requirement	2
1.1.3	Minimum requirement	2
1.2.1	Minimum requirement	2
1.2.2	Minimum requirement	2
1.3.1	Minimum requirement	2
1.3.2	Minimum requirement	2
1.3.3	Minimum requirement	2
1.4.1	Minimum requirement	2
1.4.2	Minimum requirement	2
1.4.3	Minimum requirement	2
1.5.1	Minimum requirement	2
1.5.2	Minimum requirement	2
1.5.3	Minimum requirement	2
1.5.4	Minimum requirement	2
1.5.5	Critical	2
1.5.6	Regular	2
1.5.7	Regular	2
2.1.1	Minimum requirement	2
2.1.2	Minimum requirement	2
2.1.3	Regular	2
2.2.1	Minimum requirement	2
2.2.2	Critical	2
2.2.3	Regular	2
3.1.1	Minimum requirement	2
3.1.2	Minimum requirement	2
3.1.3	Critical	2
3.1.4	Critical	2
4.1.1	Minimum requirement	2
4.1.2	Minimum requirement	2
4.2.1	Minimum requirement	2
4.2.2	Critical	2
4.2.3	Regular	2
Total		66

Source: Own elaboration.

Table 28: Stable scenario 2

Indicator	Importance level	Score
1.1.1	Minimum requirement	2
1.1.2	Minimum requirement	2
1.1.3	Minimum requirement	2
1.2.1	Minimum requirement	2
1.2.2	Minimum requirement	2
1.3.1	Minimum requirement	2
1.3.2	Minimum requirement	2
1.3.3	Minimum requirement	2
1.4.1	Minimum requirement	2
1.4.2	Minimum requirement	2
1.4.3	Minimum requirement	2
1.5.1	Minimum requirement	2
1.5.2	Minimum requirement	2
1.5.3	Minimum requirement	2
1.5.4	Minimum requirement	2
1.5.5	Critical	1
1.5.6	Regular	0
1.5.7	Regular	0
2.1.1	Minimum requirement	2
2.1.2	Minimum requirement	2
2.1.3	Regular	0
2.2.1	Minimum requirement	2
2.2.2	Critical	1
2.2.3	Regular	0
3.1.1	Minimum requirement	2
3.1.2	Minimum requirement	2
3.1.3	Critical	1
3.1.4	Critical	1
4.1.1	Minimum requirement	2
4.1.2	Minimum requirement	2
4.2.1	Minimum requirement	2
4.2.2	Critical	1
4.2.3	Regular	0
Total		51

Source: Own elaboration.

It is essential to mention that in the case of these two stable scenarios, the BioTrade activity can continue, but it is recommended to be monitored and show improvements in the safeguarding of TMPK.

- **The Worst Scenario**

Assuming that all indicators are applicable, Tables 29 and 30 show two scenarios (scores between 23 and 33 points) where the BioTrade activity could represent a

severe threat for the TMPK, which means that such activity should be avoided until it improves since even the “minimum required” indicators are insufficiently complied.

Table 29 shows a scenario with 33 points, where all indicators are insufficiently complied. This scenario jeopardizes TMPK. However, Table 30 shows a worse scenario with 23 points, where only the “minimum required” indicators insufficiently comply since all the others are not fulfilled at all. This last scenario constitutes a severe threat to TMPK and should be avoided at all costs.

Table 29: Worst scenario 1

Indicator	Importance level	Score
1.1.1	Minimum requirement	1
1.1.2	Minimum requirement	1
1.1.3	Minimum requirement	1
1.2.1	Minimum requirement	1
1.2.2	Minimum requirement	1
1.3.1	Minimum requirement	1
1.3.2	Minimum requirement	1
1.3.3	Minimum requirement	1
1.4.1	Minimum requirement	1
1.4.2	Minimum requirement	1
1.4.3	Minimum requirement	1
1.5.1	Minimum requirement	1
1.5.2	Minimum requirement	1
1.5.3	Minimum requirement	1
1.5.4	Minimum requirement	1
1.5.5	Critical	1
1.5.6	Regular	1
1.5.7	Regular	1
2.1.1	Minimum requirement	1
2.1.2	Minimum requirement	1
2.1.3	Regular	1
2.2.1	Minimum requirement	1
2.2.2	Critical	1
2.2.3	Regular	1
3.1.1	Minimum requirement	1
3.1.2	Minimum requirement	1
3.1.3	Critical	1
3.1.4	Critical	1
4.1.1	Minimum requirement	1
4.1.2	Minimum requirement	1
4.2.1	Minimum requirement	1
4.2.2	Critical	1
4.2.3	Regular	1
Total		33

Source: Own elaboration.

Table 30: Worst scenario 2

Indicator	Importance level	Score
1.1.1	Minimum requirement	1
1.1.2	Minimum requirement	1
1.1.3	Minimum requirement	1
1.2.1	Minimum requirement	1
1.2.2	Minimum requirement	1
1.3.1	Minimum requirement	1
1.3.2	Minimum requirement	1
1.3.3	Minimum requirement	1
1.4.1	Minimum requirement	1
1.4.2	Minimum requirement	1
1.4.3	Minimum requirement	1
1.5.1	Minimum requirement	1
1.5.2	Minimum requirement	1
1.5.3	Minimum requirement	1
1.5.4	Minimum requirement	1
1.5.5	Critical	0
1.5.6	Regular	0
1.5.7	Regular	0
2.1.1	Minimum requirement	1
2.1.2	Minimum requirement	1
2.1.3	Regular	0
2.2.1	Minimum requirement	1
2.2.2	Critical	0
2.2.3	Regular	0
3.1.1	Minimum requirement	1
3.1.2	Minimum requirement	1
3.1.3	Critical	0
3.1.4	Critical	0
4.1.1	Minimum requirement	1
4.1.2	Minimum requirement	1
4.2.1	Minimum requirement	1
4.2.2	Critical	0
4.2.3	Regular	0
Total		23

Source: Own elaboration.

5. DISCUSSION. Strengths and weaknesses of this research to achieve the safeguarding of TMPK in a BioTrade context.

According to the background of this research, the methodology used to collect the necessary information, and the results obtained from analyzing this information, certain points of interest have been identified that should be discussed to determine the true contribution of this research. First is examined to what extent the results of this research confirm the idea that the current BioTrade principles and criteria are not an effective tool for safeguarding the TMPK. Secondly, the limitations of the methodology used that may have influenced in one way or another the results obtained will be addressed. Another issue that will be covered in this section deals with the possible challenges to implement the standard proposed in the previous section, especially considering the context of Indigenous and local communities. Finally, and as a recommendation, possible gaps of the present research will be identified which should be covered in the near future by means of new research topics that could complete the focus of this study.

5.1 Current BioTrade principles and criteria, and TMPK safeguarding

It is crucial to evaluate BioTrade principles and criteria and their effectiveness in TMPK safeguarding. Among the key factors that could contribute to the sustainability of communities' livelihoods are the increased opportunities to participate in decentralized resource management, and the incorporation of the respect towards traditional knowledge in natural resource management plans (Shinwari, 2010). One of these plans is the UNCTAD BioTrade Initiative.

Studies assessing the impact of trade in medicinal plants on the traditional knowledge related to them presented two opposing scenarios. On the one hand, some cases show that since the trade of medicinal plants started in Indigenous communities, the transmission of TMPK increased. Therefore, the practice of traditional medicine was promoted (Monteiro, et al., 2010; Magaña, et al., 2010; Quinlan & Quinlan, 2007). The greatest knowledge and use of medicinal plants is maintained in areas that also serve as major centres of local trade. Thus, local trade in medicinal plants is the key factor in promoting traditional knowledge about the

use of medicinal plants (Asad Salim, et al., 2019). On the other hand, the number of cases that point to the commercial activity of medicinal plants as a threat to the continuity of TMPK is more significant (Reyes-García, 2009; Baquero, et al., 2009; Bussmann & Sharon, 2015; Bravo, 2015; González, et al., 2018).

After analyzing the contexts of the different cases, it is evident that TMPK is threatened when the commercial activity is not only at the local level nor the production is carried out in a traditional way (Asad Salim, et al., 2019). In other words, TMPK is under threat when the trade in medicinal plants involves a relationship between the private company (usually multinational) and the local or Indigenous community, which may cause the distortion or potential loss of TMPK.

There is a worldwide scientific consensus on the beneficial effects of herbal medicine, and medicinal plants now occupy a central position in research and alternative medicine. According to the World Health Organization, 80% of the population in developing countries remains dependent on native medicinal plants to satisfy their primary healthcare needs. These facts, combined with the increasing loss of traditional knowledge due to the rural migration and the hazards to which Plant Genetic Resources (PGR) are exposed, make efforts to investigate and protect both these resources and the traditional knowledge associated to them, highly relevant in every aspect (Ribeiro, et al., 2010).

Over time, the productive relationship between private companies and Indigenous or local communities has led to several conflicts based on the power imbalance and interest differences (Calvano, 2008). For instance, the commercialization of plant medicine, in combination with unregulated exploitation practices and the lack of coordinated efforts for conservation, have driven many of the herbal medicinal plants to the borderline of disappearance (Bhat, et al., 2013; Kunwar, et al., 2013). Therefore, there is a demand for sustainable use and management of medicinal plants, grounded in traditional knowledge (Kunwar, et al., 2013). However, as explained in the previous sections, the only international tool that regulates the commercial relationship between both stakeholders (private sector and Indigenous communities) in the trade of biodiversity products such as medicinal plants, is the BioTrade Initiative with its principles and criteria.

The trade of medicinal plants has local economic importance for low-income and mostly illiterate populations. However, the modernization of this activity has caused the loss of some traditional knowledge, such as ecological information about the plants and their uses (Carvalho, 2004). Therefore, in the absence of measures to regulate the commercial activity of these plants, both the traditional knowledge of medicinal plants and the ecosystem that originated them are in danger (Carvalho, 2004).

At the beginning of this research, and based on the case of guayusa BioTrade, it was stated the idea that the current BioTrade principles and criteria do not help ensure sustainable commercial activity regarding TMPK safeguarding when a medicinal plant linked to Indigenous traditional knowledge is commercialized. This idea was confirmed after evaluating these principles and criteria in the light of the most significant international treaties regarding TMPK safeguarding.

After the research carried out in this study, it was corroborated that the current system of trade in natural resources combined with intellectual property rights is not in itself capable of stopping the erosion and displacement of traditional knowledge and Indigenous practices. In fact, the protection of intellectual property rights related to traditional knowledge through benefit sharing could provide an incentive to accelerate the sale of these traditions and begin to capitalize on them (Cottier, 1998). Therefore, although protecting traditional knowledge with intellectual property rights is beneficial, it is necessary to combine this aspect with public policies that cover other aspects that are also related to the trade of natural resources, especially medicinal plants (Cottier, 1998). These additional policies should include aspects related to land tenure, agricultural practices, production and consumption, among others.

Thus, upon reviewing the seven BioTrade principles and their respective criteria, it was identified that some criteria resulted repetitive and did not follow a coherent order, making their application confusing (see Table 20). For instance, principle number 5 talks about compliance with international agreements, which should be the political and legal basis for all the other principles and criteria, but apparently, it

is not. It does not specify how and at what level international agreements should be complied with since most of the agreements tend to be general and require specific focus to have any real influence on trade activity.

As observed in the research, traditional knowledge is considered a complex system whose existence influences several aspects of the community reality. Conservation-minded anthropologists have studied Indigenous cultures in search of knowledge and rules on which to base environmentally sustainable relationships between individuals and the natural world; thus, several traditional practices and systems that maintain biodiversity and ecosystems have been reviewed, concluding that Western conservationists should not dismiss these wisdoms (Becker & Ghimire, 2003). Therefore, it should be logical that more criteria are related to this knowledge for principles 1 and 2, associated with conservation and sustainable use of biodiversity. However, the reality is that current criteria for those principles are merely based on a production and consumption relationship. This focus does not contribute to safeguarding the traditional knowledge related to biological resources such as medicinal plants.

On another note, it should be stated that although there are a couple of criteria directly related to traditional knowledge, especially in the third and seventh principles, they are pretty superficial and do not accurately evaluate what happens to this knowledge when it is part of a commercial process. If it is considered that traditional knowledge associated with biological resources is more than mere information but rather the foundation of communities identity which determines the management and use of biological resources for sustainable development (CONABIO-GIZ, 2017), it can be concluded that the mentioned criteria do not consider the immaterial aspect of traditional knowledge related to biodiversity. This is evident because they are based on economic recognition for its use. Unfortunately, this approach reifies the traditional knowledge and does not present it as the complex system that it really is since it only identifies a couple of possible impacts on the holders of this knowledge but not on the knowledge itself.

Another gap identified is that although the latest update of the BioTrade Initiative (2020) recognizes tourism as a core activity, none of the principles and criteria

specifically mentions this concept. While it is true that medicinal plant tourism is a relatively new trend (Álvarez, et al., 2015), it is considered a commercial activity, and as well as medicinal plant trade, it can cause various impacts on the TMPK if not adequately regulated (Maldonado, 2006).

Finally, it should be mentioned that in order for the principles and criteria of BioTrade to be measured and monitored, it is necessary to have indicators since they constitute the only way to obtain evidence of the achievement and help in measuring the performance of any BioTrade initiative (Consejo Nacional de Evaluación de la Política de Desarrollo Social, 2013). Hence, the existence of indicators is crucial to evaluate the current situation of BioTrade initiatives and generate strategies to prevent or mitigate the negative impacts of this activity, such as those that threaten the TMPK in Indigenous and local communities. However, in the last version of BioTrade principles and criteria proposed by UNCTAD, no indicators were found.

Unfortunately, in cases such as guayusa in Ecuador, BioTrade planning for this plant has been based only on a general evaluation where only BioTrade criteria were considered for the assessment, generating inaccurate results of the current situation of this activity and, therefore, reducing the importance of the TMPK safeguarding. Thus, it can be concluded that the establishment of indicators is a fundamental aspect to obtain accurate and real results.

5.2 Limitations of the methodology used

As explained in the methodology chapter, this study was exploratory and mixed. One limitation of this study, being exploratory, is that most of the data were obtained from secondary sources that may not be up to date, which may influence the final results (Swedberg, 2018).

When identifying international agreements that could support the safeguarding of TMPK in a possible commercialization context, no specialized agreement on this subject was found. Most of the international agreements selected for the analysis deal with the safeguarding of traditional knowledge in general terms; therefore, depending on the researcher's criteria, the number of international agreements that

meet the necessary characteristics to analyze could be increased or decreased, which entails that the results may not be completely accurate.

Furthermore, one of the main challenges in analyzing the data from the selected international agreements was dealing with different terms to refer to the same subject of protection or the same safeguard actions (see Table 18). Figure 14 explains the relationship between these terms within the context studied. Thus, it can be inferred that the lack of homogeneity in the terminology used makes compliance with many of these international agreements complicated, especially at the local and community levels.

Moreover, another limitation is that the data obtained from the analysis of the agreements are primarily qualitative, implying that it may be biased to the author's personal criticism (Swedberg, 2018). For instance, the diverse terms used in the reviewed literature may be differently interpreted depending on the researcher's point of view and on the objectives of the research.

In the absence of an adequate instrument for the analysis of international agreements applied to a specific framework, as is the case of the BioTrade principles and criteria, it was necessary to propose personal steps and instruments. Thus, the instruments included consistency and comparison matrices and tables to convert qualitative data into quantitative data and better explain the information to the reader. However, the data reflected in the matrices will also depend on the author's personal understanding of the problem based on his/her own knowledge and experience.

For all the above-mentioned limitations, an attempt was made to include information from primary sources by interviewing experts on the subject. Considering that the real experts are the members of Indigenous and local communities that are involved in BioTrade and can provide evidence of its impact on the TMPK, it was ideal to have at least one interview with these people. Unfortunately, for reasons of time, distance, and lack of contacts that open a door for virtual communication with communities, it was impossible to coordinate such an interview. As an alternative, two academics were interviewed, who know about this subject. However, they do

not possess specialized knowledge, nor does their information come from their own living experience, which in one way or another detracts from the precision of the information provided.

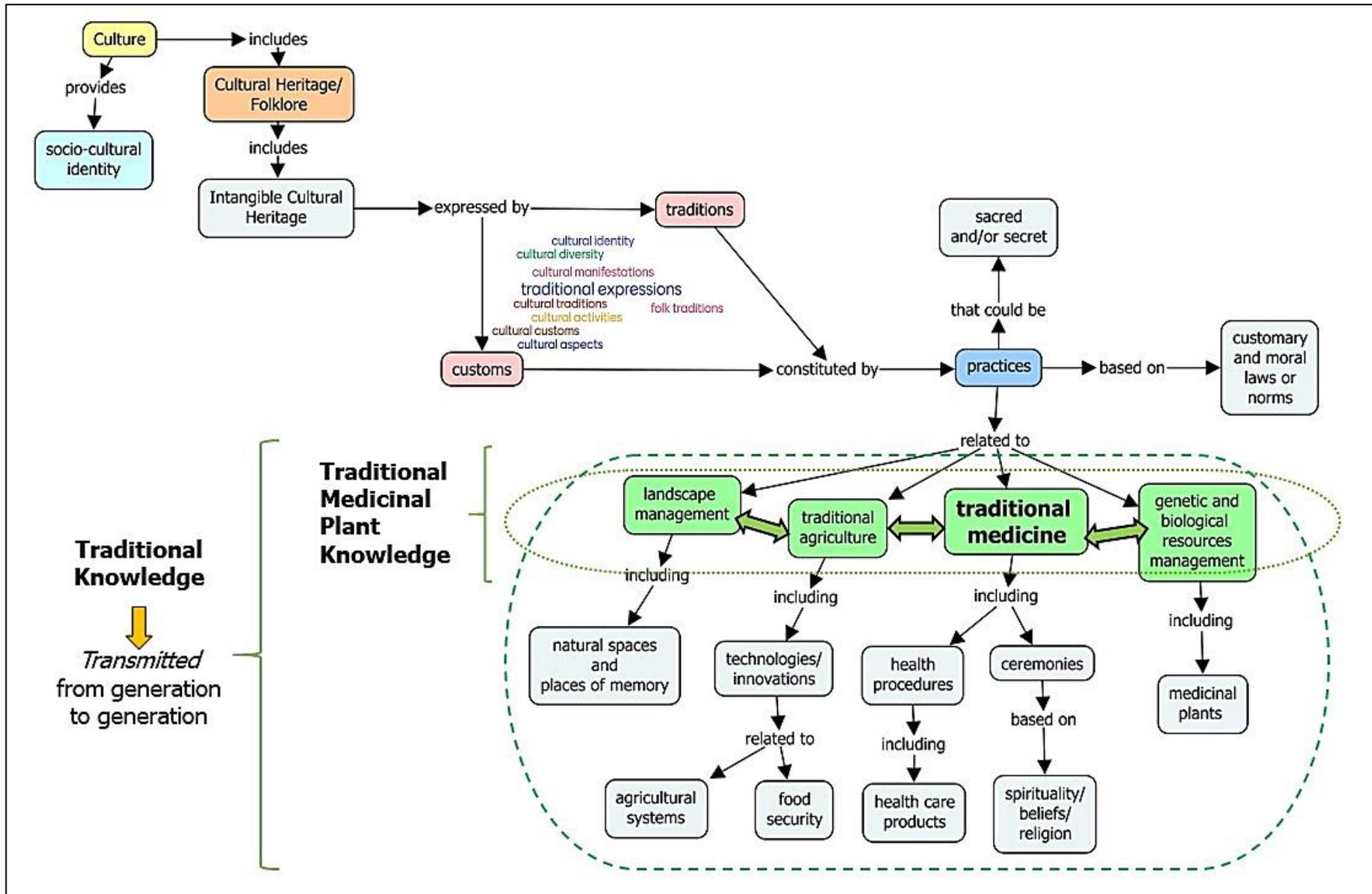
5.3 Challenges of the proposed BioTrade standard

Taking into account that the debate on the protection of folklore and traditional knowledge has impacted various policy areas including international trade and considering the dissatisfaction with the international trade system in developing countries, it has become a priority to extend the protection of traditional knowledge to other areas beyond the field of intellectual property (Yu, 2003) . This is the main reason why this study has proposed a standard to support the safeguarding of the TMPK, giving it a different value and meaning than the one that has referred to it until now in the conventional international trade system.

However, whereas the proposed standard is mostly a product of the literature review, and there is no sample test of it in a genuine BioTrade initiative, it is not easy to judge its effectiveness at this point of the research. Therefore, it constitutes a basic guideline that could undoubtedly be improved after obtaining the first results in real-time. Apart from that, the following are some challenges that could arise when implementing the standard for the first time.

Although ideally public policies should be established in clear, simple, direct language and using the right words for readers to understand and comply with them (Secretaría Mexicana de la Función Pública, 2004), in practice, as evidenced in the results section, many international agreements related to TMPK do not meet this requirement. Therefore, the first significant challenge in applying the BioTrade standard is to socialize with the community the international policies that must be complied with, as these policies generally use formal terms that are difficult for laypersons to understand. In addition, many members of the community may use only their own language, which is a huge hurdle to overcome in implementing the standard, as it will be necessary to translate both the international policies and the principles and criteria of the standard into the native language of the community to ensure the transparency of the process and contribute to the preservation of this language (López, 2021).

Figure 14: Relationship among subjects of protection from Table 18



Source: Own elaboration

Another challenge is ensuring that the relationship between producers and private enterprises is based on values such as respect, trust, participation, and information sharing. Unfortunately, there are few cases in which BioTrade initiatives maintain and practice these values, as the imbalance of power and conflicts of interest between both parties complicate the commercial relationship (Calvano, 2008). In most cases, the differing interests between the private company and the Indigenous community are evident. On the one hand, the main objective of the private company is to generate economic profit, which means that all other non-financial obligations are relegated or ignored. On the other hand, the communities perceive this situation as a disadvantage, as their needs are only addressed if they threaten or enhance the company's survival (Calvano, 2008). In addition, the individual values of each stakeholder make common values challenging to construct. The private company, for its side, bases its operation on economic rationality and faith in technology, while the Indigenous community, on the other hand, is concerned with environmental protection, cultural preservation, and the improvement of their quality of life, all as a whole (Reyes-García, 2009). Therefore, to achieve the values that the standard proposes, both stakeholders' time, effort, and willingness are needed to ensure that the commercial activity is flourishing in economic aspects and that it is sustainable and allows the safeguarding of TMPK.

Apart from that, there are some specific challenges to the application of new principles and criteria. For instance, principle 1 may be very ambitious, but it is definitely necessary for TMPK safeguarding to be adequate. The main challenge in this principle is that it not solely depends on compliance with the international agreements mentioned in the standard but also on assessing compliance with national laws and regulations depending on the location of the BioTrade initiative. This fact may imply developing a national standard that should be applied in parallel to the one proposed by this research to ensure that the evaluation of a BioTrade initiative is accurate (López, 2021). Thus, to assess compliance with national regulations, it is necessary to specify in criterion 1.1 the main national measures related to the protection of TMPK and determine as indicators which policies and recommendations must be met. However, in some countries, national measures in this area are weak or non-existent (World Intellectual Property Organization, 2017).

At the international level, the significance of the sustainable management of biodiversity - which contributes to human well-being and economic progress - is recognized as one of the core principles of the Convention on Biological Diversity (CBD). The private sector plays an important role in the responsible management of these natural resources, and can also be a strong agent of change, addressing consumer demand for sustainable products (TRAFFIC, 2015). Worldwide, an increased number of companies are assuming leadership in the environmentally responsible use of resources and pursuing sustainability initiatives with their stakeholders (TRAFFIC, 2015). However, another major challenge for applying the BioTrade standard is to engage private companies in research and data collection before commercial activity if there is no national body in charge. For example, principle 1 requires research on customary community laws in order to meet criterion 1.2. Similarly, Principle 2 requires collecting information on medicinal plants and related traditional knowledge to meet criterion 2.1. Unfortunately, most companies are unwilling to do this because of the investment of resources involved and the lack of government support, as is generally the case in developing countries (Calvano, 2008).

This situation is exacerbated in the absence of community participation, as much of the information required can be obtained with less effort if the community wishes to become involved in documenting its own traditions and customary uses of medicinal plants, where the protection of vulnerable species is a priority. Moreover, it is also possible that this traditional knowledge has been lost over time or that it has been modified and does not maintain its former meaning, since in general, traditional knowledge is dynamic and constantly adapts to the community's reality (CONABIO-GIZ, 2017).

One issue that could be a challenge as business development proceeds is: how to incorporate the notion of "commercial use" of knowledge by maintaining its traditional transmission and use? On the one hand, the standard proposes that the private company establishes educational programs in the best way, using this knowledge for both workers and community members. However, this implies an investment of both time and money that companies are probably unwilling to assume. On the other hand, there is also the possibility that community members may lose interest in learning and

transmitting this knowledge, as they find in the commercial activity a better way to invest their time and obtain economic income (Bussmann & Sharon, 2015).

The commercial use of TMPK implies that there should be fair remuneration. For example, in criterion 1.4, the BioTrade standard proposes the fair and equitable sharing of the benefits derived from the use of TMPK. However, in the case of Indigenous communities, it is not always easy to identify who is the owner of this knowledge and to whom the economic recognition is due (Jarrett, 2019). Therefore, one of the biggest challenges is criterion 4.2, which seeks to clarify the rights for the use and commercialization of medicinal plants as this can contribute to reaching an agreement with the community and identify who deserves the benefits. Thus, in order to avoid conflicts, it is advisable to agree on the mechanisms and rules for the distribution of benefits before receiving them and ensure that they reach everyone according to the criteria decided by the community (Noejovich, 2013); since although rare, the internal heterogeneity of the communities could complicate a consensus and therefore delay the evaluation process of commercial activity (Rowse, 2014). Therefore, if possible, it is recommended that workshops or meetings be held systematically with community members in which documents are drafted and signed by the community leaders. In this way, the agreements established between the interested stakeholders can be supported and chronologically ordered to avoid possible conflicts.

At the end of the proposed standard, a results-based monitoring strategy was also advised. This strategy certainly needs to be adapted to the specific context of a nation, community, or culture in which the BioTrade initiative is developed since, according to this context, different criteria could or could not be applicable. However, the challenge is to find the right professional body in charge of this, as monitoring cannot be carried out by either the private company or the community because it would lack objectivity. Thus, the support of the government or a non-governmental institution would be needed.

Managing the community's expectations involved in a BioTrade initiative is another crucial challenge to face. The process of empowering communities in the medicinal plant business is not immediate, and it may even take a few years before its benefits

start to be noticed. Therefore, it is very likely that the community will place high expectations on the first evaluation using the standard, and the results will discourage its commitment. It is very likely that if a BioTrade initiative is new, it will obtain a low score in the evaluation. However, it is important to socialize with the community the possible strategies for improvement and achieve their engagement with the BioTrade initiative. It must be remembered that the main idea of the proposed standard is not to eliminate the commercial activity of medicinal plants, but on the contrary, to offer a guide so that it is adequate, sustainable, and contributes to the safeguarding of the TMPK.

5.4 Further research linked to the scope of this study

During this study, a series of limitations hindered the analysis and interpretation of the results obtained. Therefore, certain aspects that can contribute to this research and that could be used as a basis for future studies with similar approaches are mentioned below.

Firstly, it is considered imperative that the standard proposed in this document be applied to an existing case of BioTrade of medicinal plants. This case could be the commercialization of guayusa (*Ilex guayusa*) in Ecuador since it was the inspiration for this study. However, as mentioned earlier, this standard can be applied in different contexts, as long as the medicinal plant part of the BioTrade initiative has a traditional knowledge that is considered as intangible heritage or source of identity for a community.

Secondly, it is recommended to compare the results of the application of the standard in new BioTrade initiatives versus its application in initiatives with some years of experience. This will help to identify if time is indeed an essential factor in strengthening the relationship between the private company and the community. It would also mean that BioTrade activities become sustainable in the long run when values such as respect, participation, trust, and information sharing are consolidated, which could be reflected in a better score in the standard's evaluation. In addition, this comparison will be helpful to identify whether criteria or indicators should be added to the proposed standard, as indeed the BioTrade initiatives with more experience in the

market can contribute with detailed information on their biggest mistakes and successes, which is undoubtedly enriching for new initiatives.

On another critical point, it would be interesting to identify national agreements and regulations from different countries around the world that support the safeguarding of the TMPK, analyze their recommendations, and consider those that are more significant and applicable in international terms in order to complement the proposed standard with new criteria or indicators that are more specific.

Last but not least, implementing a monitoring system together with a certification for the proposed standard is considered fundamental since it constitutes a motivation for BioTrade initiatives to comply with the requirements. Therefore, the mentioned monitoring system should be detailed and consider each possible result for the indicators proposed in the standard to recommend enhancing strategies adaptable to different cultural realities and measured according to an established enhancing timeline.

CONCLUSIONS

The main objective of this thesis was to demonstrate that the current BioTrade principles and criteria established by UNCTAD do not support the safeguarding of traditional knowledge related to medicinal plants in their commercialization processes and also to find a way to improve this aspect in order to achieve sustainable trade and protect this type of knowledge with regulated commercial practices.

Thus, several international agreements were identified which support the idea of safeguarding traditional knowledge for its cultural importance and its contribution to the development of Indigenous and local communities. Most of these international agreements present clear recommendations for meeting this goal, although no agreement was found that is based explicitly on the safeguarding of TMPK. However, the analysis of the policies contained in the agreements allowed to focus on the mentioned recommendations on TMPK safeguarding.

The difficulty in regulating a wide variety of situations, activities, and actors, with requirements that also involve long, complex, and dynamic processes, is one of the weakest aspects of international legislation on access to genetic resources and protection of traditional knowledge. Therefore, findings showed that the BioTrade principles and criteria do not contemplate many international recommendations to safeguard TMPK. Although BioTrade offers interesting proposals to regulate traditional knowledge in the public domain related to plants and crops whose suppliers are communities and Indigenous peoples, it does so only in a very general way. According to the current BioTrade principles and criteria analysis, it was possible to conclude that, unfortunately, traditional knowledge has been reified. A price has been established for its use, but without considering that it is an element of continuous dialogue that resurfaces, develops, is remembered, and transformed when combined with Western technologies and knowledge; and therefore, it should not be treated merely as a commercial product.

Consequently, after analyzing both the principles and criteria of BioTrade in force, inconsistencies and unnecessary repetitions were found. Moreover, some gaps were

identified that prevent current BioTrade principles and criteria from being a convenient tool to regulating the commercial activity of medicinal plants in Indigenous and local communities.

According to the above, the main contribution of this work consists in the design of a BioTrade standard that regulates the commercial activity of medicinal plants with related traditional knowledge, promoting good commercial practices that contribute to the safeguarding of TMPK, and at the same time provide adequate economic income to Indigenous and local communities. This research revealed that the application of policies and regulations in community contexts is not necessarily linear; on the contrary, it is influenced by the specific reality of each community. Through a better understanding of this process, it is possible to draw valuable lessons, ideas, and reflections for the implementation of regulatory measures to safeguard the TMPK and build bridges between different cultures and ways of seeing the world.

Hence, the main challenge of the proposed standard is to implement such measures flexibly and according to the particular situation of each community. This would allow commercial activity to move forward, and to prevent these measures from remaining only on paper. This tool should not function as a straitjacket but rather as a framework that guides the way towards fair and transparent partnerships between communities and private companies that will generate concrete benefits for all.

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ANNEXES

➤ Interview Questionnaires in Spanish

Mi Nombre es Anabel Cuichán, soy estudiante del programa de Maestría en Manejo de Recursos Naturales de la TH-Köln (Alemania). Como parte de mi proceso de titulación me encuentro escribiendo una tesis relacionada con impulsar la salvaguarda del conocimiento tradicional de plantas medicinales (CTPM) en los procesos de BioComercio. Para cumplir con este objetivo he realizado una revisión de los acuerdos internacionales más significativos que apoyan la salvaguarda de este tipo de conocimiento en un posible contexto de comercialización y los he tomado como referencia para elaborar un estándar de BioComercio que sea aplicable a las plantas medicinales que tienen un valor sagrado o cultural implícito, estableciendo una crítica para el actual estándar de BioComercio propuesto por la UNCTAD en el año 2020. Los acuerdos internacionales analizados fueron:

1. Indigenous and Tribal Peoples Convention, 1989.
2. Universal Declaration on Bioethics and Human Rights, 2005.
3. United Nations Declaration on the Rights of Indigenous Peoples, 2007.
4. Agreement on Trade Related-Aspects of Intellectual Property Rights, 1994.
5. WHO Traditional Medicine Strategy, 2014.
6. WIPO The Protection of Traditional Cultural Expressions: Draft Articles, 2019.
7. Convention on Biological Diversity, 1992.
8. Global Strategy for Plant Conservation, 2002.
9. Nagoya Protocol, 2004.
10. Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems, 2008.
11. UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore, 1989.
12. Convention for the Safeguarding of the Intangible Cultural Heritage, 2003.
13. Convention on the Protection and Promotion of the Diversity of Cultural Expressions, 2005.

Por lo tanto, el siguiente cuestionario tiene el objetivo de recolectar información de una fuente primaria y desde la experiencia propia de expertos en el área del patrimonio cultural inmaterial y su salvaguarda. El cuestionario está constituido por 10

preguntas de carácter abierto, por lo que se solicita ser lo más explícito posible en sus respuestas.

Agradezco de antemano el tiempo prestado, y aprovecho para aclarar que la información obtenida tiene propósitos netamente académicos, por lo que, en el documento final, su nombre será debidamente referenciado.

Nota: *no es necesario que tenga experiencia en este tema particular. Es posible que las preguntas sean respondidas por inferencias desde su criterio profesional o asumiendo escenarios o contextos específicos de la realidad de su país. De ser este el caso, favor explicarlo detalladamente.*

Cuestionario 1

Nombre: Miguel Ángel Hernández Macedo

Institución: Centro Regional para la Salvaguardia del Patrimonio Inmaterial de América Latina CRESPIAL, (Consultor).

Lugar y Fecha: 02.06.2021

1. Desde su criterio profesional, ¿considera usted que el CTPM es un recurso significativo para el desarrollo sostenible de las comunidades Indígenas? Explique su respuesta.

Efectivamente los conocimientos tradicionales suelen estar ligados no sólo a una función medicinal sino a la memoria, cosmovisión e identidad de los pueblos Indígenas. Está asociado a la mirada particular de territorio, de la naturaleza y están vinculados a la organización social. La salvaguardia de estos conocimientos representa la búsqueda de continuidad de la cultura misma que es la base del desarrollo integral de los pueblos. De otro lado, los CTPM pueden ser utilizados, además de sus funciones tradicionales, como símbolos de reconocimiento del saber tradicional y que puede permitir obtener beneficios de su divulgación y de ser el caso su comercialización.

2. Desde un enfoque de políticas públicas, ¿qué tan importante es la salvaguarda del CTPM, como parte del patrimonio inmaterial, en la realidad

particular de su país?, ¿existen leyes nacionales vigentes que apoyan esta propuesta.?

Se considera sumamente importante debido al alto grado de vulnerabilidad de los grupos Indígenas en el país, que se han visto amenazados en la cultura, en territorio, en lengua y que tienen enorme precariedad en salud y nutrición. En ese sentido, el Ministerio de Cultura, a través de la Dirección General de pueblos Indígenas desarrolla una serie de iniciativas para fortalecer los derechos de estos grupos culturales. Sobre el tema particular de CTPM, se formuló una estrategia nacional de protección y salvaguardia de los conocimientos tradicionales, sin embargo no llegó a implementarse debido a la reestructuración del Estado. Desde el lado de la protección intelectual, el Perú cuenta con la Ley N° 27811.- Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos Indígenas vinculados a los recursos biológicos. Que establece un marco de protección de estos conocimientos y establece un marco financiero.

Desde el patrimonio inmaterial, existe un marco normativo general que establece la posibilidad de declarar conocimientos tradicionales como patrimonio cultural de la nación, que además de reconocer la importancia a nivel nacional de los conocimientos y de sus portadores, también exige el desarrollo de acciones de salvaguarda.

3. ¿Cree usted que la implementación de un estándar de BioComercio que garantice la salvaguarda del CTPM sería útil para el desarrollo sostenible de las comunidades Indígenas de su país? ¿considera a la salvaguarda del CTPM como una prioridad? o ¿existen otros aspectos del patrimonio cultural inmaterial que son más prioritarios para el desarrollo sostenible de las comunidades Indígenas.? Explique sus respuestas.

En tanto se establezcan mecanismos claros de participación de los representantes Indígenas que garanticen el enfoque de desarrollo priorizado considero que un estándar puede resultar útil, es necesario que se brinden las condiciones para el acceso transparente de los acuerdos y que se acompañe de mecanismos de fortalecimiento de capacidades en los pueblos Indígenas. Como prioritario se puede establecer el uso de la lengua en tanto a partir de ella se establecen otros aspectos de la cultura.

4. Ya que toda iniciativa de BioComercio está basada en la relación existente entre la empresa privada y la comunidad local, ¿cuáles cree usted que son los valores principales que debe mostrar la relación entre empresa privada y la comunidad antes y durante un proceso de BioComercio donde el CTPM está involucrado.?

Considero que un valor fundamental es la transparencia que puede analizarse a partir los mecanismos participativos en los cuales se da cuenta de los alcances de los protocolos. Asegurar la correcta difusión de los beneficios que puedan lograrse a partir de estos acuerdos.

5. ¿Conoce algún caso en el que la comercialización de una planta medicinal endémica o sagrada en su país haya causado impactos negativos sobre el conocimiento tradicional relacionado con esta? En caso de que su respuesta sea positiva, explique detalladamente el contexto y los impactos causados.

Ninguna

6. En la literatura revisada se menciona que el comercio de plantas medicinales tiene varios impactos negativos sobre el conocimiento tradicional relacionado con estas. Podría desde su criterio explicar ¿por qué estos impactos son considerados negativos para el desarrollo sostenible de las comunidades Indígenas? Explique la razón para cada uno de ellos. En caso de conocer otros impactos negativos, por favor menciónelos.

- ***Pérdida del CTPM debido a la extinción de especies por sobreexplotación.***

Cualquier política relacionada al uso de plantas endémicas deberá contar con un análisis de la sostenibilidad tanto del recurso como la posible afectación medio ambiental debido a su explotación, en otro aspectos si la especie es sagrada sería necesario delimitar y comunicar los posibles riesgos a su símbolos y significados culturales, los cuales podrían perderse o deslucirse.

- ***Interrupción de la transmisión intergeneracional del CTPM.***

Está principalmente relacionado a la pérdida de significado y a la reducción de la existencia del recurso.

- ***Desinterés de las nuevas generaciones en aprender el CTPM.***

Tiene que ver con otros procesos de pérdida de la cultura.

- ***Apropiación y uso ilegal del CTPM (biopiratería).***

Tiene que ver con procedimientos de circulación de información sin tomar en consideración las restricciones establecidas por lo mismo pueblos. Hay que tener en consideración que muchas veces los procesos de comercialización de conocimientos se establecen en condiciones desfavorables para los pueblos Indígenas, debido a ciertas vulnerabilidades estructurales como la pobreza.

7. Dentro de los principales acuerdos internacionales que apoyan a la salvaguarda del conocimiento tradicional de plantas medicinales, existen cuatro propuestas que más sobresalen:

- **Considerar la salvaguarda del CTPM como un derecho inalienable de los pueblos y comunidades Indígena**
- **Considerar la salvaguarda del CTPM dentro del sistema nacional de propiedad intelectual.**
- **Considerar la salvaguarda del CTPM como indispensable para la sostenibilidad de la biodiversidad y viceversa.**
- **Considerar la salvaguarda del CTPM dentro del sistema de protección del patrimonio cultural inmaterial.**

Explique desde su criterio profesional ¿cuál piensa que es el aporte de estos enfoques para la prevención y/o mitigación de los posibles impactos negativos que la comercialización de plantas medicinales causa sobre el conocimiento tradicional relacionado con ellas? ¿Cuál/cuáles es la propuesta más prioritaria desde su punto de vista?

Considero que cada una de las propuestas es necesaria y se debe abordar en conjunto pues tratan dimensiones del patrimonio y de la cultura que deben ser trabajadas con urgencia. En ese sentido se busca que las instituciones y normativas alrededor de los CTPM se articulen de forma eficiente sin que se reduzca el impacto de cada una. Si es necesario priorizar consideraría la salvaguardia como un derecho

inalienable y a partir de esta noción se pueden establecer marcos de salvaguardia según sus diferentes dimensiones.

8. La mayoría de los acuerdos internacionales analizados recomiendan que existan medidas legislativas, administrativas o políticas a nivel nacional que apoyen directa o indirectamente a la salvaguarda del CTPM. Sin embargo, no en todos los países existen estas medidas. De ser este el caso, ¿qué recomendaría usted para regular el BioComercio de plantas medicinales en comunidades Indígenas y evitar que esta actividad cause impactos negativos sobre el CTPK?

Si se toma como base que la protección de los CTPM es un derecho, se pueden orientar los protocolos y normativas internacionales que guían el respeto por los pueblos Indígenas. Incluyendo los procedimientos de regulación ad hoc de la cultura de estos pueblos.

9. Los acuerdos internacionales analizados sugieren que se generen programas educativos para promover el CTPM. Desde su criterio profesional, ¿considera usted que el transmitir el CTPM a productores y trabajadores de manera formal, puede aportar a la salvaguarda de este en el contexto de BioComercio.? ¿Sería adecuado extender la transmisión formal del CTPM a la comunidad como parte de la iniciativa de BioComercio?, ¿cuáles son las ventajas y/o desventajas de este proceso? Explique su respuesta.

Desde el patrimonio inmaterial los procesos de transmisión de los saberes y conocimientos son la base de la salvaguardia, ya sea a través de la educación formal como no formal, ello, sin embargo, está ligado a los procesos de consentimiento y de participación comunitaria que son la base de toda acción. En ese sentido, se podría establecer con cuidado que aspectos serán priorizados para su promoción y difusión a públicos más allá de los pueblos Indígenas, y cuales aspectos solo deben ser tomados en consideración para su transmisión dentro de las mismas comunidades. Habría que asegurarse también el control del acceso a la información. Todo ello tiene que ver con la relación establecida entre las instituciones, las empresas y las comunidades, para coordinar las metodologías de recogida y difusión de información.

10. Los acuerdos internacionales analizados sugieren que el acceso al CTPM y su uso (generalmente con fines comerciales) sea autorizado por sus legítimos dueños quienes deberán además recibir parte de los beneficios económicos derivados de este uso. En el caso de no existir un reconocimiento legal que otorgue la propiedad de este conocimiento a una comunidad o a ciertos miembros de esta, ¿cómo sugiere usted que la empresa privada aborde este asunto con la comunidad para salvaguardar el CTPM.? ¿Considera usted que el CTPM es una propiedad comunitaria? o ¿sus dueños son aquellos que lo transmiten y lo practican.?

Creo que es necesario tener en consideración también a los agentes estatales relacionados a los sistemas de protección de las culturas Indígenas, así como a otros actores de la sociedad civil. En muchos casos no es necesario un reconocimiento formal de propiedad para poder realizar acuerdos que beneficien a las comunidades. Los aspectos comunitarios de la propiedad generalmente se definen dentro del seno de cada comunidad, si bien en algunos casos existen elementos patrimoniales que son aprendidos y transmitidos por grupos específicos dentro de una comunidad, es necesario tener en consideración que, para muchas comunidades, es parte fundamental de su cultura brindar soporte a los individuos considerados especialistas.

Cuestionario 2

Nombre: Jesús López Villada

Institución: Independiente (experiencia con manejo de plantas medicinales en comunidades Indígenas)

Lugar y Fecha: 06/06/2021

1. Desde su criterio profesional, ¿considera usted que el CTPM es un recurso significativo para el desarrollo sostenible de las comunidades Indígenas? Explique su respuesta.

Por supuesto que sí. En primer lugar, el conocimiento tradicional de plantas medicinales permite que las comunidades Indígenas utilicen esos conocimientos para curar las enfermedades que tienen y qué mejor farmacia que una farmacia local para

curar esas patologías. Desde el punto de vista de la sostenibilidad ambiental es una de las mejores opciones que pueden tener las comunidades Indígenas.

En segundo lugar, estos conocimientos pueden permitir a las comunidades Indígenas el desarrollo de productos farmacéuticos y complementos alimenticios artesanales a base de plantas (cremas, jabones, tinturas, extractos secos, etc.) para la venta local, obteniendo unos ingresos económicos adicionales para mejorar su calidad de vida. En este sentido para obtener productos de calidad sería necesario que algunos miembros de las comunidades Indígenas se capacitaran en la elaboración de estos productos. Esa capacitación puede ser en universidades locales o mediante cursos impartidos por personal altamente preparado. De este modo se combinaría el conocimiento ancestral con las técnicas de farmacia, garantizando la calidad de los productos y el desarrollo local. Es importante que las comunidades elaboren estos preparados a base de plantas de mayor valor añadido y no sólo se queden en el cultivo y recolección de las plantas, beneficiándose en gran medida los intermediarios.

2. Desde un enfoque de políticas públicas, ¿qué tan importante es la salvaguarda del CTPM, como parte del patrimonio inmaterial, en la realidad particular de su país?, ¿existen leyes nacionales vigentes que apoyan esta propuesta?

Actualmente que yo sepa en Ecuador no hay ninguna legislación que de forma directa proteja los conocimientos ancestrales Indígenas sobre plantas medicinales. Incluso hay voces que indican que el Código de Economía Social de los Conocimientos, Creatividad e Innovación y el Código Orgánico del Ambiente favorecen los intereses de transnacionales y empresas farmacéuticas en detrimento de las comunidades Indígenas.

Sin embargo, sí existen algunos códigos de ética de Medicina ancestral y también existe legislación para la elaboración y comercialización de productos farmacéuticos o complementos alimenticios a base de plantas. Esa legislación se puede encontrar en la web de la agencia de regulación ARCSA.

3. ¿Cree usted que la implementación de un estándar de BioComercio que garantice la salvaguarda del CTPM sería útil para el desarrollo sostenible de

las comunidades Indígenas de su país? ¿considera a la salvaguarda del CTPM como una prioridad? o ¿existen otros aspectos del patrimonio cultural inmaterial que son más prioritarios para el desarrollo sostenible de las comunidades Indígenas.? Explique sus respuestas.

En mi opinión la elaboración y desarrollo de un estándar de biocomercio sí que sería importante para salvaguardar los conocimientos ancestrales de plantas medicinales y garantizar el desarrollo sostenible de las comunidades Indígenas. En este sentido también pienso que esos estándares de biocomercio tendrían que ser tanto a nivel nacional como internacional. Evidentemente también hay otros aspectos ancestrales que son necesarios salvaguardar. Para mí tendría que ser un proceso totalmente integral, no sólo con las plantas medicinales. Un ejemplo de ello es la lengua que ayuda a la transmisión de los conocimientos incluyendo los conocimientos de plantas medicinales. Por tanto, de aquí deducimos que, si desaparece la lengua, sobre todo lenguas de tradición oral que no tienen el lenguaje escrito, también desaparecen un considerable número de conocimientos ancestrales en plantas medicinales.

4. Ya que toda iniciativa de BioComercio está basada en la relación existente entre la empresa privada y la comunidad local, ¿cuáles cree usted que son los valores principales que debe mostrar la relación entre empresa privada y la comunidad antes y durante un proceso de BioComercio donde el CTPM está involucrado?

En primer lugar, pienso que siempre que sea posible las propias comunidades Indígenas son las que tendrían que desarrollar sus pequeños emprendimientos relacionados con sus conocimientos ancestrales en base de plantas medicinales. Si se demuestra que ese preparado tiene unos efectos muy positivos para determinadas patologías y se deciden comercializar a nivel internacional, es necesario desarrollar un estándar de biocomercio en el que se indiquen claramente cuáles son los beneficios, derechos, deberes, etc. de cada una de las partes tanto a nivel económico como a nivel intelectual.

5. ¿Conoce algún caso en el que la comercialización de una planta medicinal endémica o sagrada en su país haya causado impactos negativos sobre el conocimiento tradicional relacionado con esta? En caso de que su respuesta sea positiva, explique detalladamente el contexto y los impactos causados.

Conozco algunos casos. El primero de ellos es la patente de la ayahuasca que se puede encontrar en este link:

<https://www.iceers.org/es/gringo-patentar-ayahuasca/>

Afortunadamente la patente ya venció y su alcance era limitado, por lo que no tuvo consecuencias serias para las comunidades amazónicas del Ecuador.

Otro caso que conozco es la de una mujer Shuar del parque etnobotánico Omaere en la ciudad del Puyo. Su esposo Chris Canaday me comentó que habían llegado personas extranjeras para conocer los conocimientos ancestrales en plantas medicinales de la comunidad shuar. El caso es que estas personas comenzaron a comercializar productos basados en sus conocimientos y sin su autorización, lo cual generó una gran desconfianza y desde entonces en esta comunidad no comparte sus conocimientos ancestrales para la elaboración de productos vegetales en base de plantas.

Otro caso conflictivo ha sido el de la guayusa con la empresa norteamericana RUNA (runa.com). Actualmente esta empresa vende productos a base de guayusa incluyendo bebidas energéticas sobre todo en el mercado Norteamérica y a través de portales electrónicos como Amazon. Parece ser que una de las razones del conflicto fue la de no compartir un premio internacional recibido por los estudiantes. Eso después se conllevó otra serie de problemas en este enlace se puede encontrar más detalles: <https://bibdigital.epn.edu.ec/handle/15000/19862?mode=full>

6. En la literatura revisada se menciona que el comercio de plantas medicinales tiene varios impactos negativos sobre el conocimiento tradicional relacionado con estas. Podría desde su criterio explicar ¿por qué estos impactos son considerados negativos para el desarrollo sostenible de las comunidades Indígenas? Explique la razón para cada uno de ellos. En caso de conocer otros impactos negativos, por favor méncionelos.

Los efectos negativos que más se observan son por un lado la sobreexplotación y por otro la biopiratería.

- **Pérdida del CTPM debido a la extinción de especies por sobreexplotación.**

Un caso quizá grave que sobre todo sucede en Perú es el de la uña de gato y aunque en Ecuador no hay datos me imagino que la situación debe ser similar. Esta planta tiene

muchas propiedades de fortalecimiento del sistema inmunitario y especialmente contra el cáncer, por lo cual es una planta que tiene una alta demanda a nivel mundial. Esta situación ha provocado que haya problemas ambientales por la sobreexplotación.

- **Interrupción de la transmisión intergeneracional del CTPM**

La transmisión de conocimiento ancestral intergeneracional puede estar provocada mayormente por la pérdida de las lenguas. Estas lenguas son de tradición oral, no tienen lengua escrita y el hecho de que haya empresas nacionales o multinacionales que contacten con estas comunidades puede favorecer que se imponga el castellano como lengua vehicular y poco a poco se vaya perdiendo la lengua nativa. Entonces es un tema que hay que considerar cuidadosamente para no perder esta lengua porque perderla también significa perder esos conocimientos ancestrales. Aquí se puede encontrar más información al respecto. <https://elpais.com/ciencia/2021-06-11/el-conocimiento-medicinal-indigena-se-extingue-sin-dejar-rastro.html>

Otro aspecto importante para considerar es la pérdida de biodiversidad ocasionada por el cambio climático y la deforestación provocada por el crecimiento de la frontera agrícola. Este tema también puede dar lugar a la pérdida de plantas autóctonas y con ello a la pérdida de ese conocimiento ancestral relacionado con el uso medicinal de estas plantas.

<https://gk.city/2021/03/21/deforestacion-bosques-tropicales-ecuador/>

- **Desinterés de las nuevas generaciones en aprender el CTPM.**

No tengo datos suficientes para afirmar o desmentir este hecho.

- **Apropiación y uso ilegal del CTPM (biopiratería).**

Es uno de los efectos negativos más comunes y del que se han descrito algunos ejemplos en la pregunta anterior. Estos hechos generan una gran desconfianza hacia las empresas y por tanto al uso de estos preparados a base de plantas.

https://elpais.com/sociedad/2006/05/24/actualidad/1148421601_850215.html

<https://elpais.com/clima-y-medio-ambiente/2021-06-15/los-guardianes-de-la-amazonia-quieren-su-parte-de-la-fiebre-del-acai.html>

https://www.elespanol.com/ciencia/nutricion/20200617/bayas-todas-beneficios-salud-fruto-energetico-amazonas/496450588_0.html

7. Dentro de los principales acuerdos internacionales que apoyan a la salvaguarda del conocimiento tradicional de plantas medicinales, existen cuatro propuestas que más sobresalen:

- **Considerar la salvaguarda del CTPM como un derecho inalienable de los pueblos y comunidades Indígena**
- **Considerar la salvaguarda del CTPM dentro del sistema nacional de propiedad intelectual.**
- **Considerar la salvaguarda del CTPM como indispensable para la sostenibilidad de la biodiversidad y viceversa.**
- **Considerar la salvaguarda del CTPM dentro del sistema de protección del patrimonio cultural inmaterial.**

Explique desde su criterio profesional ¿cuál piensa que es el aporte de estos enfoques para la prevención y/o mitigación de los posibles impactos negativos que la comercialización de plantas medicinales causa sobre el conocimiento tradicional relacionado con ellas? ¿Cuál/cuáles es la propuesta más prioritaria desde su punto de vista?

El primero de ellos es fundamental y ya no sólo como derechos de los pueblos Indígenas sino también como derechos de la naturaleza. En mi opinión no se puede patentar la vida. En cuanto al segundo punto opino que sí se pueden registrar o patentar preparados de esos productos indicando cantidades, productos vegetales, forma de preparación, qué procesos tienen lugar, etc. En mi opinión si puede ser posible que sea al menos protegido con algún tipo de figura legal. Esos preparados o productos evidentemente después pueden dar lugar a ciertos beneficios para las comunidades Indígenas que puede a la sostenibilidad tanto ambiental como socioeconómica de esas comunidades. Por último, hay que comentar que para mí no habría ninguna de las cuatro formas de protección que sobresalga sobre las otras, sino que para conseguir un nivel de protección integral es necesario considerar todas esas opciones para que de ese modo se proteja los conocimientos ancestrales de las comunidades Indígenas.

8. La mayoría de los acuerdos internacionales analizados recomiendan que existan medidas legislativas, administrativas o políticas a nivel nacional que

apoyen directa o indirectamente a la salvaguarda del CTPM. Sin embargo, no en todos los países existen estas medidas. De ser este el caso, ¿qué recomendaría usted para regular el BioComercio de plantas medicinales en comunidades Indígenas y evitar que esta actividad cause impactos negativos sobre el CTPM?

En cuanto a medidas legislativas se recomienda leer la tesis bajo el título: Tendencias jurídicas en el Ecuador con respecto a los derechos colectivos de las comunidades Indígenas sobre sus conocimientos tradicionales.

En cuanto a temas administrativos sí que solicitaría que los procesos para el registro sanitario y legalización de productos preparados a base de plantas en elaborados por comunidades Indígenas tengan es un proceso ágil, rápido y simplificado.

Por último, en cuanto a políticas por un lado tendrían que aprobarse políticas nacionales que garanticen la protección de los conocimientos tradicionales de plantas medicinales y después también suscribir e impulsar acuerdos internacionales para la protección de esos conocimientos.

9. Los acuerdos internacionales analizados sugieren que se generen programas educativos para promover el CTPM. Desde su criterio profesional, ¿considera usted que el transmitir el CTPM a productores y trabajadores de manera formal, puede aportar a la salvaguarda de este en el contexto de BioComercio.? ¿Sería adecuado extender la transmisión formal del CTPM a la comunidad como parte de la iniciativa de BioComercio?, ¿cuáles son las ventajas y/o desventajas de este proceso? Explique su respuesta.

En mi opinión los procesos educativos para la protección de los conocimientos ancestrales de productos medicinales o plantas son muy importantes. En primer lugar, van a ayudar a preservar esos conocimientos ancestrales. En segundo lugar, van a proporcionar una alternativa de ingresos económicos a las comunidades. También es importante que existan capacitaciones de cómo preparar esos productos a base de plantas medicinales con un mínimo de calidad. En ese sentido pienso que la colaboración de las universidades y de otros técnicos cualificados es fundamental. También sería necesario aciertas capacitaciones en el ámbito comercial, es decir contabilidad básica, un poquito de no sé si llamarlo marketing o estrategias de ventas, aunque sea a nivel local para que de ese modo el proyecto tenga éxito. En este caso

resulta especialmente importante la participación de las mujeres. El conjunto de estas actividades e iniciativas pueden dar cierta Independencia económica a las mujeres de las comunidades Indígenas.

10. Los acuerdos internacionales analizados sugieren que el acceso al CTPM y su uso (generalmente con fines comerciales) sea autorizado por sus legítimos dueños quienes deberán además recibir parte de los beneficios económicos derivados de este uso. En el caso de no existir un reconocimiento legal que otorgue la propiedad de este conocimiento a una comunidad o a ciertos miembros de esta, ¿cómo sugiere usted que la empresa privada aborde este asunto con la comunidad para salvaguardar el CTPM.? ¿Considera usted que el CTPM es una propiedad comunitaria? o ¿sus dueños son aquellos que lo transmiten y lo practican.?

Aunque no existe ninguna figura legal que reconozca la propiedad de sus preparados a las comunidades Indígenas entiendo qué moral y éticamente es una obligación de la compañía suscribir algún tipo de contrato donde se indiquen los acuerdos alcanzados con la comunidad y que beneficien a ambas partes, Pienso que son conocimientos ancestrales adquiridos a lo largo de milenios y ese derecho se tiene que reconocer de algún modo en dicho contrato. En mi opinión no es que haya dueños, pero sí que de algún modo ese conocimiento pertenece a esa comunidad y después si hay alguien que lo quiere utilizar pues evidentemente tiene que negociar con esa comunidad para establecer los beneficios para cada uno de ellos. No puede ser que los conocimientos ancestrales adquiridos a lo largo de cientos y miles de años sean utilizados impunemente por una persona o empresa ajenas a la comunidad sin llegar a un acuerdo. Todo el esfuerzo realizado por la comunidad para obtener ese conocimiento se tiene qué recompensar y respetar de algún modo.

➤ **Interview Questionnaires in English (my translation)**

My name is Anabel Cuichán, I am a student of the Master's program in Natural Resources Management at TH-Köln (Germany). As part of my graduation process, I am writing a thesis related to promote the safeguarding of traditional knowledge of medicinal plants (TKPM) in BioTrade processes. To meet this objective, I have conducted a review of the most significant international agreements that support the safeguarding of this type of knowledge in a possible commercialization context, and I have taken them as a reference to elaborate a BioTrade standard that is applicable to medicinal plants that have an implicit sacred or cultural value, establishing a critique for the current BioTrade standard proposed by UNCTAD in the year 2020. The international agreements analyzed were:

1. Indigenous and Tribal Peoples Convention, 1989.
2. Universal Declaration on Bioethics and Human Rights, 2005.
3. United Nations Declaration on the Rights of Indigenous Peoples, 2007.
4. Agreement on Trade Related-Aspects of Intellectual Property Rights, 1994.
5. WHO Traditional Medicine Strategy, 2014.
6. WIPO The Protection of Traditional Cultural Expressions: Draft Articles, 2019.
7. Convention on Biological Diversity, 1992.
8. Global Strategy for Plant Conservation, 2002.
9. Nagoya Protocol, 2004.
10. Conservation and Adaptive Management of Globally Important Agricultural Heritage Systems, 2008.
11. UNESCO Recommendation on Safeguarding of Traditional Culture and Folklore, 1989.
12. Convention for the Safeguarding of the Intangible Cultural Heritage, 2003.
13. Convention on the Protection and Promotion of the Diversity of Cultural Expressions, 2005.

Therefore, the following questionnaire aims to collect information from a primary source and the experience of experts in the area of intangible cultural heritage and its safeguarding. The questionnaire consists of 10 open-ended questions, so please be as explicit as possible in your answers.

Thank you in advance for your time and take this opportunity to clarify that the information obtained is for purely academic purposes, and therefore, in the final document, your name will be duly referenced in the final document.

Note: it is not necessary that you have experience in this particular subject. It is possible that the questions are answered by inferences from your professional judgment or assuming specific scenarios or contexts of the reality of your country. If this is the case, please explain in detail.

Questionnaire 1

Name: Miguel Ángel Hernández Macedo

Institution: Centro Regional para la Salvaguardia del Patrimonio Inmaterial de America Latina CRESPIAL

Place and date: 02.06.2021

- 1. In your professional opinion, do you consider the TMPK to be a significant resource for the sustainable development of Indigenous communities? Explain your answer.**

Indeed, traditional knowledge is often linked to a medicinal function and the memory, cosmovision, and identity of Indigenous peoples. It is associated with a particular view of the territory, of nature and is linked to social organization. The safeguarding of this knowledge represents the pursuit of cultural continuity, which is the basis for the integral development of peoples. On the other hand, the TMPK can be used, in addition to their traditional purposes, as symbols of recognition of traditional knowledge, which can allow obtaining benefits from its dissemination and, if necessary, its commercialization.

- 2. From a public policy approach, how important is the safeguarding of the TMPK, as part of the intangible heritage, in the particular reality of your country? are there national laws in force that support this proposal?**

It is considered extremely important due to the high degree of vulnerability of Indigenous groups in the country, which have been threatened by culture, territory,

language, and enormous precariousness in health and nutrition. In this sense, through the General Directorate of Indigenous Peoples, the Ministry of Culture develops a series of initiatives to strengthen the rights of these cultural groups. On the particular issue of TMPK, a national strategy for the protection and safeguarding of traditional knowledge was formulated. However, it was not implemented due to the restructuring of the State. On the intellectual protection side, Peru has Law N° 27811 - Law that establishes the regime for the protection of the collective knowledge of Indigenous peoples linked to biological resources. It establishes a framework for the protection of this knowledge and establishes a financial framework.

From the intangible heritage point of view, a general regulatory framework establishes the possibility of declaring traditional knowledge as the nation's cultural heritage. However, in addition to recognizing the national importance of knowledge and its bearers, it also requires safeguarding actions.

3. Do you think that implementing a BioTrade standard that guarantees the safeguarding of the TMPK would be helpful in the sustainable development of Indigenous communities in your country? Do you consider the safeguarding of the TMPK as a priority? or are there other aspects of intangible cultural heritage that are a higher priority for the sustainable development of Indigenous communities? Explain your answers.

As long as precise mechanisms are established for the participation of Indigenous representatives that guarantee the prioritized development approach, I consider that a standard can be helpful. It is necessary to provide the conditions for transparent access to the agreements and to be accompanied by capacity-building mechanisms for Indigenous peoples. Language can be established as a priority since it is the basis on which other cultural aspects are established.

4. Since every BioTrade initiative is based on the relationship between the private company and the local community, what do you think are the central values that the relationship between the private company and the community should show before and during a BioTrade process where the TMPK is involved?

I consider that a fundamental value is a transparency that can be analyzed from the participatory mechanisms in which the scope of the protocols is reported. Ensure the correct dissemination of the benefits that can be achieved from these agreements.

5. Do you know of any case in which the commercialization of an endemic or sacred medicinal plant in your country has caused negative impacts on the traditional knowledge related to it? In case your answer is positive, please explain in detail the context and the impacts caused.

None.

6. In the literature reviewed, it is mentioned that the trade of medicinal plants has several negative impacts on the traditional knowledge related to these plants. Could you explain why these impacts are considered harmful for the sustainable development of Indigenous communities? Please explain the reason for each one of them. If you know of other negative impacts, please mention them.

- Loss of the TMPK due to the extinction of species due to overexploitation.

Any policy related to the use of endemic plants should include an analysis of the sustainability of both the resource and the possible environmental impact due to its exploitation. In other aspects, if the species is sacred, it would be necessary to delimit and communicate the possible risks to its symbols and cultural meanings, which could be lost or tarnished.

- Interruption of the intergenerational transmission of the TMPK.

It is mainly related to the loss of meaning and the reduction of the existence of the resource.

- Disinterest of new generations in learning the TMPK.

It is related to other processes of cultural loss.

- Illegal appropriation and misuse of the TMPK (biopiracy).

It is related to procedures for the circulation of information without considering the restrictions established by the people. It must be taken into account that many times

the processes of commercialization of knowledge are established under unfavourable conditions for Indigenous peoples due to specific structural vulnerabilities such as poverty.

7. Among the leading international agreements that support the safeguarding of traditional knowledge of medicinal plants, four proposals stand out the most:

- **To consider the safeguarding of the TMPK as an inalienable right of Indigenous peoples and communities.**
- **To consider the safeguarding of the TMPK within the national intellectual property system.**
- **To consider the safeguarding of the TMPK as indispensable for the sustainability of biodiversity and vice versa.**
- **To consider the safeguarding of the TMPK within the system for the protection of intangible cultural heritage.**

Explain from your professional criteria, what do you think is the contribution of these approaches for the prevention and/or mitigation of the possible negative impacts that the commercialization of medicinal plants causes on the traditional knowledge related to them? Which is/are the most priority proposal from your point of view?

I consider that each of the proposals is necessary and should be addressed as a whole because they deal with dimensions of heritage and culture that must be worked on urgently. In this sense, the institutions, and regulations around the TMPK should be efficiently articulated without reducing the impact of each one. If it is necessary to prioritize, I would consider safeguarding as an inalienable right, and, based on this notion, safeguarding frameworks can be established according to its different dimensions.

8. Most of the international agreements recommend legislative, administrative or political measures at the national level that directly or indirectly support the safeguarding of the TMPK. However, these measures do not exist in all countries. If this is the case, what would you recommend regulating the

BioTrade of medicinal plants in Indigenous communities and prevent this activity from causing negative impacts on the TMPK?

If it is taken as a basis that the protection of the TMPK is a right, the international protocols and regulations that guide the respect for Indigenous peoples can be oriented. Including the procedures for ad hoc regulation of the culture of these peoples.

9. The international agreements suggest the generation of educational programs to promote the TMPK. From your professional criteria, do you consider that transmitting the TMPK to producers and workers in a formal way can contribute to safeguarding it in the context of BioTrade? Would it be appropriate to extend the formal transmission of the TMPK to the community as part of the BioTrade initiative? What are the advantages and/or disadvantages of this process? Explain your answer.

From the point of view of intangible heritage, the processes of transmission of knowledge and know-how are the basis of safeguarding, whether through formal or non-formal education. However, this is linked to the processes of consent and community participation that are the basis of any action. In this sense, it could be carefully established which aspects will be prioritized for promotion and dissemination to audiences beyond the Indigenous peoples and which aspects should only be considered for transmission within the communities themselves. Control of access to information should also be ensured. All this has to do with the relationship established between the institutions, companies, and communities to coordinate information collection and dissemination methodologies.

10. The international agreements analyzed suggest that access to and use of the TKPMC (generally for commercial purposes) should be authorized by its legitimate owners, who should also receive part of the economic benefits derived from this use. If there is no legal recognition that grants the owner of this knowledge to a community or specific members, how do you suggest that the private company addresses this issue with the community to safeguard the TMPK? Do you consider that the TMPK is community property? Or are its owners those who transmit and practice it?

I believe that it is also necessary to consider state agents related to protecting Indigenous cultures and other actors of civil society. However, formal recognition of ownership is unnecessary to make agreements that benefit the communities in many cases.

Community aspects of ownership are generally defined within each community. In some cases, there are heritage elements learned and transmitted by specific groups within a community. However, it is necessary to consider that for many communities, it constitutes a fundamental part of their culture to provide support to individuals who are considered specialists.

Questionnaire 2

Name: Jesús López Villada

Institution: Independent (experiencia con manejo de plantas medicinales en comunidades Indígenas)

Place and date: 06.06.2021

1. In your professional opinion, do you consider the TMPK to be a significant resource for the sustainable development of Indigenous communities? Explain your answer.

Of course, it is. First of all, the traditional knowledge of medicinal plants allows Indigenous communities to use that knowledge to cure their diseases, and what better pharmacy than a local pharmacy to cure those pathologies. From the perspective of environmental sustainability, it is one of the best options for Indigenous communities. Secondly, this knowledge can allow Indigenous communities to develop pharmaceutical products and handmade food supplements based on plants (creams, soaps, tinctures, dry extracts, etc.) for local sale, obtaining additional income to improve their quality of life. In this sense, to obtain quality products, it would be necessary that some Indigenous communities be trained in the elaboration of these products. This training could be in local universities or through courses given by highly qualified personnel. This would combine ancestral knowledge with pharmaceutical techniques, guaranteeing the quality of the products and local development. It is essential that the communities develop these preparations based on plants with higher

added value and not only remain in the cultivation and collection of the plants, benefiting to a great extent the intermediaries.

2. From a public policy approach, how important is the safeguarding of the TMPK, as part of the intangible heritage, in the particular reality of your country? are there national laws in force that support this proposal?

Currently, as far as I know, no legislation in Ecuador directly protects Indigenous ancestral knowledge about medicinal plants. There are even voices that indicate that the Code of Social Economy of Knowledge, Creativity and Innovation and the Organic Environmental Code favour the interests of transnationals and pharmaceutical companies to the detriment of Indigenous communities.

However, there are some codes of ethics for traditional medicine, and there is also legislation for the elaboration and commercialization of pharmaceutical products or food supplements based on plants. This legislation can be found on the website of the regulatory agency ARCSA.

3. Do you think that implementing a BioTrade standard that guarantees the safeguarding of the TMPK would be helpful in the sustainable development of Indigenous communities in your country? Do you consider the safeguarding of the TMPK as a priority? or are there other aspects of intangible cultural heritage that are a higher priority for the sustainable development of Indigenous communities? Explain your answers.

In my opinion, the elaboration and development of a BioTrade standard would be essential to safeguard the ancestral knowledge of medicinal plants and to guarantee the sustainable development of Indigenous communities. In this sense, I also think that these BioTrade standards would have to be national and international. Other ancestral aspects need to be safeguarded. For me, it would have to be an integral process, not only with medicinal plants. An example of this is the language that helps transmit knowledge, including the knowledge of medicinal plants. Therefore, we deduce from this that if language disappears, especially languages of the oral tradition that do not have written language, a considerable amount of ancestral knowledge of medicinal plants also disappears.

4. Since every BioTrade initiative is based on the relationship between the private company and the local community, what do you think are the central values that the relationship between the private company and the community should show before and during a BioTrade process where the TMPK is involved?

Firstly, I think that whenever possible, the Indigenous communities themselves should develop their own small enterprises related to their ancestral knowledge based on medicinal plants. Suppose it is demonstrated that this preparation has very positive effects for specific pathologies, and they decide to commercialize it at an international level. In that case, it is necessary to develop a BioTrade standard in which the benefits, rights, duties, etc., of each of the parties are clearly indicated, both at an economic and intellectual level.

5. Do you know of any case in which the commercialization of an endemic or sacred medicinal plant in your country has caused negative impacts on the traditional knowledge related to it? In case your answer is positive, please explain in detail the context and the impacts caused.

I know a few cases. The first one is the ayahuasca patent which can be found at this link:

<https://www.iceers.org/es/gringo-patentar-ayahuasca/>

Fortunately, the patent has already expired, and its scope was limited, so it did not have severe consequences for the Amazonian communities of Ecuador.

Another case I know of is a Shuar woman from the Omaere ethnobotanical park in Puyo city. Her husband Chris Canaday told me that foreign people had arrived to learn about the ancestral knowledge of medicinal plants of the Shuar community. The case is that these people began to commercialize products based on their knowledge and without their authorization, which generated a great distrust, and since then, this community does not share their ancestral knowledge for the elaboration of plant products based on plants.

Another conflictive case has been that of guayusa with the North American company RUNA (runa.com). This company currently sells guayusa-based products, including energy drinks, mainly in the North American market and electronic portals such as Amazon. It seems that one of the reasons for the conflict was not sharing an international award received by the students. This then led to a series of other

problems, and more details can be found at this <https://bibdigital.epn.edu.ec/handle/15000/19862?mode=full>

6. In the literature reviewed, it is mentioned that the trade of medicinal plants has several negative impacts on the traditional knowledge related to these plants. Could you explain why these impacts are considered harmful for the sustainable development of Indigenous communities? Explain the reason for each one of them. If you know of other negative impacts, please mention them.

The adverse effects most frequently observed are, on the one hand, overexploitation and, on the other, biopiracy.

- Loss of the TMPK due to the extinction of species due to overexploitation.

A severe case in Peru is that of the "uña de gato," and although there is no data in Ecuador, I imagine that the situation must be similar. This plant has many properties to strengthen the immune system and especially against cancer, which is why it is a plant that is in high demand worldwide. This situation has caused environmental problems due to overexploitation.

- Interruption of the intergenerational transmission of the TMPK.

The intergenerational transmission of ancestral knowledge may be caused mainly by the loss of languages. These languages are an oral tradition; they do not have a written language, and the fact that there are national or multinational companies that contact these communities may favor the imposition of Spanish as the vehicular language, and little by little, the native language will be lost. Here can be found more information about it. <https://elpais.com/ciencia/2021-06-11/el-conocimiento-medicinal-indigena-se-extingue-sin-dejar-rastro.html>

Another vital aspect to consider is the loss of biodiversity caused by climate change and deforestation caused by the growth of the agricultural frontier, which can also lead to the loss of native plants and thus to the loss of ancestral knowledge related to the medicinal use of these plants.

<https://gk.city/2021/03/21/deforestacion-bosques-tropicales-ecuador/>

- Disinterest of new generations in learning the TMPK.

I do not have sufficient data to affirm or disprove this fact.

- Illegal appropriation and use of the TMPK (biopiracy).

This is one of the most common adverse effects and of which some examples have been described in the previous question. These facts generate a great distrust towards the companies and therefore towards the use of these herbal preparations.

7. Among the leading international agreements that support the safeguarding of traditional knowledge of medicinal plants, four proposals stand out the most:

- **To consider the safeguarding of the TMPK as an inalienable right of Indigenous peoples and communities.**
- **To consider the safeguarding of the TMPK within the national intellectual property system.**
- **To consider the safeguarding of the TMPK as indispensable for the sustainability of biodiversity and vice versa.**
- **To consider the safeguarding of the TMPK within the system for the protection of intangible cultural heritage.**

Explain from your professional criteria, what do you think is the contribution of these approaches for the prevention and/or mitigation of the possible negative impacts that the commercialization of medicinal plants causes on the traditional knowledge related to them? Which is/are the most priority proposal from your point of view?

The first of them is fundamental and not only as rights of Indigenous peoples but also as rights of nature. In my opinion, life cannot be patented. Secondly, I believe that it is possible to register or patent preparations of these products, indicating quantities, vegetable products, way of preparation, processes, etc. In my opinion, if it is possible, it can be protected at least with some kind of legal body. These preparations or products can give rise to certain benefits for the Indigenous communities that can contribute to these communities' environmental and socio-economic sustainability. Finally, it is necessary to comment that for me there would not be any of the four forms of protection that would stand out over the others but to achieve an integral level of

protection it is necessary to consider all these options so that in this way the ancestral knowledge of the Indigenous communities is protected.

8. Most of the international agreements recommend legislative, administrative, or political measures at the national level that directly or indirectly support the safeguarding of the TMPK. However, these measures do not exist in all countries. If this is the case, what would you recommend regulating the BioTrade of medicinal plants in Indigenous communities and prevent this activity from causing negative impacts on the TMPK?

Regarding legislative measures, it is recommended to read the thesis under the title: "Tendencias jurídicas en el Ecuador con respecto a los derechos colectivos de las comunidades Indígenas sobre sus conocimientos tradicionales" (Legal trends in Ecuador with respect to the collective rights of Indigenous communities on their traditional knowledge).

Regarding administrative issues, I would request that the processes for the sanitary registration and legalization of products prepared from plants in Indigenous communities have an agile, fast, and simplified process.

Finally, in terms of policies, on the one hand, national policies should be approved to guarantee the protection of traditional knowledge of medicinal plants, and, on the other hand, international agreements should be signed and promoted to protect such knowledge.

9. The international agreements suggest the generation of educational programs to promote the TMPK. From your professional criteria, do you consider that transmitting the TMPK to producers and workers in a formal way can contribute to safeguarding it in the context of BioTrade? Would it be appropriate to extend the formal transmission of the TMPK to the community as part of the BioTrade initiative? What are the advantages and/or disadvantages of this process? Explain your answer.

In my opinion, educational processes for protecting ancestral knowledge of medicinal products or plants are essential. In the first place, they will help to preserve this ancestral knowledge. Secondly, they will provide an alternative economic income for the communities. It is also important that there is training on preparing these medicinal plant-based products with a minimum of quality. In this sense, I think that the

collaboration of universities and other qualified technicians is fundamental. It would also be necessary to have training in the commercial area, that is, basic accounting, a little bit of I do not know if I should call it marketing or sales strategies, even if it is at a local level so that the project can be successful. The participation of women is particularly important in this case. All these activities and initiatives together can give some economic independence to women in Indigenous communities.

10. The international agreements analyzed suggest that access to and use of the TKPMC (generally for commercial purposes) should be authorized by its legitimate owners, who should also receive part of the economic benefits derived from this use. If no legal recognition grants the owner of this knowledge to a community or specific members, how do you suggest that the private company addresses this issue with the community to safeguard the TMPK? Do you consider that the TMPK is community property? Or are its owners those who transmit and practice it?

Although there is no legal institution that recognizes the ownership of their preparations to the Indigenous communities, I understand that morally and ethically, the company should sign some kind of contract where the agreements reached with the community are indicated and that benefit both parties. In my opinion, it is not that there are owners, but that in some way that knowledge belongs to that community, and then if there is someone who wants to use it, then obviously they have to negotiate with that community to establish the benefits for each one of them. It cannot be that ancestral knowledge acquired over hundreds and thousands of years is used with impunity by a person or company outside the community without reaching an agreement. All the effort made by the community to obtain this knowledge must be somehow rewarded and respected.

