

Evidence on the Safety of Traditional Coca Leaf Use in Colombia



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1 Center for Services and Trade of the National Learning Service.

2 Research in Genetic Toxicology and Cytogenetics.

3 Research in Electron Mycroscopy.

4 Center for Education, Training and Research for the Integral Development of the Community.

Introduction

P. 10

01. Results

P. 13

1.1. Systematic Review

P. 14

1.2. Case Study in Toribío, Cauca

P. 15

1.3. Regulatory Framework for the Medicinal Uses of Coca Leaf in Colombia

P. 18

02. Combining results

P. 19

03. Conclusions

P. 21

Chapter 1

Safety in the Traditional Use of Coca Leaf in Colombia: Scoping Review

P. 23

01. Objectives

P. 25

1.1. General Objective

P. 25

1.2. Specific Objectives

P. 26

02. Methodology

P. 26

2.1. Eligibility Criteria

P. 27

2.2. Study Compilation and Selection

P. 27

2.3. Reading the Papers

P. 27

2.4. Classification

P. 28

03. Results

P. 29

04. Discussion **P. 34**

- 4.1. History and Botany P. 35
- 4.2. Evidence of Use in Colombia P. 41
- 4.3. Quantitative Safety Studies P. 49
- 4.4. Qualitative Safety Studies P. 56
- 4.5. Combining the Findings P. 58
- 4.6. Discussion of Findings Compared to Previous Systematic Reviews P. 61
- 4.7. Gaps in Available Evidence and Implications for Future Research P. 62
- 4.8. Limitations of the Review Process P. 63

05. Conclusion **P. 65**

- 5.1. Technical Conclusion on the Safety of Traditional Use P. 65
- 5.2. Implications for Public Policy and Surveillance P. 65
- 5.3. Recommendations for Future Research P. 65

Chapter 2

Safety in the Traditional Use of Coca Leaf in Colombia: A Case Study in Toribío, Cauca

P. 66

01. Methodology **P. 67**

- 1.1. Institutional Context and Inter-institutional Collaboration P. 67
- 1.2. Fieldwork Design P. 68
- 1.3. Sampling Strategy P. 70

Table of contents

02. Toribío Context	P. 71
2.1. Indigenous Governance and Territorial Autonomy	P. 74
2.2. Relevance for this Review	P. 74
03. Results and Descriptive Analysis of the Information Obtained in the Field	P. 76
3.1. Analytical Approach and Systematization	P. 76
3.2. Support of Digital Tools and Knowledge-based Approach	P. 77
3.3. Meaning of <i>Esh</i> 's: "There is no Nasa without Coca"	P. 78
3.4. <i>Pajarita</i> is Planted in <i>Tul</i> and Roasted in <i>Cayana</i> : Cultural Knowledge and Traditional Practices	P. 80
3.5. Coca Use Practices: <i>mambear</i> to Understand, Diagnose, and Cure	P. 91
3.6. Sanitary Safety of the Coca Leaf: Quality, Uses, and Traditional Control	P. 90
04. Conclusions	P. 94

Chapter 3

Regulatory Framework for the Medicinal Uses of Coca Leaf in Colombia

P. 95

01. The Two-fold Status of Coca Leaf in Colombian Legislation	P. 98
1.1. Constitutional and Jurisprudential Recognition of Traditional Uses	P. 99
1.2. Protecting Coca Leaf as Cultural Heritage	P. 100
1.3. Limitations to Regulatory Recognition in Non-Indigenous Contexts	P. 101
1.4. Towards a Human Rights-based Interpretation	P. 103

02. Coca Leaf Within the Indigenous Peoples Healthcare System	P. 107
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03. Legal pathway for the coca leaf for medicinal purposes outside the indigenous territories	P. 111
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04. Conclusion	P. 113
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References

P. 115

Introduction

This document forms part of the critical review process being carried out by the World Health Organization (WHO) regarding the inclusion of the coca leaf in Schedule I of the Single Convention on Narcotic Drugs, 1961. This review, initiated at the request of the Plurinational State of Bolivia and supported by the Republic of Colombia, offers a unique opportunity within the international drug control regime to reassess, in light of new evidence, the criteria applied to substances of natural origin with traditional uses, such as the coca leaf.

The first major challenge of this process lies in the very architecture of the international drug control system. The prevailing classification model, established in the 1960s and 1970s, was primarily designed to assess synthetic chemical substances developed by the pharmaceutical and chemical industries using standardized biomedical parameters, including clinical trials and toxicological studies.

In practice, this system has operated almost exclusively as a mechanism for the inclusion of new substances in the control schedules. Consequently, it has not been tested against contemporary realities, such as natural products with traditional uses that are not supported by pharmaceutical or industrial actors, or by conventional clinical evidence (GCDP, 2019).

The coca leaf represents one of the clearest examples of this disconnect between the system's design and the reality it seeks to regulate. Unlike cannabis—whose rescheduling in 2018 was preceded by regulatory changes, the establishment of medicinal markets in some countries, and abundant clinical evidence—the coca leaf has been analyzed almost exclusively as a raw material for the production of cocaine. Its traditional, nutritional, ritual, and therapeutic uses have historically been rendered invisible. Although it has been safely consumed for centuries by Andean and Amazonian communities, its cultural, nutritional, and spiritual value remains poorly documented. The lack of conventional scientific evidence does not reflect an absence of knowledge, but rather a historical gap resulting from stigma, prohibition and limited investment in the subject.

This asymmetry in the production and validation of evidence is not accidental. Various studies have documented some of the limitations of the international drug control system, which faces difficulties when addressing the classification of plant-based drugs *vis-à-vis* other types of drugs (Buxton et al., 2017). The coca leaf, along with kratom, ayahuasca, and psilocybin mushrooms, has been subject to regulatory frameworks marked by a lack of conventional scientific evaluation and persistent biases. In the case of coca, these biases are exacerbated by its association with the illicit production of cocaine.

The limitations described above are further reinforced by the design of the critical review processes led by the World Health Organization (WHO), which rely almost exclusively on conventional scientific and epidemiological evidence as a basis for decision-making. This report puts forward arguments to suggest that indicators such as intoxications, mortality, problematic use, or treatment demand are insufficient, in the case of the coca leaf, to assess its risks or justify its international control as a narcotic drug. Its use is geographically restricted to no more than six countries in South America, is not associated with problematic consumption, and is not subject to systematic epidemiological surveillance in countries such as Colombia. Consequently, the indicators and questionnaires commonly used by WHO do not provide sufficiently specific or relevant information for the assessment of the coca leaf as a narcotic drug.

In light of these limitations, other forms of evidence should also be acknowledged, particularly the traditional knowledge accumulated by Indigenous and peasant communities. Transmitted orally across generations and embedded within their own healthcare and spiritual systems, this knowledge has enabled the safe, sustainable, and culturally meaningful use of the coca leaf as food, medicine and a cultural practice. Although not documented in the conventional scientific literature or validated through clinical trials, these bodies of knowledge constitute legitimate forms of empirical knowledge.

The World Health Organization itself has emphasized the need to strengthen the role of traditional medicine in primary healthcare, to promote research and evidence generation, and to ensure respect for cultural diversity and the rights of Indigenous Peoples in public health policies (WHO,

2013, 2025). Likewise, the literature on public health and ethnomedicine underscores the importance of intercultural approaches that recognize traditional knowledge as part of legitimate scientific knowledge (Mignone et al., 2007; PAHO, 2002).

In Colombia, this knowledge is supported by constitutional and jurisprudential frameworks that recognize the use of the coca leaf as an integral part of the cultural heritage of Indigenous Peoples, as well as by technical studies conducted by the National Institute of Health, which conclude that its consumption in natural forms does not pose significant risks to human health.

However, stigma and restrictions arising from the current international control of the plant have limited the visibility and institutional recognition of this knowledge. Article 49 of the Single Convention on Narcotic Drugs, 1961, mandated the elimination of coca leaf chewing within 25 years, as it was considered harmful. This provision, challenged by Bolivia through well-founded legal arguments, is now widely regarded as incompatible with contemporary principles of human rights, traditional medicine and the protection of Indigenous Peoples (ERIA, 2023).

Contemporary regulatory frameworks provide for multiple categories of substances intended for human consumption, including prescription medicines, herbal medicines, dietary supplements, functional foods and cosmetics. Various substances—such as caffeine or menthol—may serve functions across multiple categories. Similarly, the coca leaf may simultaneously have nutritional, medicinal and ritual uses in Indigenous healthcare systems. Imposing a single definition of legitimate medical use disregards the epistemological pluralism recognized even in the official commentaries to the Single Convention, which indicate that the term “medical purposes” does not have a single meaning and must be interpreted in accordance with the state of medical science in each context.

Indeed, according to the criteria established by WHO for traditional herbal medicines, it is reasonable to argue that the coca leaf could meet the minimum requirements for recognition as a traditional medicinal product, particularly when chewed (*mambeo*). Nevertheless, this possibility has historically been dismissed due to the lack of systematic documentation and the explicit prohibition set out in Article 49 of the Single Convention, 1961.

The purpose of this document and its annexes⁵ is to contribute scientific, legal and cultural evidence to the WHO critical review process, with a view to substantiating the safety of coca leaf as a product for human consumption. The report includes a scoping review of the existing scientific literature; a case study of the Indigenous community of Toribío (Cauca), including interviews on use practices and risk perceptions; and a analysis of the regulatory framework that supports its legality within the Indigenous healthcare system in Colombia.

This research does not claim to exhaust all the evidence on the uses of coca leaf—much of which remains undocumented—but rather offers an alternative way of understanding associated practices by highlighting the voices of those who sustain them and recognizing the traditional knowledge built up over generations. In this sense, it complements the information submitted by the Government of Colombia in November 2024 and seeks to contribute to the deliberations of the Expert Committee on Drug Dependence by encouraging the adoption of a methodological approach that recognizes diverse forms of evidence and takes into account the perspectives of the ethnic communities concerned.

1. Results

The Safety Assessment of the Traditional Use of the Coca Leaf, using mixed methods, was conducted in three interrelated phases under a qualitative research approach aimed at describing and analyzing the traditional and contemporary uses of coca leaf in Colombia, as well as the regulatory frameworks associated with its consumption. These phases were as follows: a scoping review; a case study on traditional practices in Nasa Indigenous territories⁶ in Cauca; and a review of the regulatory framework. The conclusions for each phase are presented below.

5 Only available in Spanish on <https://elementaddhh.org/evidencia-sobre-la-seguridad-del-uso-tradicional-de-la-hoja-de-coca-en-colombia/>

6 A legal figure in Colombia where land is collectively held by an Indigenous community.

1.1 Systematic Review

The scoping review systematized 31 relevant studies on the safety of the traditional use of the coca leaf (*Erythroxylum coca* and *Erythroxylum novogranatense*) in Colombia. The evidence collected shows a predominant pattern of oral consumption through whole leaves (dried or fresh), *mambe*—a powdered preparation combining roasted leaves with alkaline plant ash—and artisanal infusions. These culturally regulated forms of use occur in ritual, therapeutic, nutritional, and identity-related settings and are intergenerationally regulated in terms of frequency, dosage and preparation. Under these conditions, no acute or chronic adverse effects were systematically reported, nor was cumulative toxicity observed in populations with prolonged exposure.

From a botanical perspective, the predominant species used were *Erythroxylum coca*, var. *coca* and *E. novogranatense* var. *novogranatense*, cultivated in different regions of the country. The phytochemical studies included in this review report contents in dry leaves ranging from 0.4% to 1.2%, along with the presence of other alkaloids, such as cinnamoylcocaine, tropacocaine, ecgonine methyl ester, and cuscohygrine, in varying proportions depending on the plant variety and origin. The literature also describes the selection of specific varieties based on organoleptic and morphological attributes and associated cultural values.

The traditional and contemporary uses of the plant were documented in the Andean, Amazonian, and Caribbean regions of Colombia, including the departments of Cauca, Nariño, Putumayo, Caquetá, Vaupés, Guaviare, Cundinamarca, Antioquia, Santander, Boyacá, as well as the Sierra Nevada de Santa Marta. The populations that use the plant include Indigenous communities, rural, and urban users, with ongoing patterns of use that respond to different purposes and degrees of formalization.

These uses were classified into four non-exclusive functional categories: ritual-spiritual, therapeutic, dietary, and sociocultural-identity. These practices range from traditional coca chewing and *mambeo* with alkaline substances to infusions, ointments, functional foods and encapsulated extracts. Overall, there is a progressive integration of the leaf into practices associated with personal care and nutrition through preparations

with low alkaloid concentrations, which users perceive as harmless and for which no adverse effects have been documented. This diversity of uses reflects a complex network of meanings that transcends conventional medicinal or food categories and encompasses dimensions of food sovereignty, cultural continuity, and symbolic reconfiguration.

From a public health safety perspective, the available clinical, toxicological and observational studies do not report clinically significant adverse effects and indicate exposure levels well below known toxicological thresholds. In particular, an official assessment by Colombia's National Institute of Health (2023) concluded that prolonged daily consumption of an infusion prepared with 1 g of dried coca leaf does not pose an unacceptable risk to human health, with a hazard quotient below 1 in accordance with international food risk assessment standards.

Furthermore, according to WHO technical criteria for traditional herbal products, the coca leaf meets essential conditions: prolonged use with no systematic evidence of harm, verifiable botanical identification, and preparation in accordance with culturally standardized methods. Consequently, the evidence gathered supports a safety profile compatible with international public health regulatory frameworks.

Taken together, these findings support the need for a critical reassessment of the international status of the coca leaf that clearly differentiates it from its concentrated psychoactive derivatives. Such differentiation is consistent with scientific evidence, public health principles and the rights of the peoples who traditionally use it.

1.2. Case Study in Toribío, Cauca

The municipality of Toribío (Cauca) has a unique institutional and demographic configuration in Colombia. More than 98% of the municipality's population self-identifies as Indigenous (from the Nasa People), and the territory comprises three Indigenous territories. This structure has facilitated coordination between the municipal administration and Indigenous governance systems, traditional authorities, and Indigenous councils (*cabildos*). Within this framework, there is a local market for the distribution of coca leaf for medicinal and ritual uses, coordinated by the Nasa Project in conjunction with the Indigenous healthcare system.

For the Nasa People, the coca leaf (or 'Esh's' in Nasa Yuwe) has deep spiritual, therapeutic, and organizational connotations. Although the study does not address the Indigenous worldview in depth, it describes the central role of the coca leaf in spiritual development, organizational cohesion, the maintenance of social and individual harmony, and collective decision-making.

Mambeo, or the ritual chewing of coca, is practiced in spaces designated for deliberation, consultation, or problem-solving. According to testimonies, the stimulating effects of the alkaloids present in the plant facilitate concentration and enable individuals to 'hear' nature's messages, thereby reestablishing unity between body, territory and thought. Thus, *mambeo* is not merely a symbolic act but a channel of connection with guiding forces that shape healing and decision-making processes.

Indigenous communities in Toribío grow coca exclusively for traditional purposes. The variety grown, known as *Pajarita caucana*, is planted in Nasa Tul, a polyculture system that combines food, medicinal, and ritual species and is located in vegetable gardens near households. This cultivation method protects the plant from contact with agricultural inputs and pesticides.

Although cultural mandates and the Nasa Life Plan establish that each family should grow its own coca leaf for ritual purposes, land scarcity has forced communities to prioritize commercial crops such as coffee or marijuana. As a result, many families now maintain only a few plants or rely on purchasing coca leaf to sustain their cultural practices. To address this situation, the Nasa Project has established a local market that provides access to high-quality coca leaf, integrating its distribution with the Indigenous healthcare system and the project's store. The leaves are harvested by designated elders, who supply them for ritual and community use.

Harvesting is carried out manually, with each leaf picked individually, in contrast to the "scraping" method used for crops destined for cocaine production. This procedure maintains the plant's health and prevents the damage that can make chewing difficult.

In Toribío, roasted coca leaves are chewed with a catalyst known as *mambe*. Unlike in other regions, ash from *yarumo* (*Cecropia spp.*) and flour are not used as ingredients. In Toribío, *mambe* consists of a powder made

from locally sourced limestone, which is heated for more than 12 hours and then pulverized with the addition of water. Its function is to improve flavor and facilitate the release of alkaloids from the leaf.

Traditional coca use is a collective practice in nature and is usually guided by cultural and spiritual authority figures, such as *Thë Walas*, *Kiwe Thë*, midwives, or healers. Participation in rituals requires trust, relational closeness, and spiritual disposition. For example, a personal consultation involves the symbolic offering of items such as *chirrincho* (a traditional distilled spirit), tobacco, and coca leaf to the elder or eldress. Through the ritual chewing of coca, engagement with the offerings, and dialogue, the authority figure interprets the signs received and provides guidance.

In collective rituals, the leaf is distributed and chewed until the ritual process “comes to fruition”, that is, until it fulfills its purpose of harmonization. It also serves diagnostic and therapeutic functions and is employed in cases of stomach pain, toothache, headache, anemia, and as an energizing agent. It may be combined with other plants, such as moringa (*Moringa oleifera*), to enhance its effects. The plant is generally used as a first line of treatment before resorting to western healthcare systems.

The sanitary quality of the leaf is closely linked to the cultural processes of cultivation, harvesting, roasting and storage. The amount used per session varies: a ritual *mambeada* is estimated to require between 15 and 35 grams per person, while collective events may use between five pounds and one *arroba* (approximately 11.5 kg) of coca leaf.

Use is neither habitual nor associated with labor activities; rather, it is regulated by participation in cultural events. Older individuals who frequently attend rituals are the primary users.

During the fieldwork, no cases of intoxication were reported, nor were specific restrictions on use identified for children or pregnant women. In fact, minors participate in rituals from an early age, and pregnant women consume coca leaf as part of their spiritual preparation for childbirth. The only contraindications identified were excessive concomitant use of tobacco with coca (which may cause dizziness or vomiting), consumption while under the influence of alcohol, and inadequate oral hygiene, which could lead to tooth decay with prolonged use.

The study's findings support the conclusion that, within the context of the Nasa People, culturally validated practices substantiate the safety of the traditional use of the coca leaf as a product for human consumption. Recognizing this body of knowledge constitutes not only an imperative grounded in public health and Indigenous Peoples' rights, but also an opportunity to advance intercultural and rights-based approaches in the assessment of natural products with deep ancestral roots.

In addition, gathering information on patterns of use in other regions of the country—using similar methodologies—would enable a more in-depth characterization of conditions of use and their relationship to the cultural diversity of ethnic communities.

Moreover, within the framework of the development and implementation of the Sistema Indígena de Salud Propio e Intercultural⁷ (SISPI, in Spanish), the findings support recognizing the coca leaf as a traditional medicine with established uses, grounded in the ancestral practices of the peoples who have historically used it or have incorporated its consumption into their cultural and spiritual systems.

1.3. Regulatory Framework for the Medicinal Uses of Coca Leaf in Colombia

The coca leaf occupies a complex and strategic position within the Colombian regulatory framework, as it holds a twofold status: as a controlled substance under international drug control commitments and as an expression of the right to cultural identity protected under the constitutional rights of Indigenous Peoples. This dual status reflects historical tensions between obligations arising from international treaties and the duty of the Colombian State to guarantee the full exercise of fundamental rights, particularly those of Indigenous Peoples.

The national legal system has expressly recognized that traditional uses of the coca leaf within Indigenous healthcare systems are lawful. However, regulatory limitations persist with respect to its development outside Indigenous territories, particularly in the phytotherapeutic and food

7 Indigenous and Intercultural Healthcare System.

sectors. This situation constrains the possibility of expanding its lawful use under established health and quality standards, thereby limiting both safe access to the plant and its incorporation into wellness and self-care strategies.

A constitutional and jurisprudential analysis shows that the legal protection of the coca leaf is not confined to its cultural dimension. The Constitutional Court has repeatedly acknowledged its potential health-related and productive benefits, provided that a safety, traceability, and control framework is guaranteed. In this regard, the Court has reaffirmed the right of Indigenous Peoples to preserve and develop their traditional healthcare practices and to access the natural resources necessary to do so, including the coca leaf as a medicinal plant.

2. Combining results

The three components analyzed—the systematic review of the scientific literature, the territorial case study in Toribío (Cauca), and the analysis of the Colombian legal framework—make it possible to identify a discrepancy between the current classification of the leaf and the effective exercise of Indigenous communities’ rights, particularly the right to health.

First, although limited in scale and institutional recognition, the available scientific evidence corroborates the traditional knowledge documented in the field, as both describe a pattern of prolonged, safe, and socially regulated use. The practice of chewing coca leaf or preparing infusions does not correspond to compulsive consumption patterns, nor is it associated with clinically relevant adverse effects. However, the international control system has prioritized conventional biomedical indicators—such as intoxication, dependence, and mortality—while disregarding culturally grounded and non-standardized forms of evidence, including those emerging from the SISPI and from peasant and Indigenous practices.

At the local level, the case of Toribío demonstrates that the coca leaf serves not only as a medicinal resource but also as a fundamental component of local healthcare systems, conflict resolution mechanisms, diagnostic practices, nutrition, and ritual life.

At the regulatory level, the Colombian legal system has made progress in recognizing the traditional use of the coca leaf, establishing constitutional and jurisprudential conditions that allow for its protection as inherent to the guarantee of Indigenous Peoples' right to cultural identity. However, the current international classification remains an obstacle to the development of differentiated regulations at the national level, as it fails to draw clear distinctions between the leaf in its natural state and its concentrated psychoactive derivatives, both of which are equally classified as narcotic drugs under Schedule I of the Single Convention on Narcotic Drugs, 1961.

In this context, the critical review process led by the World Health Organization can benefit from the perspectives of Indigenous Peoples in order to develop a more equitable, evidence-based, and culturally responsive classification framework.

From a territorial perspective, the findings of the Toribío case study further reinforce the evidence regarding safety under everyday conditions of use. In Nasa communities in Cauca, the study documented the agroecological cultivation of specific varieties such as *Erythroxylum novogranatense* var. *novogranatense* ("pajarita"), grown in polyculture within the Nasa Tul agricultural system, with functional and ritual uses integrated into the SISPI. No cases of poisoning were reported in the interviews, and spontaneous community controls were identified to limit the number of plants per family, suggesting practices of self-regulation and prudent management of the botanical resource.

The analysis further reinforces the need for a clear distinction between the coca leaf and cocaine within international regulatory frameworks. It is proposed that traditional use be defined on the basis of criteria such as alkaloid concentration, route of administration, forms of preparation, botanical variety, and cultural or functional purpose. This approach is consistent with the principle of regulatory proportionality and with the mechanisms established in international conventions for excluding substances that do not meet the relevant technical criteria from the control regime.

Finally, the information obtained through this research also provides elements for assessing the potential risks of diversion or misuse of medicinal

or industrial products derived from the coca leaf. Article 2(9) of the Single Convention on Narcotic Drugs, 1961, provides that parties are not required to apply the provisions of the Convention to drugs which are commonly used in industry for non-medical or scientific purposes, provided that certain criteria are met, namely that they are harmless, are not liable to be abused, and that harmful substances—in this case, ecgonine alkaloids—cannot be recovered in practice. In this regard, substantial arguments are presented demonstrating that the coca leaf and its preparations are not harmful to human health. Moreover, emerging evidence indicates that the recovery of controlled alkaloids such as cocaine is not feasible in practice, given the diverse cultivation methods and transformation processes involved in the production of value-added coca-based products. If the harmlessness and non-recoverability criteria are deemed applicable to the coca leaf through implementation of the aforementioned exception, then its removal from Schedule I of the Single Convention would not entail unknown risks associated with the plant.

3. Conclusions

The comprehensive analysis of the available scientific, regulatory, and contextual evidence on the traditional use of coca leaf in Colombia supports the conclusion that, under controlled conditions, the safety profile of this plant is consistent with the technical criteria established by the World Health Organization for traditional herbal products. The information compiled through the scoping review, case studies, and regulatory analysis consistently points out to a pattern of sustained and culturally regulated use that is not associated with clinically relevant adverse effects.

The continued inclusion of the coca leaf in Schedule I of the Single Convention on Narcotic Drugs, 1961, is not consistent with its profile as documented in this review. In light of the systematic evidence, a reassessment of its international control status is technically warranted, in accordance with the mechanisms provided for in multilateral treaties and based on the principles of scientific evaluation defined by the WHO. Furthermore, the criterion regarding the convertibility of a substance—in this case Coca Leaf and its preparations—into a recognized narcotic (i.e., cocaine) is not applicable since the leaf and its traditional preparations cannot, strictly

speaking, be converted into cocaine in practice. Accordingly, removing the coca leaf from Schedule I of the Convention would not entail the removal of concentrated alkaloid preparations from international control; rather, it would maintain the control measures aimed at preventing the extraction and purification of cocaine from such substances.

While the present research highlights that the full body of evidence regarding coca use by Andean and Amazonian communities has not yet been comprehensively documented, the absence of additional scientific evidence does not, in itself, sufficiently justify maintaining the classification of the coca leaf as a narcotic drug under Schedule I of the Single Convention on Narcotic Drugs, 1961. The research identified no evidence to justify maintaining the current level of control over the coca leaf. Indeed, if the WHO were to initiate a review of coca leaf for possible scheduling under the international drug control treaties—as though it were a new substance subject to control—the existing body of evidence would not support a recommendation for its inclusion.

Conversely, the review process presents an opportunity to incorporate and amplify the voice of ethnic communities regarding the traditional and ancestral uses of plants. The historical omission of such perspectives has resulted in policies that, by failing to account for this knowledge, have generated negative impacts and infringed upon the human rights of these communities. Therefore, efforts should be directed toward advancing more inclusive and culturally appropriate models of research and evidence validation, particularly in relation to plant-based substances with recognized traditional uses.

The study's findings also indicate that, in Colombia, the coca leaf constitutes an essential component of Indigenous healthcare systems within the framework of the SISPI, and that its use complies with the principles of legitimacy, safety, and cultural relevance.

Overall, this body of evidence provides a robust technical and legal foundation for supporting differentiated classification processes, the preparation of technical monographs, and the development of public policies grounded in actual risk. These measures can contribute to the regulated recognition of the traditional use of coca leaf in Colombia, based on public health and human rights principles.

In conclusion, the study confirms that coca leaf is traditionally and legally used for medicinal purposes in Colombia. This use is deeply rooted in community healthcare practices and has been formally integrated into the SISPI, which is protected by the Constitution. In this context, coca chewing is not a recreational or illicit act, but a recognized therapeutic practice. Therefore, the continued prohibition of this practice under international drug control treaties is legally and ethically questionable, particularly in light of the conventions' stated commitment to respecting traditional medical systems and the rights of Indigenous Peoples.

Chapter 1

Safety in the Traditional Use of Coca Leaf in Colombia: Scoping Review⁸

Many communities in Colombia have long used coca (*Erythroxylum coca* and *Erythroxylum novogranatense*) leaves for traditional, medicinal, cultural, and productive purposes. However, their long-standing inclusion in international drug control schedules, together with limited scientific documentation of their uses and safety profile, has hindered their recognition within public health regulatory frameworks and in national and international drug policy regimes.

This scoping review aims to identify and systematize the available scientific evidence on the safety of the traditional use of coca leaf, characterizing their principal consumption practices, sociocultural contexts, and patterns of preparation and use.

A systematic search was conducted across academic databases (PubMed, Scopus, EMBASE, Cochrane Library, LILACS, and SciELO), as well as grey literature, regulatory documents, and sources suggested by subject-matter experts. The inclusion criteria focused on studies describing traditional consumption practices or providing relevant safety data. Texts primarily addressing illicit cocaine trafficking or forced eradication,

8 Annex 2 contains the references of the scoping review contained in this chapter.

as well as those lacking full-text access, were excluded. Study selection was conducted independently by pairs of reviewers. The results were organized into four analytical categories: (i) plant history and botany; (ii) empirical evidence on use in Colombia; (iii) quantitative safety evidence; and (iv) qualitative safety evidence.

A total of 31 studies met the inclusion criteria. Most research describes a pattern of oral consumption of whole leaves, typically accompanied by alkalizing agents (such as lime), in fractional doses taken throughout the day. Consumption habits are deeply shaped by traditional norms and practices that define their frequency and purpose. Under these conditions, no acute or chronic adverse effects were systematically reported, nor was cumulative toxicity observed in populations with prolonged exposure.

The data collected suggest an acceptable safety profile for the traditional consumption of coca leaf. Cultural practices of preparation and use, together with the absence of evidence of long-term harm, support a favorable assessment from an evidence-based public health perspective.

When used in its traditional forms, the safety profile of coca leaf is consistent with the standards applicable to traditional herbal products recognized within health regulatory frameworks. Although still limited, the available scientific documentation provides sufficient grounds to advance toward a differential recognition of coca leaf, as opposed to their psychoactive derivatives, such as cocaine.

Coca leaf (*Erythroxylum spp.*) have been used by various Andean and Amazonian cultures for millennia as food, in rituals, and for social and medicinal purposes. Their consumption, documented through archaeological, ethnobotanical, and anthropological records, has been closely linked to traditional healthcare systems and to the ways of life of numerous Indigenous communities (1).

In Colombia, regulatory restrictions stemming from its classification as a controlled substance under the Single Convention on Narcotic Drugs, 1961 have limited research on coca leaf, as well as their lawful use and acceptance for health purposes. Recent studies have shown that, although there are community-based experiences aimed at promoting alternative uses of the coca leaf, these efforts face legal and operational challenges that restrict their development within the current regulatory framework (2).

The ongoing interest in reviewing this classification has prompted a growing effort to gather and systematize scientific evidence to assess the safety conditions associated with the traditional use of coca leaf. In this context, the present scoping review aims to identify and characterize traditional forms of coca leaf consumption in Colombia and to examine whether the available evidence provides relevant elements for assessing their safety, with a view to supporting evidence-based regulatory decision-making.

This exercise is based on the recognition of traditional use as a valid form of knowledge, the assessment of which may inform processes of health-related recognition, in accordance with the technical frameworks established by international organizations such as the WHO. In line with this approach, the analysis is structured into distinct thematic categories in order to address this issue in a comprehensive manner.

Taken together, these components provide an updated overview of the available body of evidence and of the challenges associated with the appropriate incorporation of traditional knowledge into contemporary healthcare regulatory systems.

1. Objectives

This scoping review aimed to identify and characterize traditional forms of coca leaf consumption in Colombia and to examine whether the available evidence provides relevant information for assessing the safety of such use.

1.1. General Objective

To map the available evidence on the safety of the traditional use of coca leaf, integrating experimental studies, ethnographic research and historical records in order to characterize their consumption habits and patterns of administration, and to provide technical elements for the assessment of their regulatory status.

1.2. Specific Objectives

- a. To identify the different forms of coca leaf consumption in Colombia described in the literature.
- b. To describe the contexts and patterns of use of coca leaf in Colombia.
- c. To examine the safety outcomes associated with these uses.
- d. To compare findings across the sources reviewed and to identify information gaps.

2. Methodology

The following research question was formulated to guide this scoping review and to structure the search strategies across the selected databases.

Table 1. Research question

RESEARCH QUESTION	What evidence exists regarding the traditional consumption of coca leaf in Colombia, and to what extent does this evidence support their safe use?
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Based on this question, a literature search was conducted that included the Consejo Latinoamericano de Ciencias Sociales (CLACSO) Network of Virtual Libraries in the Social Sciences in Latin America and the Caribbean; the Cochrane Collaboration; Dialnet; LILACS; PubMed; SciELO; Scopus; the Transnational Institute; and the institutional repositories of Universidad Nacional de Colombia (UNAL), Universidad de Antioquia (UdeA), Universidad Industrial de Santander (UIS), Universidad del Cauca (UniCauca), and Universidad de los Andes (UniAndes). Grey literature identified through subject-matter experts was also included.

2.1. Eligibility Criteria

For this review, all types of research studies (clinical, ethnographic, review, etc.) published in Spanish, English, French, German, or Portuguese and focusing on the traditional, cultural, spiritual, medicinal, bromatological, or productive uses of coca leaf were included. The review excluded documents that (i) focused on drug trafficking, cocaine, or crop eradication; (ii) were not related to Colombia or to comparable consumption practices; (iii) did not address the research question; or (iv) were not accessible in full text.

2.2. Study Compilation and Selection

Duplicate records were removed, after which an eligibility assessment was conducted based initially on the titles and accessibility of the records. The title screening was carried out independently by two reviewers. In cases of disagreement, a third reviewer was consulted to reach a final decision. Following this phase, the same procedure was applied to the selected records, this time through abstract screening conducted independently by two reviewers, with a third reviewer consulted in cases of disagreement. The search prioritized information explicitly describing the actual conditions of use (dose, frequency, forms of consumption, intended and adverse effects, and restrictions by population group), as well as relevant regulatory, community, or institutional frameworks influencing coca leaf consumption in these contexts.

2.3. Reading the Papers

The selected papers were reviewed in full by two independent reviewers, who classified the documents according to their predominant thematic focus. Any discrepancies in interpretation or categorization were resolved through joint discussion or, where necessary, consultation with a third reviewer. To systematize the extracted information in a structured manner, artificial intelligence (AI) tools (3) were used to support the preliminary development of certain results tables. All outputs generated through this process were subsequently reviewed, revised, and validated manually by the research team responsible for the full-text assessment.

2.4. Classification

The selected articles were classified into one or more of the following categories:

- **History/Botany:** This category includes studies documenting the earliest evidence of human use of coca leaf, based on archeological, ethnohistorical, anthropological and botanical sources. Both material records (e.g., ceramics, lime gourds, leaf remains, and *poporos*) and mythological narratives, chronicles from the colonial or republican period, and comparative analyses between species of the genus *Erythroxylum* were considered. Studies grouped under this category reconstruct the historical development of coca use, including its domestication, geographical expansion, cultural diversity in its preparation and consumption, and the sociocultural, ritual, medicinal, and productive contexts that shaped its traditional use.
- **Evidence of Use in Colombia:** This category encompasses studies documenting the contemporary use of coca leaf in diverse Colombian communities. It aims to establish a body of evidence to identify the current forms and characteristics of coca leaf consumption in Colombia across Indigenous, rural, urban, and productive settings. Studies grouped in this category highlight the geographical, cultural, and functional diversity of coca leaf use in the country, thereby contributing to the assessment of actual risk and to the development of differentiated, evidence-based policies.
- **Quantitative Safety:** This category includes studies presenting numerical or measurable data related to the safety of coca leaf use, even when not originally designed for that specific purpose. It encompasses research that, within the framework of evaluations of chemical composition, metabolism, physiological responses, or therapeutic effectiveness, reports quantifiable indicators relevant to safety, such as alkaloid content, plasma or urinary concentrations, hormonal responses, and clinical parameters, among others. These studies were included in order to identify and assess all quantitative empirical evidence that may

contribute to the analysis of the risks and safety of coca leaf use in humans, even when such evidence was generated as a secondary or complementary outcome.

- **Qualitative Safety:** This category includes studies that document aspects related to the safe use of coca leaf based on non-quantifiable evidence obtained through observation, interviews, narratives, ethnographies, systematizations, experiential analysis, or case studies. All information describing the occurrence of adverse effects, traditional practices regulating the use, and community knowledge about risks and care, as well as the cultural perception of the safety of the leaf is considered relevant. Although these studies do not present numerical measurements, they provided substantial information on safe use habits, social contexts that shape risks, and preparation and administration practices that have historically prevented negative outcomes.

3. Results

The search was conducted between 6 and 15 May 2025 across various academic databases and institutional repositories. The search strategies employed, as well as the filters applied in each database, are described in detail in the supplementary material accompanying this document.

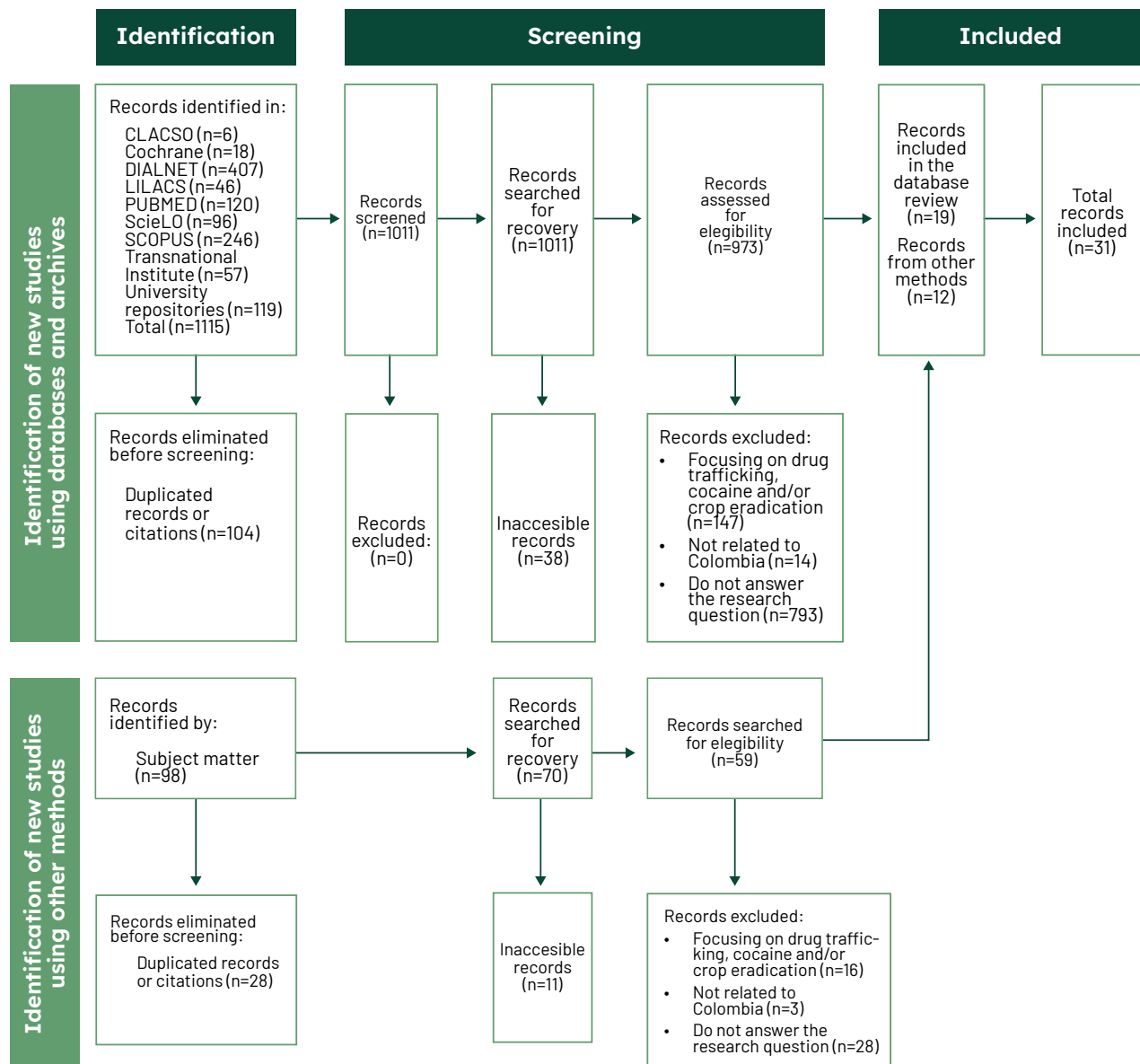
The initial search yielded the following results: six records in the Consejo Latinoamericano de Ciencias Sociales (CLACSO); 18 in the Cochrane Collaboration; 407 in Dialnet; 46 in LILACS; 120 in PubMed; 96 in SciELO; 246 in Scopus; 57 in the Transnational Institute; 39 in the institutional repository of Universidad Nacional de Colombia (UNAL); 21 in that of Universidad de Antioquia (UdeA); 12 in that of Universidad Industrial de Santander (UIS); 10 in that of Universidad del Cauca (UniCauca); and 37 in that of Universidad de los Andes (UniAndes), for a total of 1,115 records.

After duplicate records were removed, a total of 1,011 records remained. Title screening and verification of full-text availability reduced this number to 87 records, and subsequent abstract screening led to the selection of 19 articles for full-text review.

Concurrently, grey literature and sources identified by subject-matter experts were compiled, yielding 98 additional records. Of these, 28 were excluded as duplicates and 11 due to lack of full-text availability, resulting in 59 documents eligible for screening. Title screening excluded 32 records, and abstract screening excluded an additional 15, leaving 12 documents for full-text review.

Overall, 31 records were included in the full-text review and in-depth analysis stage. The selection and screening process is summarized in Figure 1.

Figure 1. Flow diagram of systematic review according to PRISMA 2020 criteria (4).



The 31 records ultimately included in this review, together with their thematic classification, are presented in Table 2 below.

Table 2. Summary of records included in this review.

TITLE	AUTHORS	PUBLISHING YEAR	CLASSIFICATION
Contribución al estudio de la masticación de las hojas de coca	Uscátegui (5)	1954	Evidence of use in Colombia
Mama Coca: un estudio completo de la coca	Henman (6)	1978	History and botany/ Evidence of use in Colombia
Coca leaf chewing: a public health assessment	Negrete (7)	1978	Quantitative Safety
Botanical perspectives on coca	Plowman (8)	1979	History and botany/ Evidence of use in Colombia
Amazonian coca	Plowman (9)	1981	History and botany/ Evidence of use in Colombia
The therapeutic value of coca in contemporary medicine	Weil (10)	1981	Qualitative Safety
Coca chewing for exercise: hormonal and metabolic responses of nonhabitual chewers	Favier et al. (11)	1996	Qualitative Safety
Effects of coca chewing on hormonal and metabolic responses during prolonged submaximal exercise	Favier et al. (12)	1996	Qualitative Safety
La coca: algunas notas sobre su uso tradicional en Venezuela y otros países de América	Bermúdez (13)	1998	Evidence of use in Colombia
Coca leaf chewing as therapy for cocaine maintenance	Hurtado (14)	2000	Quantitative Safety

Aspectos farmacológicos y socioculturales del consumo de hoja de coca en indígenas koguis respecto al consumo de cocaína en ambientes urbanos	Zambrano y Vaca (15)	2002	Evidence of use in Colombia/Qualitative Safety
El mambe frente al dinero entre los Yucuna del Amazonas	Fontaine (16)	2003	Evidence of use in Colombia
Primer estudio psicofisiológico y toxicológico de la Harina de Coca	Llosa et al. (17)	2006	Quantitative Safety
Los Mitos de la Coca	Henman y Metaal (18)	2009	Qualitative Safety/Regulatory Aspects
Historia de la coca	Enokakuiodo y Echeverri (19)	2010	Evidence of use in Colombia
Análisis semiótico de la ceremonia de iniciación al consumo ritual de la hoja de coca en la cultura ika	Gómez (20)	2011	Evidence of use in Colombia
Coca: High Altitude Remedy of the Ancient Incas	Biondich y Joslin (21)	2015	Qualitative Safety
Reconocimiento Fitoquímico y etnobotánico de <i>Erythroxylum coca</i> en la población Nasa del Departamento del Cauca - Colombia	Scarpetta (22)	2017	Evidence of use in Colombia
La industrialización de la hoja de coca: un camino de innovación, desarrollo y paz en Colombia	Open Society Foundation (23)	2018	Evidence of use in Colombia/Qualitative Safety
La hoja de coca en la gastronomía Colombiana	Fundación Tierra de Paz y OSF (24)	2020	Evidence of use in Colombia/Qualitative Safety
<i>Erythroxylum</i> en el foco: revisión interdisciplinaria de un género ignorado	Restrepo et al. (25)	2020	Qualitative Safety

Usos agroindustriales de la hoja de coca en comunidades indígenas del departamento del Cauca, Colombia durante el postconflicto	Caicedo et al. (2)	2021	Evidence of use in Colombia
Coca, territorio y salud: Usos medicinales de las especies de <i>Erythroxylum</i> en una comunidad rural de Santander (Colombia)	Beltrán (26)	2023	Evidence of use in Colombia
Concepto Científico: Posibles peligros de la hoja de coca como alimento	Grupo de Evaluación de Riesgos en Inocuidad de Alimentos (ERIA)(27)	2023	Quantitative Safety
Ver un mundo en una hoja: Representaciones de los usos de la planta de coca en el corregimiento de Lerma - sur del Cauca	Sevilla (28)	2023	Evidence of use in Colombia
La invención de la cultura gastronómica de la hoja de coca	Arciniegas (29)	2024	Evidence of use in Colombia/Qualitative Safety
Sobre el uso tradicional de la coca en pueblos indígenas amazónicos	Cabieses (30)	2024	Evidence of use in Colombia
Del cóndor al águila: una nueva modalidad de consumo y producción de la hoja de coca	Cuéllar (31)	2024	Evidence of use in Colombia
Proyecto de investigación para el estudio farmacognóstico, fitoquímico y bromatológico de coca (<i>Erythroxylum coca</i> y <i>Erythroxylum novogranatense</i>)	Departamento de Farmacia Universidad Nacional de Colombia (32)	2024	History and botany/Qualitative Safety
Narrativas de la comercialización alimentaria de la hoja de coca en Colombia: de los discursos a las prácticas	Arciniegas (33)	2025	Evidence of use in Colombia

From Tradition to Science: Chemical, Nutritional, and Cytotoxic Characterization of <i>Erythroxylum coca</i> from Indigenous Colombian Communities	Marentes et al. (34)	2025	Quantitative Safety
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Additionally, summary tables presenting the results for each identified category are provided in the supplementary material section of this document.

4. Discussion

The term “traditional” has been used to describe long-standing practices within specific communities. However, in normative, regulatory, and healthcare contexts, its interpretation has often been limited to criteria of seniority or immutability, which can restrict recognition of dynamic social processes. From a legal-anthropological perspective, various studies suggest that tradition should not be understood as a static practice or merely as something rooted in the past, but rather as a set of culturally situated knowledge and customs that are open to transformation and reinvention (35). This view acknowledges that communities can adapt their practices, incorporate new technologies, or modify patterns of use without compromising their cultural legitimacy.

In line with this approach, the WHO technical guidelines define traditional use as that which is linked to a specific cultural system, transmitted from generation to generation, sustained over time, and for which there is no systematic evidence of harm (36). From this perspective, the coca leaf can be analyzed as a herbal product for traditional use, both in healthcare and regulatory contexts, as it has long been used by various communities in Colombia, based on local knowledge.

According to the General Guidelines for Research and Evaluation of Traditional Medicine (35), a prolonged history of use may constitute sufficient evidence of safety in the absence of experimental studies, provided that basic conditions—such as botanical identification, standardization of

preparation methods, and verification of usage practices—are met. Rigorous analysis of clinical reports documenting adverse events may also be considered sufficient to support a preliminary safety profile, as long as there are no warning signs or changes in the form, dosage, or context of use. Additional toxicological studies, focusing on areas such as immunotoxicity, genotoxicity, carcinogenicity, or reproductive toxicity, are warranted only when there is reasonable doubt about the product’s safety or a lack of information in critical areas—particularly for effects that are not detectable through direct clinical observation.

On this basis, the discussion will be guided by WHO guidelines for the recognition of plant-based products in healthcare systems, in order to analyze the scientific evidence gathered on the safety of the traditional use of coca leaf.

Although the uses of coca leaf identified in this review include food, social, ceremonial, and industrial contexts that are not strictly medical, this discussion focuses on a pharmacological safety assessment. This perspective applies criteria based on the quantification of dose, exposure, and toxicity, in accordance with the specialized literature, which recommends considering variables such as chemical composition, history of use, consumption patterns, route of administration, subsequent monitoring efforts, and quantifiable safety margins (37).

This approach does not seek to disregard the legitimacy or complexity of traditional knowledge regarding the coca leaf, particularly as developed and maintained by Indigenous and rural communities. Rather, it builds on this recognition to establish a structured dialogue with pharmacological evaluation frameworks. The application of criteria such as the determination of alkaloid content, risk assessment, and monitoring of adverse effects aims to demonstrate the compatibility of these practices with current health safety standards.

4.1. History and Botany

The four studies included in this section provide evidence on the origins and transformations of human use of the coca leaf in South America, approached from archaeological, ethnohistorical, and botanical perspec-

tives. The review encompasses articles that document both the earliest material and narrative records associated with coca consumption, as well as the processes of domestication and taxonomic classification of species within the genus *Erythroxylum*.

4.1.1. History of Human Use of the Coca Leaf

Based on the review, the earliest evidence of human use of *Erythroxylum* spp. comes from archaeological findings dating back approximately 13,000 years before present (BP), indicating the cultivation and possible incorporation of the plant into the diet of populations located in what is now the Atacama Desert in Chile (32). This evidence, together with the discovery of coca leaves and lime gourds in pre-ceramic period burials (2500–1800 BCE) at Huaca Prieta, Peru, and sculptural representations of chewing in the Valdivia culture around 3000 BCE (6), establishes a long and sustained history of traditional use in the central Andes. This data is consistent with ethnobotanical interpretations that place the origin and expansion of cultivation within early agricultural systems, in which coca played symbolic, medicinal, and productive roles integrated into social organization (8). According to Uscátegui (5), historical and archaeological evidence indicates that coca chewing spread from Nicaragua, Panama, the Colombian Andes, Ecuador, Peru, and Chile, and, in more recent times, reached Brazil via the Amazon.

In Colombia, the earliest material evidence of coca leaf use dates back to the 1st century CE, represented in sculptures from the archaeological site of San Agustín depicting individuals with bulging cheeks and utensils associated with chewing, such as coca bags and gourds (6). Similar evidence has been found in burial sites in Tierradentro and among the Quimbaya people, where metal *poporos* and lime gourds have been discovered. In the Altiplano Cundiboyacense, colonial chronicles refer to its use among the Muisca from the 16th to 18th centuries, both in religious rituals and in everyday life, with active cultivation in locations such as Soatá and Duitama (6). This historical and geographical continuity supports the hypothesis of sustained traditional use of coca in present-day Colombia, with the leaf being the part used, predominantly in dried form.

The texts analyzed describe various uses of the coca leaf, all of which are embedded within specific cultural systems. Reports include its ritual use in initiation ceremonies, funerals, and religious offerings, as well as its consumption as food and an energy source in Amazonian communities (6,8). In the Andean region, coca is closely associated with agricultural systems and community practices of trade and redistribution (6). Among the Muisca people, its use during priestly fasts and as a funerary element underscores its symbolic and spiritual significance (6). No adverse effects or evidence of toxicity were reported in any of the cases described. On the contrary, material findings, historical chronicles, and the continuity of cultural practices attest to its prolonged use, which is socially regulated and widely perceived as safe in the contexts in which it has historically been practiced.

4.1.2. Botanical and Phytochemical Characterization of the Coca Leaf

The genus *Erythroxylum*, belonging to the family *Erythroxylaceae*, comprises approximately 250 species distributed throughout tropical regions worldwide. However, it is primarily the species *E. coca* and *E. novogranatense* that have been domesticated and traditionally used due to their tropane alkaloid content (6,8).

E. coca is cultivated on the humid slopes of the central Andes, primarily in Bolivia and Peru. This drought-sensitive species requires partial shade, well-drained soil, and high humidity. Its leaves are broader and dark green, with a higher average cocaine concentration compared to other *Erythroxylum* species.

Conversely, *E. novogranatense* exhibits greater ecological tolerance and has adapted to lower-humidity conditions in regions such as Valle del Cauca, the Sierra Nevada de Santa Marta, and other areas of the Colombian Caribbean (6). This species comprises two varieties: *novogranatense*, cultivated mainly in Colombia and northern Ecuador, and *truxillense*, reported in northern Peru in the late 1970s. Both varieties have lower cocaine content but higher concentrations of methyl salicylate, a compound responsible for their characteristic sweet taste when chewed (6,8).

From a phytochemical perspective, *Erythroxylum* leaves contain a complex profile of secondary metabolites, including tropane alkaloids, flavonoids, terpenes, and fatty acids. Identified alkaloids include benzoylmethylecgonine (cocaine), tropacocaine, benzoylecgonine, B-hygrine, dihydrocuscuhygrine, and various cinnamoylcocaines. According to available evidence, only cocaine exhibits significant psychoactive activity, acting as a central nervous system stimulant by inhibiting the reuptake of dopamine, norepinephrine, and serotonin. Other alkaloids, such as tropacocaine, have mild local anesthetic effects, while compounds such as benzoylecgonine and methylecgonine show no appreciable stimulant effects even at doses 30 to 60 times higher than those encountered in traditional consumption and are considered non-toxic (21).

In addition, non-alkaloid compounds such as phytol, nonacosane, and stearic acid have been identified, along with flavonoids and terpenes, which have been experimentally associated with antioxidant, anti-inflammatory, and antimicrobial properties. Phytochemical differences between varieties and preparation methods have direct implications for pharmacological safety, as they influence stimulant potency, systemic absorption, and the metabolite load resulting from traditional consumption (22).

According to data compiled by the National Institute of Health of Colombia (27), *E. novogranatense* var. *novogranatense* (mean: 0.77 mg/100 mg) and var. *truxillense* (mean: 0.72 mg/100 mg) have average cocaine concentrations higher than *E. coca* var. *coca* (mean: 0.63 mg/100 mg), although their maximum reported ranges are lower. In contrast, *E. coca* var. *Ipadu*, from the Amazon, has the lowest concentration (mean: 0.25 mg/100 mg). Regarding secondary alkaloids, the *E. novogranatense* varieties show higher concentrations of cinnamoylcocaine, particularly the cis- and trans-isomers, compared to *E. coca*, in which these compounds are present in significantly lower proportions.

Table 3. Alkaloid concentration found in different species of the genus *Erythroxylum* (38)

VARIETY	COCAINE (MG/100 MG)	CINAMOYLCOCAINE (MG/100 MG)	CIS-CINNAMOYLCOCAINE (MG/100 MG)	TRANS-CINNAMOYLCOCAINE (MG/100 MG)
<i>E. coca</i> Var. <i>Coca</i>	0,63 (0,23-0,96)	0,068 (0,0011-0,532)	0,05 (0-0,44)	0,018 (0-0,11)
<i>E. coca</i> Var. <i>Ipadu</i>	0,25 (0,11-0,41)	0,005 (0-0,084)	0,005 (0-0,084)	Not reported
<i>E. novogranatense</i> Var. <i>novogranatense</i>	0,77 (0,55-0,93)	0,38 (0,107-0,65)	0,28 (0,072-0,53)	0,092 (0,035-0,12)
<i>E. novogranatense</i> Var. <i>Truxillense</i>	0,72 (0,42-1,02)	0,23 (0-0,93)	0,15 (0-0,68)	0,077 (0-0,43)

In addition to the findings of this review, the report *Características Agro-culturales de los Cultivos de Coca en Colombia* (Agronomic Characteristics of Coca Crops in Colombia 2005–2010), prepared by the Sistema Integrado de Monitoreo de Cultivos Ilícitos (SIMCI, in Spanish) project in partnership with the United Nations Office on Drugs and Crime (UNODC)(39), provides empirical evidence on the regional distribution and local nomenclature of coca leaf varieties cultivated in the country. This information bridges the gap between the traditional knowledge of growers and the formal taxonomic criteria used in botanical classification.

The table below summarizes information from this report on selected coca leaf varieties grown in different regions of Colombia. The data were collected using a probabilistic design implemented in multiple phases, combining satellite imagery with fieldwork and including direct surveys of farmers within sampling areas selected according to the national distribution of coca crops.

Plant variety identification was conducted through morphological recognition of the plants and the common names provided by growers, supplemented by taxonomic analysis. Taxonomic classification was possible in cases where the document provided an explicit scientific designation or established relationships with cultivated and wild species.

The reported percentages correspond to the relative frequency of each variety within the total number of plots sampled by region during Phase II of the study (2007–2010), which focused on the regional technical characterization of coca cropping systems.

This information helps identify geographical patterns of use and the potential coexistence of cultivated and hybrid species across different regions of Colombia.

Table 4. Botanical classification and geographical distribution of coca leaf varieties grown in Colombia (2007-2010)(39)

COMMON NAME	SCIENTIFIC NAME (REPORTED OR SUGGESTED)	PREDOMINANT GEOGRAPHIC LOCATION	TAXONOMIC JUSTIFICATION ACCORDING TO THE DOCUMENT
Peruvian	<i>E. coca</i> var. <i>Coca</i> ; <i>E. novogranatense</i> var. <i>Novogranatense</i> ; <i>E. aff. Citrifolium</i> hybrid	Catatumbo (100%), Sierra Nevada (21,8%)	Unstable morphotypes with shared traits between <i>E. coca</i> and <i>E. novogranatense</i> , possibly by hybridization; are associated with wild crops.
Pajarito	<i>E. novogranatense</i> Var. <i>novogranatense</i>	Sierra Nevada (64,7%), Región Central (25%)	Direct allocation according to stable morphological classification.
Cuarentana	<i>E. coca</i> var. <i>Coca</i> ; <i>E. novogranatense</i> var. <i>Novogranatense</i> ; <i>E. aff. hybrid. Citrifolium</i>	Central Region (50,8%)	Unstable morphotypes with shared traits between <i>E. coca</i> and <i>E. novogranatense</i> , possibly by hybridization; associated with wild crops.
Wild	<i>Erythroxylum aff. citrifolium</i> (not formally cultivated)	Not defined; present in blends	Reported as a wild species that coexists with cultivated varieties and may be involved in hybridization processes.

The botanical and phytochemical characterization of *Erythroxylum* varieties cultivated in Colombia provides evidence of the genetic, ecological, and functional diversity of coca leaf in the country. Differences in alkaloid content, leaf morphology, and ecological adaptability reflect both domestication and cultural selection processes, and also influence pharmacological potency and the risk profiles associated with traditional use.

This knowledge base is essential for properly contextualizing the safety assessment and for understanding the contemporary uses of coca leaf across their diverse sociocultural settings.

4.2. Evidence of Use in Colombia

The results presented in this section are based on 19 studies documenting the uses of coca leaf in Colombia. The systematized evidence highlights a remarkable diversity of contexts, preparations, and practices, spanning Indigenous communities as well as rural, urban, and productive settings. This mapping provides a key foundation for understanding current patterns of use and for advancing a technical characterization of safety, taking into account sociocultural and functional conditions.

The studies included span heterogeneous observation periods, with records ranging from the past few decades to the present. Accordingly, the analysis does not aim to depict a static situation, but rather to describe consumption patterns that coexist, evolve, and transform over time.

This section examines the territories and populations in which coca leaf use has been documented, the methods of preparation and administration, the intended purposes of consumption, and the relevant factors for evaluating health safety.

4.2.1. Geographic Distribution and Population Groups

The studies reviewed show a wide geographic spread of coca leaf use in Colombia, with clearly identifiable clusters in the Andean, Amazonian, and Caribbean regions.

One of the most complex and well-documented traditions of ritual and everyday coca leaf use is concentrated in the southwestern Andes, particularly in the department of Cauca, primarily among the Nasa People and extending to rural communities in the northern part of the department. This region hosts a high concentration of *Erythroxylum novogranatense* var. *novogranatense* and hybrids (Pajarito variety), as described in the botanical characterization. Ethnographic records also document traditional use among non-Indigenous communities in southern Cauca, including local forms of *mambe* (6).

In the Sierra Nevada de Santa Marta, ritual use of coca is maintained among the Kogi, Arhuaco, and Wiwa peoples, who associate the plant with spiritual and philosophical practices, predominantly based on the cultivation of *Erythroxylum novogranatense*.

Reports also document coca use among the Murui, Uitoto, Tucano, and Si-kuani peoples in the Amazon region. These communities employ specific methods of preparation and consumption, such as green mambe and black mambe—or coca mixed with plant ashes—which predominantly utilize *Erythroxylum coca* var. *ipadu*. These practices are closely linked to ritual, therapeutic, and cosmological systems and are embedded within specific community relationships.

In urban settings such as Bogotá and Medellín, as well as in rural markets in Valle del Cauca and the Caribbean, emerging patterns of coca leaf consumption among non-Indigenous users have been documented. These practices are characterized by diverse motivations, access channels, and perceptions of the leaf, often framed within self-care, ethnobotanical interest, or cultural reappropriation.

Table 5 below summarizes this information, presenting the data organized by region, population group, and specific location. This visualization highlights patterns of territorial concentration as well as the cultural diversity that characterizes coca leaf use across the country.

Table 5. Geographic Distribution and Population Groups

GEOGRAPHIC REGION	POPULATION GROUP	SPECIFIC LOCATION
Southwestern Andes	Nasa, Yanakona/Yanacona, Paéz/Paeces, Kokonuko, Guambianos (Misak), Pijaos, Quillacinga, Coaiquer/Koaikeres, Popayaneses, peasants of Lerma, folk cooks and urban consumers (22,24,28,29,33)	Northern Cauca; Lerma, Popayán (Cauca)
Colombian Amazon	Bora, Witoto/Huitoto, Cubeo/Kubeo/Kobeua, Tukano, Barasana, Macuna/Mukuna, Yucuna/Yukuna, Miraña (Tupiguarani), Miraiia, Yahuna Ocaina, Rosiggaro (Arawak), Koreguaje, Inga, (9,13,16,19,30)	Amazon, Miriti-Paraná River, Araracuara (Putumayo y Vaupés)

Sierra Nevada de Santa Marta	Kogi, Ika, Arawak, Arhuaco, Kankuáma, Guajiro, Tairona, Tubebo/Tunebo/úua, Sanká. (8,15,20)	Indigenous communities of the Sierra Nevada (Magdalena)
Northeastern Andean region	Rural peasant communities (26)	Capitanejo (Santander)
Altiplano cundiboyacense	Muisca, Chibcha, Guane, Quimbaya (6)	Soatá and Duitama (Boyacá)
Central Andean region	San Agustín and Tierradentro cultures, and Prehispanic Andean communities (6)	San Agustín, Tierradentro and Popayán (Huila and Cauca)
Colombian Caribbean	Urban consumers and producers in local networks (31)	Apotecario del Cóndor, Santa Marta (Magdalena)
Large cities	Consumers in Bogotá, Medellín, Cali, among others (23,33)	Market squares, gastronomic fairs and solidarity networks
Extended Andean Region	Indigenous Peoples mentioned (with no local specification)(5)	General - Andean and Amazonian regions

The documented geographical and cultural diversity demonstrates both the persistence of traditional practices in Indigenous and rural contexts and the emergence of new uses in urban and commercial settings. Identifying territories, actors, and consumption patterns provides a basis for comparative analysis of preparation methods, attributed meanings, and safety conditions—topics that are discussed in the following sections.

To estimate the Indigenous population potentially consuming coca leaf in their various forms, data from the 2018 Indigenous population census were used (40). The analysis focused on the Awá/Coaiquer, Bara, Barasana, Bora, Coreguaje, Cubeos, Desano, Inga, Macuna, Miraña, Muisca, Nasa, Ocaina, Pijao, Quillacinga, Tayrona (Arhuaco, Kanluamo, Kogui, and Wiwa), Tanimuca, Tatuyo, Tukano, Uitoto (Muruí and Muinane), U’wa, Yanacona, Yucuna, and Yuruti peoples, all of whom were referenced in the articles included in this review and for whom census data were available

According to these estimates, there are 380,431 people over the age of 15 in the communities considered. Taking into account that women in the Sierra Nevada and Amazon communities traditionally do not consume coca leaf, and applying an estimated usage rate of 70%, approximately 231,485 individuals are estimated to use coca leaf. This calculation is limited to the Indigenous population recorded in the census and does not include estimates for rural or urban populations that consume coca leaf.

4.2.2. Traditional Forms of Presentation and Consumption

The studies reviewed document a remarkable diversity in the traditional forms of coca leaf presentation in Colombia, shaped both by geographical conditions and the cultural practices of each population group.

In Amazonian Indigenous communities such as the Yucuna, Murui, Uitoto, and Macuna, the production of *mambe*—a fine powder obtained by roasting and grinding dried coca leaves mixed with vegetable ash—is predominant (13,16,19,30). These preparations, used in both rituals and daily life, retain a symbolic and spiritual significance in addition to their physiological energizing function.

In the Andean region, particularly among the Nasa, Kogi, and Muisca peoples, the use of the whole coca leaf—commonly dried—for chewing is documented, often in combination with alkaline substances (6,15,22). This practice is also reported in rural communities in northeastern Colombia, where medicinal use of leaf infusions at home has been described (26). In addition to oral administration, traditional topical preparations such as poultices, ointments, and oil macerates have been identified, used locally to treat muscle pain, wounds, and skin conditions (22).

A central component of these practices is the addition of an alkaline reagent, which serves to facilitate the oral absorption of the alkaloids in coca leaf by raising the pH of the mouth. This practice is widely documented in Indigenous communities throughout the Amazon and Andean regions.

In the Amazon, the preparation is systematically mixed with plant ashes obtained from species such as cecropia, guamo, or white yarumo (16,19,30). In the Andes, particularly among the Nasa people, calcium oxide-based reagents are used, produced by calcinating limestone through highly complex technical and ritualistic collective processes (6). The resulting preparation, known locally as *kuétan*, can vary in texture, potency, and color depending on the mineral source and is administered in small amounts together with the chewed leaf. In some communities, such as the Kogi, carbonates are employed to alkalize saliva during *mambeo* (15).

These practices are not limited to ceremonial contexts; they constitute traditional methods of administering bioactive compounds, grounded in artisanal technologies and accumulated empirical knowledge. The addi-

tion of alkaline substances not only affects the bioavailability of alkaloids but also forms part of a cultural control system, encompassing specific quality criteria, symbolic regulation, and intergenerational technical knowledge.

The diversity of contemporary coca leaf use in Colombia is evident across a wide range of social, cultural, and geographic contexts. Table 6 summarizes the information collected from the studies in this category, organizing the records by geographic region, population group, and form of presentation. This systematization highlights distinct patterns of use among Indigenous and rural communities as well as urban consumers and links preparation and consumption practices to specific territories. The comparative approach also facilitates the analysis of variables relevant to safety assessment, including the incorporation of alkalis, the transformation of the leaf into byproducts, and its use in ritual, dietary, or therapeutic contexts.

Table 6. Forms of presentation of the coca leaf by region, population group and documentary source

GEOGRAPHICAL REGION	POPULATION GROUP OR MAIN ACTOR	DOCUMENTED PRESENTATIONS
Colombian Amazon	Witoto, Macuna, Ocaina, Tanimuca, Yucuna, and Uitoto Indigenous Peoples, among others (9,13,16,19,30)	<i>Mambe</i> (dried or roasted pulverized leaf + vegetable ash), piled powder, ritual infusion
Southwestern Andean region (Cauca)	Nasa and Yanacona Indigenous communities, Lerma peasants in local transformations (2,22-24,29)	Dried leaf, fresh leaf, coca flour, <i>mambe</i> , infusions, ointments, macerates, cookies, functional beverages
Sierra Nevada de Santa Marta	Kogui, Arhuaco, Wiwa, Ika Indigenous Peoples (8,15,20)	Fresh or dried leaf for chewing, <i>mambeo</i> , ritual use with <i>poporo</i> .
Northeastern Andean region	Rural peasant communities (26)	Dry leaf, medicinal infusions, fresh leaf
Altiplano cundiboyacense	Muisca people	Chewed leaf in rituals, fasting and agricultural work
Caribbean region	Urban consumers and artisanal producers (31)	Infusions, capsules, flour, beverages and functional fragrances
Bogotá, Medellín, Cali, Tolima	Urban consumers (23,33)	Flour, <i>mambe</i> , cookies, infusions, gourmet preparations, beverages, extracts, ointments

Central Andean Region (archeological)	San Agustín and Tierradentro cultures, and Prehispanic Andean communities (6)	Chewed leaf with alkali
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4.2.3. Patterns of Use

The studies reviewed reveal considerable variability in the frequency, regularity, and forms of coca leaf consumption, depending on the population group, cultural context, and intended purpose.

Daily, frequent, and sustained consumption is reported among Amazonian Indigenous communities—such as the Yucuna, Murui, Witoto, Tanimuca, and Tukano—particularly in male ritual contexts. In these settings, *mambe*, or coca powder mixed with vegetable ash, is administered collectively during moments of deliberation, teaching, and social cohesion (13,16,30). This pattern has also been documented among the Kogi and Arhuaco peoples of the Sierra Nevada de Santa Marta, where consumption—symbolically regulated through the use of the *poporo*—structures daily life and marks the stages of male life (15).

In Andean communities such as the Nasa and Yanacona in southwestern Colombia, coca leaf use remains an integral part of everyday life, although variations exist in its forms and frequency of consumption. Both the ritual chewing of leaves with *mambe* (alkali) and the preparation of infusions, functional foods, and agro-industrial products have been documented (2,22). Consumption in these settings may be **regular or sporadic**, but its integration into daily life is maintained through family, community, or productive practices, without systematic measurement of dosage or frequency.

Non-Indigenous rural farming communities, such as those in Santander and southern Cauca, report more **occasional** use, generally aimed at alleviating specific symptoms or providing an energy boost for agricultural work (26,28).

In urban contexts, patterns of coca leaf use are more heterogeneous and **intermittent**. The quantity consumed is primarily determined by the commercially available forms, such as infusions and herbal teas, capsules, beverages, or functional foods (23,29,31).

The wide range of usage patterns—from ritual and collective practices to sporadic individual consumption—has important implications for risk assessment, particularly regarding dosage, frequency of exposure, and method of administration. Notably, these patterns highlight clear differences between contexts in which cultural norms regulate use and those in which consumption is entirely self-directed.

4.2.4. Settings of Coca Leaf Use

Evidence from Colombia demonstrates a wide diversity of contexts for coca leaf consumption, which vary according to population group, cultural setting, and form of presentation. These contexts can be grouped into four broad categories: ritual-spiritual, therapeutic, nutritional, and socio-cultural identity.

Ritual and Spiritual Use

The consumption of *mambe* is a central element of collective life among Amazonian Indigenous peoples (Yucuna, Murui, Tanimuca, Tukano, and others) and is integrated into practices of ritual speech regulation, knowledge transmission, and spiritual harmonization (13,16,30). In the Sierra Nevada de Santa Marta, the Kogi and Arhuaco peoples maintain similar practices through the use of the *poporo*, which holds spiritual and philosophical significance (15,20). In the southwestern Andes, Nasa communities preserve the ritual use of the coca leaf, particularly through *mambeo* and its role in community events (22).

Therapeutic Use

The use of coca leaf to alleviate symptoms such as fatigue, digestive discomfort, headaches, and respiratory conditions, or to facilitate sleep, has been documented across rural, Indigenous, and urban settings (22,26,28). These applications occur both through chewing and in homemade preparations, including infusions, poultices, and ointments. Although functional effects—such as energizing, analgesic, digestive, and immunomodulatory properties—are reported, no adverse effects or signs of toxicity have been observed in the documented contexts.

Food Use

Studies conducted in Cauca and in cities such as Bogotá and Medellín document the use of coca leaf in food products—such as flour, cookies, beverages, and infusions—for dietary fortification, nutritional improvement, and, in some cases, as part of food sovereignty initiatives (23,24,29). These products, prepared primarily from pulverized dried leaf, contain low concentrations of alkaloids. Notably, a study by Fundación Tierra de Paz and OSF (2020) reports that, in most preparations, the final concentration of cocaine does not exceed 0.05%, which aligns with a widespread perception of harmlessness and the absence of reported adverse effects among consumers (24).

Identity and Sociocultural Use

The use of the coca leaf is closely linked to the reaffirmation of cultural, territorial, and ethnic identities in many contexts. In communities such as the Yanacona, Nasa, Kogui, and Ika, its use is reported as a central element in individual formation, the intergenerational transmission of knowledge, and the maintenance of community identity (2,20,33). In urban settings, some consumers report using coca leaf as an act of symbolic resistance or as a means of connecting with ancestral knowledge, although these practices are guided by less structured regulatory frameworks (31).

Overall, these patterns of use indicate that coca leaf consumption in Colombia cannot be reduced to a single functional profile; rather, it reflects a complex network of meanings, needs, and strategies encompassing health, spirituality, subsistence, cultural identity, and political participation. Notably, in addition to its therapeutic and nutritional applications, the transformation of the leaf into agro-industrial byproducts represents an economic strategy for Indigenous and peasant communities, particularly in Cauca. In this region, the legalization and development of the crop for non-illicit purposes is promoted as an alternative to armed conflict (2).

These initiatives encompass production processes, local marketing, and placement within gastronomic circuits, with an emphasis on the cultural and nutritional value of the coca leaf as an ancestral plant.

4.3. Quantitative Safety Studies

This section presents an analysis of seven studies that evaluated quantifiable parameters related to the safety of coca leaf use across different forms of preparation and consumption contexts. The analysis includes experimental and observational studies, as well as technical reviews employing *in vitro* methodologies, acute clinical trials, comparative analyses with regular coca leaf consumers, and technical opinions on its use in food issued by government entities.

The analysis is limited to results concerning the toxicity and safety of coca leaf use, defined as the absence of observable or measurable acute or chronic adverse effects following exposure to the leaf or its byproducts. Aspects related to therapeutic efficacy and nutritional value are not considered, as they fall outside the scope of this review.

The review prioritizes reported clinical, biochemical, and toxicological indicators according to their relevance for risk assessment in the Colombian context.

4.3.1. Comparative Studies with Regular Consumers of Coca Leaf

Based on primary research conducted with Andean populations, supplemented by a review of findings from earlier studies, Negrete (1978) presents an analysis of the physiological, nutritional, and neuropsychological effects of coca leaf consumption (7).

As part of the cognitive assessment, tests measuring attention, memory, abstract reasoning, and learning were administered to a group of daily coca leaf users and a control group of occasional users. Chronic consumers scored lower across all evaluated dimensions, with a tendency for greater deterioration associated with longer duration of use. A follow-up study conducted two years later with some of the same participants produced similar results.

In the analysis stratified by educational level, literate controls scored higher than illiterate controls, whereas no differences were observed among coca leaf users. The author interpreted this finding as a potential loss of skills acquired through schooling, although this hypothesis was not empirically verified. Differences were most pronounced in tests requiring

abstract reasoning, while performance on manual tasks was similar between literate and illiterate participants in both groups.

With regard to acute physiological effects, the author systematized previous experimental studies that documented responses such as hyperglycemia, hyperthermia, tachycardia, and increased physical endurance, both after cocaine administration and after coca leaf consumption under controlled conditions. However, these effects are influenced by the dose and the experimental context, and no marked behavioral changes were observed in field studies. Additionally, Negrete stresses that, unlike other psychoactive substances, traditional use of coca does not serve a recreational purpose, but is described by users as a functional tool for reducing fatigue, hunger, and thirst while working.

The nutritional and hepatic findings reported in the article are derived from a previous study conducted in Cachicoto, Peru (41), which identified significant differences between consumers and non-consumers in variables such as weight/height, skinfold thickness, serum albumin, and cholesterol, as well as a higher prevalence of hypochromic anemia and hepatomegaly among the consumer group. While these results are cited, the clinical methods used to detect hepatomegaly are not specified. The author notes that differences in alcohol consumption between the groups may have influenced the findings. Additionally, observed dietary patterns could reflect structural factors such as poverty and limited access to nutritional resources, and therefore any causal association with coca leaf consumption should be interpreted with caution.

The author acknowledges substantial methodological limitations in the design and execution of his studies, including the lack of control groups to account for potential confounding factors such as education, socioeconomic status, and alcohol consumption. The control group had higher educational attainment and a greater proportion of urban residents, both of which the author considers potentially influential on cognitive test performance.

Regarding the suitability of the instruments employed, it should be noted that tests with a high verbal or symbolic component were excluded, as they were considered inappropriate for a population with high illiteracy rates and low educational attainment. However, the study does not des-

cribe a formal process of cultural adaptation for the instruments used, nor does it specify which instruments were administered. The claim that the tests were comprehensible to participants is based solely on unstructured qualitative observations, with no empirical evidence provided to support the functional equivalence of the assessed tasks.

Additionally, the rural context and sociocultural conditions of the population studied limit the generalizability of the results to other groups. The author suggests that a living environment characterized by low cognitive demands, repetitive tasks, and limited intellectual stimulation could obscure the functional expression of deficits observed in standardized assessment settings. These methodological limitations, combined with the lack of strict controls for structural variables such as socioeconomic status, education, and occupation, reduce the ability to establish a causal relationship between coca leaf consumption and cognitive performance.

Consequently, the interpretation of the findings as evidence of persistent alterations in higher cognitive functions must be considered within a methodological framework constrained by multiple uncontrolled confounding factors. Although the study offers an initial empirical investigation of the neuropsychological effects of coca leaf consumption, the robustness of its results and their applicability for informing public health interventions or policymaking require critical evaluation that accounts for the structural limitations of the study's design, implementation, and interpretation.

4.3.2. Acute Clinical Assessments in Healthy Individuals

The clinical studies conducted by Favier et al. (11,12) evaluated the acute physiological effects of coca leaf consumption in the context of submaximal exercise, using controlled experimental designs with hormonal, metabolic, and cardiorespiratory measurements. The first study (11) included twelve healthy adults who were not regular coca users and who completed two submaximal exercise sessions after acute administration of 15 g of coca leaf or placebo. The second study (12) included twenty-two Andean men living at high altitude (3,600 meters above sea level), of whom eight were regular consumers (more than three times per week) and fourteen were non-consumers. In both studies, the leaves were administered ora-

lly by chewing for one hour before exercise, at an average dose of 16 g per session, combined with 1.3 g of vegetable alkali in the second study.

The parameters evaluated included insulin, glucagon, catecholamines, glucose, lactate, glycerol, free fatty acids, heart rate, oxygen consumption (VO_2), respiratory rate, and respiratory exchange ratio (RER). No adverse events were reported in either study, and all measured values remained within normal physiological ranges during and after exercise.

Although the primary objective of these studies was not to assess safety, their results provide indirect evidence of the acute tolerability of coca leaf consumption under controlled conditions in healthy individuals. However, the studies have significant methodological limitations: both included only male participants, sample sizes were small and homogeneous, and no post-exposure follow-up was conducted. Furthermore, the authors noted that the findings cannot be extrapolated to chronic consumption scenarios or to other populations.

4.3.3. Exploratory Clinical Studies on Safe Uses of Coca Leaf

This section presents two studies that offer clinical observations on the safety of coca leaf use in therapeutic settings. Both involve controlled experiences that combine the monitoring of physiological and psychosocial effects. Their exploratory nature, based on real populations under supervised conditions, makes them relevant sources of information for assessing risk profiles.

The study by Hurtado (2000) documented a clinical intervention conducted in Bolivia between 1984 and 1992 (14), in which 100–200 g of coca leaf were administered orally on a weekly basis to individuals with problematic cocaine paste use as part of a harm reduction strategy. Although the study lacked a control group and quantitative physiological measurements, improvements were observed in participants' social adaptation and mental state, with no reported physical or psychological adverse effects attributable to coca consumption. The author interprets these findings as preliminary evidence that coca leaf may help regulate compulsive use of purified alkaloids, emphasizing the importance of oral administration and traditional consumption methods as protective factors against acute toxicity.

Furthermore, The pilot study by Llosa et al. (2006) evaluated the oral administration of coca flour, either in capsules or dissolved in water, in six participants—four with no prior consumption and two undergoing treatment for cocaine addiction—under controlled clinical conditions (17). Vital signs, pupil responses, anxiety levels, and urine analyses for cocaine metabolites were monitored. In all cases, physiological parameters remained within normal ranges, and no toxic effects or signs of intoxication were observed. The authors emphasize the influence of the preparation method (alkaline or acidic) on alkaloid release and propose different applications of coca flour depending on nutritional or therapeutic objectives. Although the sample size was small and follow-up limited, the study provides preliminary information on clinical tolerability.

The methodological limitations of both studies—such as small sample sizes, lack of control groups, and limited follow-up—preclude drawing definitive toxicological conclusions. Nevertheless, they provide empirical evidence regarding the tolerability and potential benefits of the traditional and medicinal use of coca leaf under supervised conditions, distinguishing it from the problematic forms associated with the consumption of concentrated byproducts.

4.3.4. Technical and Regulatory Assessments of Food Risk

In 2023, the National Health Institute of Colombia published a scientific report using a food risk assessment methodology to evaluate whether prolonged consumption of coca leaf infusions poses a risk to human health (27). The assessment scenario considered the daily intake of one tea bag (1 g of dried leaves) over the lifetime of an average adult weighing 64.7 kg.

First, the average cocaine content in dried coca leaves was determined based on analyses conducted by Universidad Industrial de Santander, yielding 11 mg of cocaine per gram of leaf. Next, using data from previous studies on solubility, it was estimated that approximately 80% of the alkaloids are extracted during infusion preparation. Based on these calculations, a cup of infusion prepared with a 1 g tea bag could contain up to 8.8 mg of cocaine, corresponding to a daily exposure of 0.136 mg of cocaine per kilogram of body weight.

To assess whether this level of exposure poses a risk, an animal study evaluating the effects of different concentrations of cocaine in the diet of rats was used as a reference. In that study, weight loss was observed at a concentration of 2 mg of cocaine per gram of food, which was identified as the Lowest Observed Adverse Effect Level (LOAEL). Based on this value and in accordance with international food safety standards, a total uncertainty factor of 300 was applied. This factor accounts for interspecies extrapolation, intraspecies variability, the absence of long-term human exposure studies, and the use of a LOAEL rather than a No Observed Adverse Effect Level (NOAEL).

The application of this factor yielded a chronic oral reference dose of 0.57 mg/kg/day, considered the threshold below which no adverse effects are expected in humans upon continuous exposure. Based on this reference dose and the estimated exposure, a hazard quotient of 0.24 was calculated. Because a value below 1 indicates no unacceptable risk, the report concludes that, according to the available data, chronic daily consumption of coca leaf tea by adults would not pose a health hazard.

The study provides additional information on acute cocaine toxicity in humans, indicating that adverse effects occur at plasma concentrations of 0.50 mg/L and that fatalities have been reported at concentrations of 1 mg/L. It also notes that the estimated lethal oral dose ranges between 0.5 and 1.3 g/day. Although these figures were not used directly in calculating the benchmark dose, they are presented to contextualize known human tolerability margins, highlighting that the LOAEL adopted by the National Health Institute—based on weight loss in rats—is markedly conservative.

The National Health Institute acknowledged several methodological limitations in this assessment, including the absence of an officially established toxicological benchmark dose for chronic oral exposure to coca leaf in humans; the high variability of alkaloid content among different leaf samples; the lack of direct measurements of alkaloid content in infusions prepared under actual consumption conditions; and the need to develop analytical and quality control methodologies to adequately characterize products containing coca leaf.

4.3.5. In Vitro Assessments and Cellular Toxicity

The study by Marentes et al. (2025) involved an in vitro analytical and cytotoxic assessment carried out on ethanolic extracts of coca leaf collected in Colombian Indigenous territories. The study by Marentes et al. (2025) conducted an in vitro analytical and cytotoxic evaluation of ethanolic extracts of coca leaf collected from Indigenous territories in Colombia (34). Two morphotypes of *Erythroxylum coca*, known as “Palo” and “Caimo”, were analyzed to characterize their chemical composition and assess their cytotoxic potential. Exposure was performed using an indirect contact assay on murine L929 fibroblasts (clone NCTC 929), applying 25 µL of extract per sample for 24 hours. Cell viability was determined using the MTT assay (thiazolyl Blue Tetrazolium Bromide, 98%).

The results showed inhibition percentages of 60.95% for the “Palo” morphotype and 48.57% for “Caimo”, classified as moderate cytotoxicity according to the criteria of ISO Standard 10993-5. Although the study did not include in vivo models or clinical evaluation, these findings suggest a potential cytotoxic effect under specific conditions of concentration and exposure time. This underscores the need for further research to establish safety thresholds according to route of administration and form of use.

The phytochemical analysis also identified potentially bioactive compounds, including flavonoids, phenols, humulene, phytol, benzoic acid, and tropane alkaloids, whose toxicological relevance depends on their bioavailability and metabolism under real-world conditions of consumption. As a future line of research, the authors propose exploring the possible involvement of additional metabolic pathways, although this was not directly evaluated in the study.

The study has significant limitations: a single cell line was used, and no evaluation was conducted across different doses, exposure times, or complementary biological models. Therefore, the findings cannot be extrapolated to the systemic level, nor do they allow for the establishment of toxicity thresholds in humans. However, the evidence generated underscores the importance of conducting dose-response and comparative studies to explore the safety profile of different coca leaf varieties and preparation methods, in order to adequately characterize their safety under real-world conditions.

4.4. Qualitative Safety Studies

This category comprises nine studies that provide evidence on the safety of coca leaf consumption using methods such as clinical observation, narrative analysis, systematization of community experiences, and historical review. Although these studies do not employ clinical trial designs or quantitative toxicological measurements, they offer substantial insight into safe use patterns, risk mitigation practices, and cultural perceptions of coca leaf safety.

The value of this body of evidence lies in its origin, as all studies were conducted in real-life consumption settings, including Indigenous communities (15,18,25,42), therapeutic programs (10), urban food circuits (24,29) and community spaces for experimentation with unconventional uses. In these contexts, documented practices of coca leaf use—such as chewing, mameo, infusion, or capsule consumption—are characterized by fractional dosing, slow absorption, and interaction with other plant constituents that may influence the pharmacokinetics of the primary alkaloid, particularly by limiting the rate and peak plasma concentration of cocaine (32).

The study by Weil, published in 1981, is particularly noteworthy. It presents qualitative evidence on the safety of traditional coca leaf use, derived both from the author's clinical experience with non-Indigenous patients and from direct observations in Andean and Amazonian communities. The study describes oral administration of coca leaf through chewing in 250 individuals, with doses ranging from 5 to 10 grams per intake. No clinically significant adverse reactions were documented, except for isolated cases of nausea or gastrointestinal discomfort associated with the use of alkalizing agents.

Weil suggests that the absence of significant toxicity may be attributed to the route of administration, the slow absorption of alkaloids, and the potential modulating effects of other phytochemical constituents present in the leaf, which may limit peak plasma concentrations of cocaine. In his ethnographic observations, he did not identify signs of physical deterioration attributable to chronic coca use, nor evidence of physiological or psychological dependence. According to his account, regular users maintain the desired effects with stable doses over time, without

developing tolerance or experiencing withdrawal symptoms. He further notes that the traditional mode of consumption—characterized by careful preparation and sustained administration—acts as a natural barrier to abuse, in contrast to the concentrated, rapidly acting forms associated with purified cocaine use (10).

4.4.1. Coca Leaf Safety Profile

The safety profile is established based on systematic information regarding documented adverse effects, potential interactions with other substances, and known or suspected contraindications. These elements are classified as identified risks, potential risks, and missing information, forming the basis for the ongoing safety evaluation of a product (43).

The information analyzed indicates broad agreement regarding the absence of reports of clinically significant adverse effects associated with traditional or contemporary coca leaf consumption in Colombia. In Indigenous and rural contexts, the use of the leaf—whether chewed, prepared as an infusion, consumed as *mambe*, or incorporated into food—is described as a common, ritual, or functional practice that is culturally normalized. No reports of toxicity, dependence, tolerance, or physiological deterioration have been documented in these settings. Some sources also describe an explicit community perception of safety (13,16,19) and emphasize its perceived positive role in digestive, immune, respiratory, and neuromuscular health, without reporting adverse events associated with traditional patterns of use.

In urban or food-related contexts, where the leaf is incorporated as an ingredient in infusions, functional products, or gourmet preparations, the available data likewise indicate the absence of reported adverse effects. Moreover, the final concentration of cocaine in these products is typically below the pharmacologically active threshold. For example, in flours or processed foods produced in Lerma, Popayán, Bogotá, or Medellín, final concentrations have been estimated at no more than 0.05% cocaine (24), which substantially reduces the likelihood of systemic adverse effects.

No adverse drug interactions associated with coca leaf consumption were identified in the studies reviewed. In Amazonian contexts, its use in combination with vegetable ash or tobacco (*ambil*) has been documented

(9,13,19) as part of cultural frameworks that do not report associated risks. Among the Yucuna, mixing coca with tobacco, *yagé*, or alcohol is discouraged as a regulatory practice to prevent inappropriate use (16). Likewise, no pharmacologically significant combinations or reports of adverse interactions have been identified in urban or culinary settings.

Although most records do not mention explicit contraindications, some studies refer to cultural or contextual restrictions or recommendations for regulated use. Among Amazonian Indigenous Peoples, for example, coca leaf consumption is typically reserved for adult males in specific ritual contexts, reflecting a cultural restriction that may serve, among other purposes, to prevent potential adverse effects in individuals who are not prepared for its symbolic or physiological dimensions (16,19).

Coca leaf use is restricted among women of the Indigenous Peoples of the Sierra Nevada, such as the Ika and the Kankuamos. According to certain accounts, women should not consume coca leaf because of their symbolic association with sweetness and femininity, which is believed to cause spiritual imbalance and physical consequences such as infertility. However, these claims are not supported by empirical causal evidence (31).

In urban settings, although no formal health warnings have been reported, some authors note that the absence of specific regulations governing coca-derived foods precludes the establishment of clear guidelines regarding dosage, concomitant use, or health warnings (33). This regulatory gap underscores the need to advance differentiated regulatory frameworks that take into account not only chemical safety but also the cultural, functional, and symbolic conditions of use.

4.5. Combining the Findings

This review integrates different types of evidence to characterize the safety profile associated with the traditional use of coca leaf in Colombia. In accordance with guidelines issued by the WHO, data derived from toxicological and clinical studies, as well as from ethnographic sources and records of prolonged use without reported harm, were considered relevant. The findings are organized below according to the nature of the evidence and its contribution to risk assessment.

a) Ethnographic and Qualitative Evidence

Various ethnographic and testimonial studies document the traditional use of coca leaf as a cultural, ritual, and dietary practice, without reporting clinically relevant adverse events. In these accounts, the notion of safety is associated with routine consumption among Indigenous and rural populations, supported by prolonged observation and the intergenerational transmission of knowledge. Although this type of evidence does not quantify risk, it provides essential contextual elements for characterizing safety within the cultural frameworks in which its use is sustained without documented overt toxicity.

b) Clinical and Observational Evidence

Experimental and observational human studies evaluating physiological, hormonal, or metabolic parameters associated with the consumption of coca leaf in different forms and doses were identified. None of the studies reviewed reported serious adverse effects or clinical events involving acute risk or permanent harm. In some cases, mild or transient effects—such as nausea or discomfort related to the use of alkalizing agents—were noted; however, these were not considered clinically significant. This body of evidence supports a preliminary favorable safety profile, notwithstanding methodological limitations such as small sample sizes and the absence of control groups in several studies.

c) Preclinical and Toxicological Evidence

Studies in animal models and in vitro systems provided data on acute and subchronic toxicity, as well as on specific endpoints such as cytotoxicity and hematological alterations. Overall, the doses evaluated were comparable to or higher than those used in traditional contexts, and no clinically relevant toxic effects were observed. No evidence of genotoxicity or structural alterations associated with coca leaf consumption was identified in the preparations analyzed. Although these findings are consistent with the absence of reported clinical toxicity, their direct applicability to humans should be interpreted with caution, as some experimental models do not replicate the actual conditions of traditional use.

d) Methodological Assessment and Hierarchy of Evidence

The studies assessed exhibited varying levels of reliability. According to the evaluation criteria proposed by the World Health Organization, direct clinical data carry greater evidentiary weight than observational or pre-clinical studies. However, in the case of products with prolonged traditional use, the accumulated body of evidence—including sustained cultural practices and the systematic absence of reported adverse effects—is also recognized as a valid component supporting a favorable safety assessment. In this review, the consistency of findings, methodological diversity, and absence of toxicological warning signals support a convergent interpretation toward a low-risk profile within the context of documented traditional use.

e) Safety Profile Summary

Considering the totality of the evidence analyzed, the traditional use of coca leaf in Colombia—within the forms, doses, and settings described—is associated with an acceptable safety profile. This conclusion is supported by the absence of serious adverse effects, the consistency between clinical and toxicological findings, and a long-standing history of use without documented harm. However, this conclusion applies exclusively to the traditional context evaluated and should not be extrapolated to other forms of consumption, undocumented preparations, or vulnerable populations without additional research.

f) Prevalence of Traditional Use

The analysis included a population estimate based on recent census data to approximate the size of the Indigenous population in Colombia that potentially uses coca leaf in traditional contexts. Using data from the Censo Nacional de Población y Vivienda 2018⁹, the calculation focused exclusively on Indigenous Peoples with verifiable ethnographic or academic documentation of habitual coca leaf use. Groups lacking evidence of sustained practices were excluded, and usage restrictions within each cultural context were taken into account. Based on these criteria, esti-

9 2018 National Housing and Population Census.

mates indicate that at least 231, 485 individuals belonging to Indigenous communities in Colombia are current or potential users of coca leaf in its traditional forms. This figure provides an empirical baseline for understanding the scale of traditional use and reinforces the public health and sociocultural relevance of assessing its safety profile within context.

4.6. Discussion of Findings Compared to Previous Systematic Reviews

The findings of this review—which document a wide range of practices, contexts, and purposes associated with coca leaf use in Colombia—provide a basis for comparison with, and expansion upon, the systematic review published by Elementa DDHH in 2018 (42). That review identified a strong concentration of studies conducted in Peru and Bolivia, as well as a notable scarcity of indexed scientific literature from Colombia, despite widespread social recognition of traditional practices such as *mambeo*. Consistent with those findings, the present systematization confirms the limited availability of clinical or biochemical research specific to the Colombian context. However, it contributes a more detailed body of evidence regarding perceived safety, species used, preparation methods, cultural contexts of consumption, and the absence of significant adverse effects among user populations.

Both reviews highlight that the international classification of the coca leaf constitutes a structural barrier to the generation of scientific knowledge and the design of differentiated public policies. Taken together, these findings indicate that, although significant gaps in clinical validation remain, a substantial body of traditional and empirical knowledge in Colombia has yet to be systematically examined. Bridging this gap requires not only promoting new research but also establishing regulatory frameworks conducive to addressing these issues from public health, cultural, and ethnobotanical perspectives.

4.7. Gaps in Available Evidence and Implications for Future Research

The findings of this review provide insight into strategic areas that, while not undermining the conclusions regarding the safety of traditional coca leaf use, reveal key opportunities to strengthen the available body of evidence, expand understanding of its effects across diverse contexts, and consolidate more comprehensive regulatory frameworks. The principal areas for research and policy development identified are outlined below:

Updating the knowledge about user populations: This review contributes to recognizing the wide variety of social groups that consume coca leaf in Colombia. However, there remains a need for systematic and up-to-date characterizations to assess currently exposed populations. This includes the collection and analysis of sociodemographic and territorial variables, as well as patterns of use. Such information is essential to inform population-based research and to support culturally appropriate public health interventions.

Generating Specific Toxicological Parameters: Despite its long history of use without documented evidence of adverse effects, there are currently no formally established toxicological benchmark values for the whole leaf, such as acceptable exposure levels, safety margins, or specific limits for vulnerable populations. The development of these parameters through purpose-designed studies would strengthen risk assessment criteria and support the formulation of evidence-based technical regulations.

Observational Studies in Real-world Settings: The absence of longitudinal studies that follow traditional consumers within their own environments limits the ability to document physiological patterns of safe use from a biomedical perspective. The design and implementation of observational studies incorporating clinical, anthropometric, and biochemical measurements in field settings would represent a substantial advance in the scientific validation of these cultural practices.

Standardized Quality Criteria and Technical Documentation: Although no official monographs are currently available, the phytochemical, morphological, and ethnobotanical information systematized in this review provides a sufficient basis for initiating the development of technical

specifications for whole coca leaf. Verifiable data are available regarding the varieties used, average alkaloid content, presentation characteristics, and preparation practices. These inputs contribute to defining preliminary quality criteria, reference phytochemical profiles, and parameters for contaminant control. Such elements would facilitate the preparation of standardized technical documentation as a preliminary step toward formal inclusion in research, processing, or regulated-use frameworks.

Rights-based Regulatory Development: The international and national legal frameworks include provisions aimed at protecting the cultural, health, and territorial rights of communities that have traditionally consumed coca leaf. However, current regulations impose general restrictions that do not consistently differentiate between these traditional uses and those associated with the production of controlled substances.

In this context, the availability of specific scientific evidence on traditional forms of consumption constitutes a relevant input for regulatory analysis and public policy evaluation processes. The consolidation of a technical, cultural, and public health knowledge base can contribute to strengthening regulatory frameworks consistent with international commitments related to public health and human rights.

4.8. Limitations of the Review Process

The review process was constrained by regulatory restrictions affecting research on coca leaf in Colombia, particularly with regard to its traditional, therapeutic, and nutritional uses. These restrictions resulted in a limited number of systematic studies available in indexed scientific databases.

Although the search strategies were designed to exclude literature focused on drug trafficking or eradication, approximately 15% of the records retrieved corresponded to such topics, requiring their exclusion from the analysis.

Seventy-eight per cent of the 1,011 records screened in academic databases were excluded because they did not provide relevant evidence on the uses or safety of coca leaf. An additional 3.7% were not accessible in full text.

The limited availability of formal scientific literature necessitated the inclusion of supplementary sources. Thirteen documents from gray literature and expert references were incorporated, including technical reports, community systematizations, institutional documents, and non-indexed publications. These represented 41.9% of the total articles included in the review (n = 31).

With regard to the limitations of the evidence analyzed, the absence of adequate control groups, small sample sizes, lack of randomization and prolonged follow-up, insufficient control of confounding factors, and nonstandardized designs in toxicological or preclinical studies were evident. These weaknesses limit the generalizability of the findings and underscore the need for more robust studies, especially in contexts involving prolonged use or vulnerable populations.

The main methodological limitations identified in the included studies are summarized below, grouped by study design. This summary provides an overview of the most relevant patterns of bias that affect the interpretation of the findings.

Table 7. Methodological limitations of the included studies.

TYPE OF STUDY	FREQUENT LIMITATIONS
Observational (ethnographic, clinical)	No control group, uncontrolled confounding factors, selection bias.
Clinical trials (acute)	Small samples, no randomization, participants not accustomed to consumption.
In vitro preclinical studies	Use of a single cell line, no comparison of doses or times.
Risk profile assessments	Variability in alkaloid concentration, lack of reference dose, poor standardization.
Studies for therapeutic purposes	Uncontrolled design, informal clinical measurement, no physiological indicators.

5. Conclusion

5.1. Technical Conclusion on the Safety of Traditional Use

The evidence compiled in this review suggests that traditional consumption of coca leaf in Colombia, in the forms, doses, and settings documented, presents an acceptable safety profile. This conclusion is based on the convergence of qualitative, clinical, and toxicological data that do not report serious adverse events or significant clinical alterations attributable to such consumption. The documented use of this product in human populations over decades, with no reports of clinically relevant harm, meets the criteria established by the WHO for the assessment of long-established traditional herbal products. Therefore, traditional use constitutes a valid source of safety evidence, provided that there are no changes in the preparation, route of administration, or target population.

5.2. Implications for Public Policy and Surveillance

These findings are relevant to the formulation of public health policies, the regulation of traditional products, and the recognition of Indigenous and peasant cultural practices. The technical validation of the safety profile of traditional coca leaf use supports differential regulatory processes, participatory pharmacovigilance, and the strengthening of research in specific contexts.

5.3. Recommendations for Future Research

Significant gaps remain in the comprehensive toxicological characterization of coca leaf, particularly with regard to chronic, genotoxic, and reproductive effects. Further studies with greater methodological rigor are recommended, as well as mixed-methods designs that integrate clinical evaluation with empirical knowledge of contexts of use. The generation of additional scientific evidence will be key to expanding the product's risk profile, supporting its potential use in other settings, and ensuring its safe incorporation into differentiated regulatory frameworks.

Chapter 2

Safety in the Traditional Use of Coca Leaf in Colombia: A Case Study in Toribío, Cauca

This chapter systematizes the findings on the traditional uses of coca leaf in the municipality of Toribío (Cauca). The purpose of this case study is to document the specific practices of the Nasa people in the San Francisco, Tacueyó, and Toribío territories regarding the cultivation, harvesting, roasting, processing, and use of coca leaf and their food byproducts. The objective is to determine whether evidence exists in this local context to support their safety as a product intended for human consumption.

Furthermore, the fieldwork focused on identifying patterns of coca leaf use, including the characterization of types of use, combinations with other substances or plant species, doses and frequencies of consumption, as well as locally recognized indications and contraindications. The interviews included systematic questions about the existence of cases of intoxication associated with the consumption of coca leaf or its byproducts and about possible cultural or regulatory restrictions related to its use.

This study is based on the WHO definition of traditional Indigenous medicine, defined as the sum of the knowledge and practices, whether explorable or not, used in the prevention, diagnosis, or treatment of physical, mental, and social illness. The medicinal use of coca leaf by the Nasa people of Toribío may be considered knowledge that relies almost exclusively “on past experience and observation handed down orally or in writing from generation to generation” (WHO, 2019), which generally constitutes an area of primary health care.

According to the questionnaire attached to the WHO Global Report on Traditional and Complementary Medicine 2019, there are two types of practices within Indigenous traditional medicine. The first group is based on the administration of medication—the use of medicinal herbs, animal parts, and/or minerals—while the second group consists of procedures carried out primarily without the use of medication, as in the case of

acupuncture, manual practices, and spiritual therapies (WHO, 2019). This case study explores medicinal practices based on the use of coca leaf in ritual, spiritual, or collective settings in Toribío. It also recognizes that the main actors involved in coca leaf consumption are traditional doctors, healers, and midwives who treat members of the community before they “turn to Western medicine”.

This chapter is organized into four parts. First, it presents an overview of the case study, including its objectives, methodology, and characteristics of the fieldwork. Second, it describes the geographical, demographic, economic, and institutional context of the municipality of Toribío.

The third part systematizes and analyzes the information collected during the fieldwork, based on the meanings that local actors attribute to the coca leaf. It then examines elements related to its cultivation and processing (particularly drying and roasting). The fourth and final section addresses practices of use and presents an analysis of local perceptions and experiences regarding the safety of coca leaf as a product intended for human consumption.

1. Methodology

1.1. Institutional Context and Inter-institutional Collaboration

This research was conducted as part of Project MGA-2025-23-28, “Prototyping Coca-Based Products Using Extracts and Dried/Fresh Leaves in the Indigenous Territories of Toribío, San Francisco, and Tacueyó”, led by the Cauca Regional Office’s Center for Services and Trade of the Servicio Nacional de Aprendizaje¹⁰ (SENA, in Spanish). Through Resolution 648 of 2023, the Fondo Nacional de Estupefacientes¹¹ authorized this institution to “import or purchase locally [coca leaf] for use in research” in agricultural and gastronomic areas. Currently, SENA and Universidad de los Andes

10 National Learning Service.

11 National Narcotics Fund.

are the only institutions that hold this type of permit for research involving coca leaf.

The objectives of the prototype project are (SENA, 2025):

- a. To generate technical and regulatory knowledge that facilitates the legal recognition of coca leaf byproducts in regulated markets.
- b. To advance research into pharmacological applications through biosafety analysis.
- c. To standardize the process for the production of inputs such as mineralized organic liquid fertilizer fermented with coca leaf (Cocalofa).
- d. To strengthen local knowledge and value-added uses of coca leaf by consolidating previous research and developing product prototypes.

This initiative is implemented in collaboration with the SENA research groups SINERGIA and GEIITA¹², the Genetic Toxicology and Cytogenetic laboratory of Universidad del Cauca, the Mayor's Office of Toribio, the Center of Education, Training and Research for the Integral Development of the Community (CECIDIC)¹³, and Elementa Consultoría en Derechos.

1.2. Fieldwork Design

The fieldwork was carried out between 27 April and 4 May 2025, in the San Francisco, Toribío, and Tacueyó territories. The methodological strategy included two main components:

- **Participatory workshops** organized by the technical team of the SENA project

12 Group of Studies in Agricultural Research and Technological Innovation.

13 "CECIDIC is a proposal for peacebuilding, community organization support, and life education, managed and built by the community of the Indigenous Territories of Toribio, San Francisco, and Tacueyó since 1994 and recognized by traditional authorities as a vital organization in the revitalization of the Nasa life plan project. It creates, identifies, and develops dynamic processes that can be integrated into the lives of the inhabitants of the territory, from family, principles, values, knowledge, spirituality, and ancestral cultural practices within the Nasa people and among other Indigenous Peoples". See (Alcaldía de Toribio, 2020).

- **Semi-structured interviews** with key informants, including traditional authorities and officials of Indigenous and Intercultural Healthcare System (SISPI).

Participatory Workshops:

Two face-to-face workshops were held: one with the communities in the San Francisco and Toribío territories, and another with the community in the Tacueyó territory. The specific objectives of the workshops were:

- To identify key actors, social groups and economic dynamics linked to coca leaf.
- To develop a collective map of the resources, products, uses, and cultural practices associated with the plant.
- To prioritize coca leaf byproducts with potential for development and marketing.

Information on the community's expectations regarding the standardization of coca-based product manufacturing and the potential economic benefits of marketing these products outside Indigenous Territories and territories was also gathered during the workshops.

Semi-structured Interviews:

Fifteen interviews were conducted with individuals strategically selected for their knowledge of traditional, regulatory, and healthcare practices related to the coca leaf. The group of interviewees was divided into two categories: traditional authorities—elders with knowledge of the cultivation, harvesting, preparation, and consumption of the coca leaf—and SISPI officials with expertise in intercultural healthcare and the implementation of the municipality's own healthcare system.

The interviews addressed topics related to:

- a. The cultural and symbolic meaning of coca leaf.
- b. Traditional agricultural practices (cultivation, harvesting, drying).

- c. Consumption practices and patterns.
- d. Perceptions and experiences on consumer safety.
- e. Cultural and regulatory restrictions.

Relationship between the current legal framework and access to the plant for community use and commercialization.

1.3. Sampling Strategy

The selection of informants was not based on probabilistic sampling techniques or the “snowball” method. Instead, information from previous characterizations conducted by the SENA project on local actors and productive ventures in the municipality was used. Additionally, participants identified during the participatory workshops were included. Table 8 provides a general characterization of the participants interviewed.

Key individuals were identified based on the local project team’s accumulated knowledge of the territory, prioritizing those who could provide detailed and contextualized descriptions of the topics covered in the interviews.

Table 8. Participants interviewed during fieldwork.

INTERVIEWEE ¹⁴	TERRITORY	CORREGIMIENTO/ VEREDA	AGE (YEARS)	TYPE OF INTERVIEWEE
María	Tacueyó	No information	53	Elder - Entrepreneur of cannabis and coca products
Graciela	Tacueyó	No information	55	Traditional authority
Érika	Toribío	Toribío	33	SISPI Officer
Ricardo	Tacueyó	No information	30	Traditional authority

¹⁴ The names of the interviewees have been changed to protect their identity.

David	Tacueyó	Bloque Rionegro	61	Traditional authority
Lucía	San Francisco	Natalá	54	Traditional authority
Sandra	Toribío	El Manzano	60	SISPI Officer
Juan	Toribío	Vichiquí	40	SISPI Officer
Julián	Toribío	El Manzano	59	Elder
Alfredo	Toribío	Toribío	60	Autoridad tradicional
Mauricio	San Francisco	Caloto Nuevo	47	Elder
Jimena	Toribío	Toribío	50	Traditional authority
Margarita	Toribío	Vichiquí	61	Elder
Enrique	Toribío	Cuenca Río de Isabelina	55	Elder
Soledad	Toribío	Vichiquí	75	Elder

2. Toribío Context

The municipality of Toribío is located in southwestern Colombia, in the department of Cauca. It is a territory of great importance due to its biological diversity, organizational history, and strong Indigenous cultural roots. It consists of three legally constituted Indigenous Territories –San Francisco, Tacueyó, and Toribío—which cover a total area of 412 km², at altitudes ranging from 1,600 to 4,150 meters above sea level on the eastern slopes of the Central Ranges.

From an environmental perspective, Toribío has a high concentration of protected areas and strategic ecosystems: over 42% of its territory is devoted to conservation, and only 10% of the land is used for production.

This includes páramo areas (13%), primary forests (12%), and secondary forests undergoing regeneration (6.6%). These conditions create increasing pressure on the effective use of land, exacerbated by population growth and the limited availability of land suitable for agriculture.

The current population stands at 37,944 (2024), of which 93.8% live in rural areas. Ninety-seven point seven percent of the inhabitants identify as Indigenous members of the Nasa people¹⁵, making Toribío one of the territorial epicenters of the Indigenous movement in Colombia. Tacueyó is the most populated territory, followed by Toribío and San Francisco. The municipality's population has grown¹⁶ by 60.3% between 1993 and 2024¹⁷ and is concentrated in rural areas where economic activities are predominantly agricultural. At the same time, it has entered a demographic transition, which has led to a “fragmentation and reduction in the size of farms, making it increasingly difficult to restore a balance between meeting needs and intensifying family work throughout the demographic cycle of the household” (Castaño, 2016).

Although 85% of households have access to land—thanks to internal redistribution systems managed by Indigenous cabildos—the average size of plots is small. In the Toribío territory, for example, the average size is only 1 hectare (Castaño, 2016), which limits the ability to generate sufficient income from agriculture. This territorial pressure is illustrated in Figure 2, which shows the distribution of land access by territory.

The local economy revolves around subsistence systems organized around *Nasa Tul*, an ancestral farming model that combines food production with a spiritual worldview. However, activities more closely linked to the market, such as coffee cultivation and, more recently, cannabis cultivation, have gained momentum in response to economic pressure.

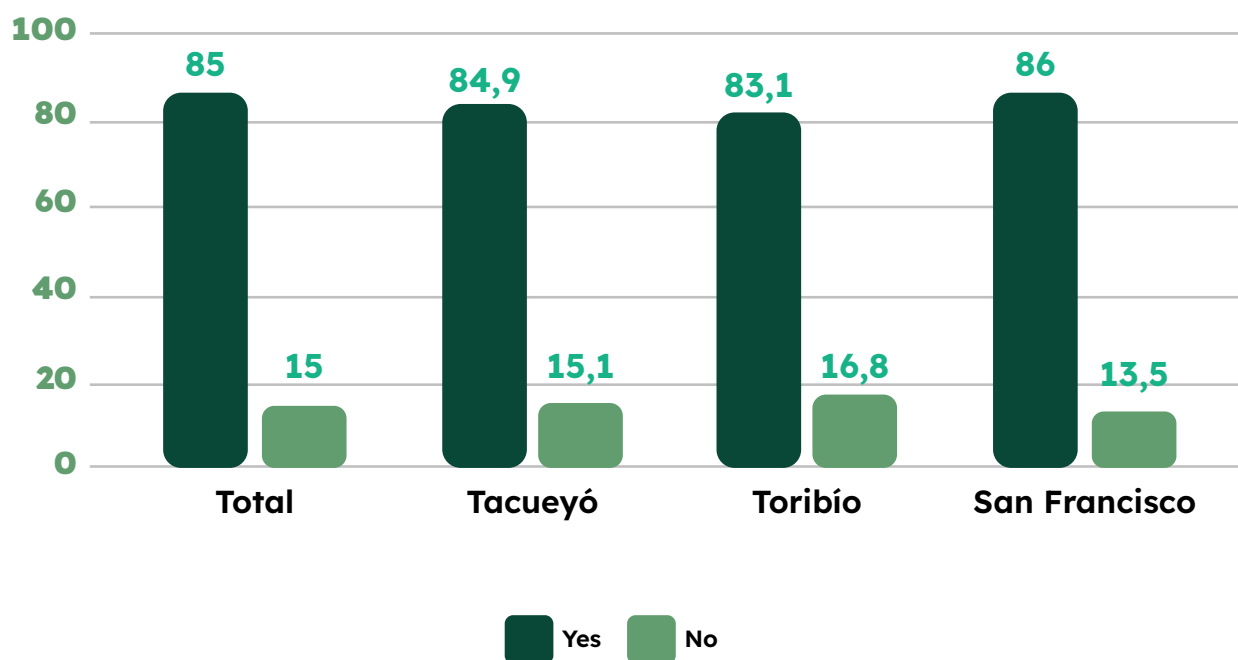
15 According to the 2018 Indigenous Census, the Nasa People represent 21% of the country's Indigenous population (9).

16 The population growth in Toribío is proportional to the growth of the Colombian population. Between 1993 and 2024, the country's population grew by 59.8%. However, population density is different: in 2014, there were 46.15 inhabitants per km² in Colombia.

17 According to data from DANE and *cabildo* censuses, the total population of Toribío in 1993 was 23,665, and in 2005, 26,512. According to data from *cabildo* censuses, as of March 2014, the total population of the municipality was 32,682, while today the population stands at 37,944. See (Castaño, 2016).

Although cannabis is now the main commercial crop¹⁸ in terms of income, communities recognize it as a “foreign” plant, unlike the coca leaf, which is part of the Nasa people’s ancestral value system.

Figure 2. Percentage of households with access to land for the municipal total and the three territories according to the 2014 Nasa Survey.



Source: Castaño, 2016, p. 277.

¹⁸ Cannabis, as the municipality’s largest commercial crop, has the potential to generate around COP 200 billion per year in the municipalities of northern Cauca (Espitia & Majbub, 2024). Marijuana arrived in the region about a century ago, and although Indigenous communities recognize its therapeutic and healing properties, it is not one of their ancestral plants (Cruz & Pereira, 2021), unlike coca. According to SIMCI, Toribío accounted for 21% of the cannabis crop applications submitted in the country (UNODC & Gobierno de Colombia, 2018). It is estimated that in 2019 there were approximately 5,000 producers in the municipality, and currently, the figure amounts to some 15,000 in the five municipalities of northern Cauca (Granados et al., 2024).

2.1. Indigenous Governance and Territorial Autonomy

Toribío has a consolidated Indigenous organizational structure, backed by colonial deeds dating back to 1701 (Proyecto Nasa, 2017). The three territories mentioned above are legally recognized as special public entities with legal status, their own assets, and administrative autonomy, in accordance with the 1991 Constitution.

The municipality is also the birthplace of the Consejo Regional Indígena del Cauca¹⁹ (CRIC, in Spanish), founded in 1971 in vereda La Susana (Tacueyó territory) (Proyecto Nasa, 2017). It is the epicenter of the Nasa Project, one of seven historic community initiatives in northern Cauca promoted in the 1980s by Nasa leader Álvaro Ulcué Chocué to revitalize Indigenous cultures, practices, and customs (Acin, 2018). The Nasa Project coordinates programs—or cabildos—on health, solidarity economy, education, justice, and political organization, in line with the Nasa people’s Life Plan.

In addition, the Nasa Project has defined its own governance structure, which coordinates the programs of the cabildos with municipal authorities and community mandates under a long-term planning vision projecting implementation until 2050 (see Figure 3).

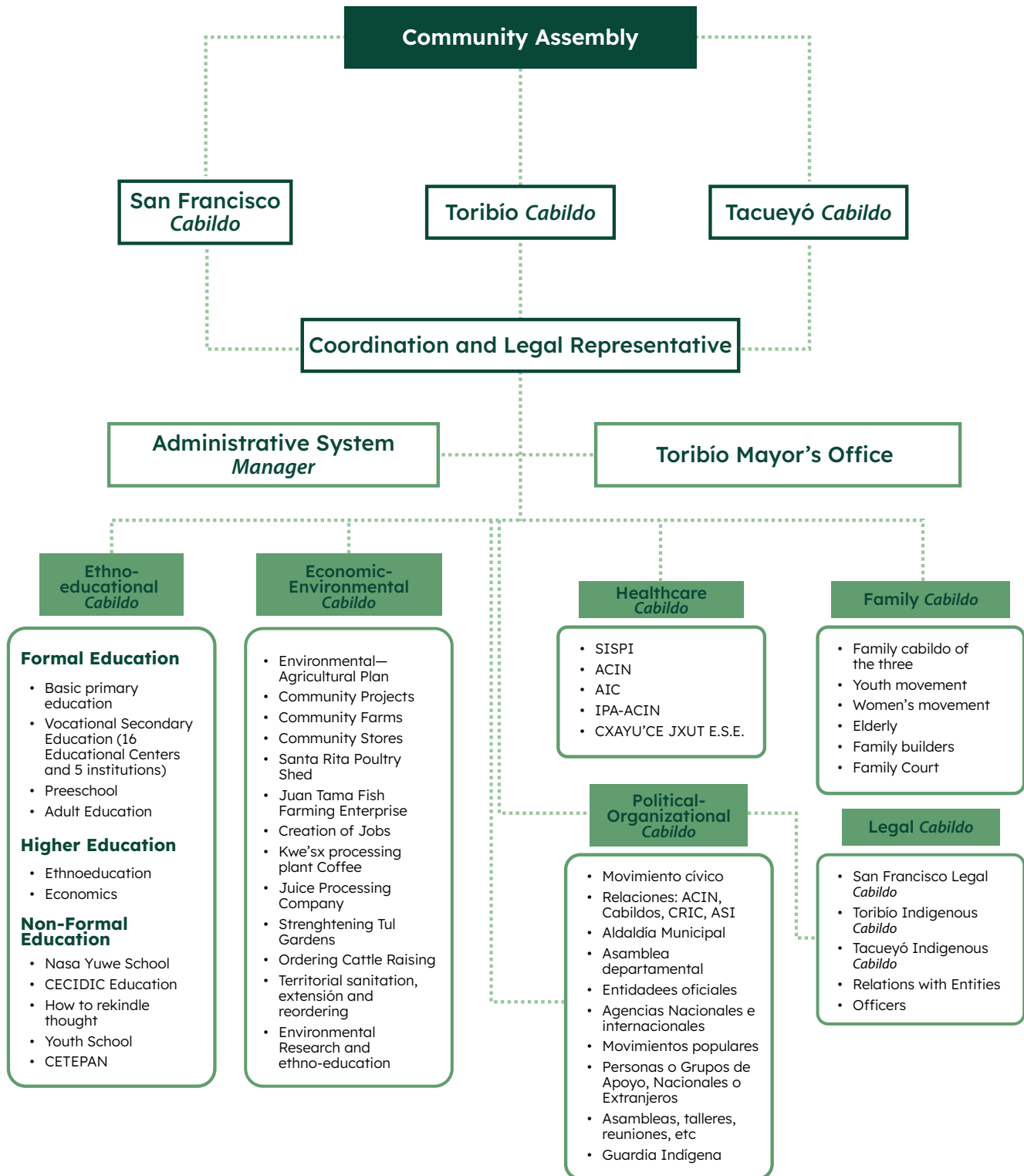
2.2. Relevance for this Review

The case of Toribío illustrates how the traditional use of coca leaf is deeply integrated into Indigenous healthcare systems, food culture, ritual practices, and community regulatory structures. This experience shows that consumption patterns are socially regulated, territorialized, and have been sustained for generations without evidence of intoxication or adverse effects.

This territorial context reinforces the viability of differentiated regulatory approaches and the technical recognition of the traditional use of coca leaf as a plant product with long-standing use, in accordance with WHO guidelines.

¹⁹ Cauca Regional Indigenous Council.

Figure 3. Organizational structure



Source: Nasa Project, 2017, p. 103.

3. Results and Descriptive Analysis of the Information Obtained in the Field

This section systematizes and analyzes the information collected during fieldwork in the municipality of Toribío, department of Cauca (Colombia), with members of the Nasa Indigenous people. Data collection was conducted through semi-structured interviews and participatory workshops, and the analysis followed an inductive, ethnographic approach, coded using qualitative analysis tools.

The text below follows the themes from the interview guide, preserving the original words and expressions of the people interviewed whenever possible. Many of these quotes are presented in quotation marks and include footnotes, which provide both the direct source (the person interviewed) and references to other sources that contextualize or support the statements.

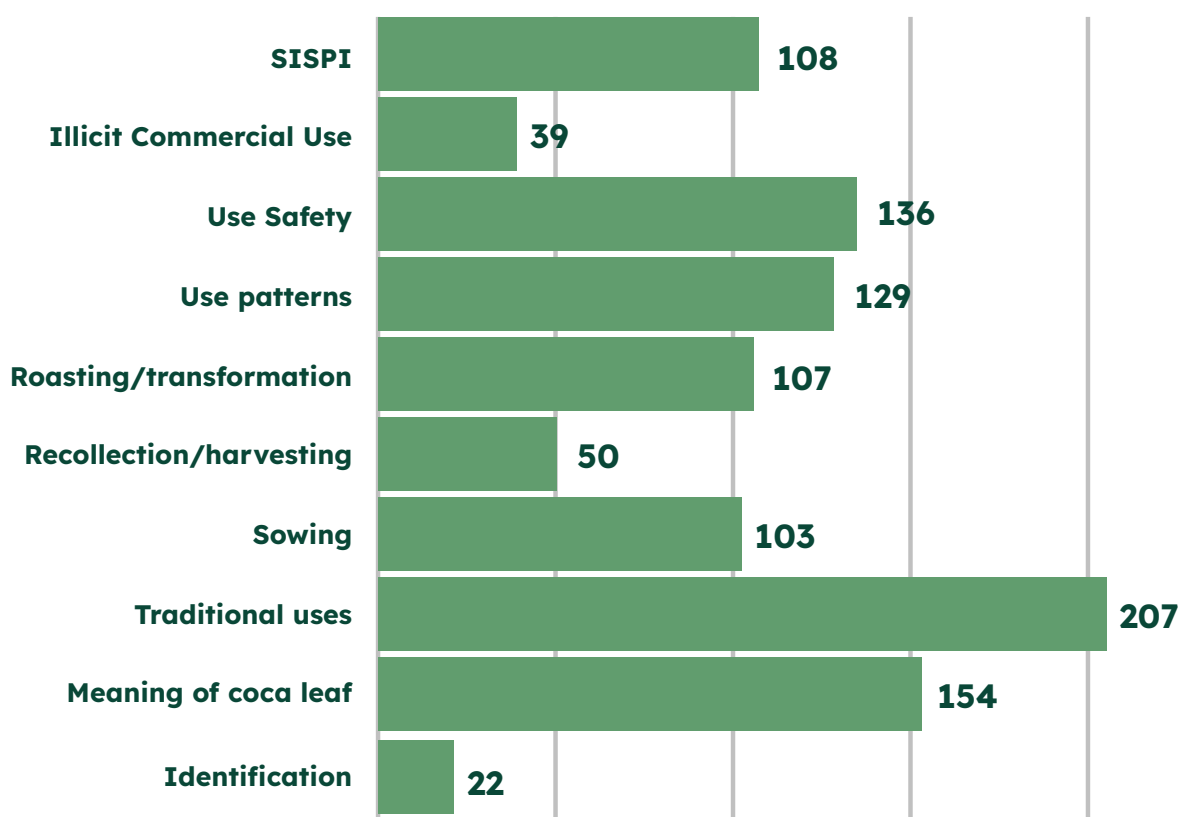
3.1. Analytical Approach and Systematization

The information was organized and coded using ATLAS.ti Web 25 (custom government version). The analytical categories and subcategories correspond to the specific objectives of the study and are described in Annex 1. To contribute to the debate on the safety of coca leaf in the context of the WHO's critical review, this chapter adopts the working assumption that spiritual, ritual, and therapeutic aspects constitute "medicinal uses". Flexible multiple coding rules were applied: the same information could be classified under several categories, with priority given to the most specific subcategory when identifiable.

Although the study focused on the traditional use of coca leaf, an additional category, "illicit commercial use", was included. This inclusion was not intended to document the illegal cocaine economy but rather to capture how the coca leaf fits into the worldview of the Nasa people, their social organization, customary law, and rituals. In addition, it describes elements of production, transformation, and use that support the safe use of coca as a product for human consumption.

The category “traditional uses” had the highest number of records, partly because it contained 18 subcategories. However, the “safety”, “usage patterns”, and “meaning of the coca leaf” categories also played a significant role, reinforcing the internal consistency of the findings. The “illicit commercial use” category had a low number of records, consistent with the explicit intention to focus the study on legitimate cultural uses and exclude the dimension associated with drug trafficking.

Figure 4. Number of records for each of the nine coded categories



Source: Prepared by the authors based on Atlas Ti data.

3.2. Support of Digital Tools and Knowledge-based Approach

Artificial intelligence technologies were used to support the initial processing of the data. The interviews were transcribed using the professional application Trint, and conversational tools from the web version of

ATLAS.ti—still in the experimental phase—were used to generate preliminary interpretive memos. These tools served to:

- a. Identify patterns linked to health safety criteria.
- b. Detect references to the combination of coca leaf with other medicinal plants or substances, such as tobacco and alcohol.
- c. Describe the local strategies employed by the community to ensure the safe use of coca leaf.

The results did not replace manual analysis and were validated and corrected by the research team. The use of these technologies is considered complementary to the qualitative approach, which emphasizes the participants' voices and the validation of their knowledge as legitimate forms of evidence within the intercultural public health framework.

3.3. Meaning of *Esh's*: “There is no Nasa without Coca”

In the Nasa Yuwe language, the coca leaf is called *Esh's*, and it holds a central place in the spiritual, organizational, and community life of the Nasa people. During fieldwork conducted in Toribío, a consistent pattern was identified linking the coca leaf to individual and collective harmony and to the exercise of Indigenous thought. In the words of one interviewee, the leaf “is considered a sacred plant; it is an ancient plant of the Andes and has always been close to our ancestors”²⁰. The coca plant reflects the decisions made in the heat of the *Tulpa* (Tumbo, 2014), provides the food and energy needed for major rituals, and allows for reflection on collective, family, and personal matters.

Chewing *Esh* is part of a spiritual process that “makes the Indigenous view [of the world] much more real”²¹, and helps to “identify the positive and negative aspects of spirituality”²² or the state of a community situation. This practice takes place in sacred locations, such as lagoons, rivers, or

20 Interview to Alfredo in Toribío Territory, April 28, 2025.

21 Interview to Alfredo in Toribío Territory, April 28, 2025.

22 Interview to Alfredo in Toribío Territory, April 28, 2025

mountains, where mambeo—the ritual consumption of coca—allows elders to perceive “natural guidance about situations that may be arising in the territory”²³. Thus, the leaf not only nourishes and energizes but also acts as a vehicle for spiritual diagnosis.

The link between *Esh*’s and the life of the people is vividly expressed in the statement: “There is no Nasa People without coca”²⁴, because “without [it] no ritual of any kind can be performed—neither family nor territorial consultations, nor the search for other plants”²⁵. Coca serves to connect with the *Ksxa’w*²⁶, because through thought one can understand the language or messages that “our God, the *Ksxa’w*, will utter through signs”²⁷. Only through the interpretation of these signs can the elder interpret the conflict or need (Salas, 2021) that the person or community is facing.

The concentrating effect²⁸ of the plant’s alkaloids increases the capacity for thought, and the Nasa people understand that this energy makes the human body a receptacle for the signs or signals of nature to act in the world. Therefore, when discussing a common issue, coca is chewed, because only through the plant can a fundamental issue in the Nasa worldview be revealed: the unity of the world. “So a cloud brings a warning, a positive or negative warning; the song of a bird, thunder, the sound of a bird at night. And then, the spiritual leader uses all these cues raised by a sign from nature so that, by chewing the coca leaf, they can identify the message that Mother Earth wants to convey. The Indigenous worldview has always been, and continues to be, integrated with what nature sees, what nature says. And I must follow the path that nature says”²⁹.

This ceremonial use of coca is associated with a cognitive function attributed to its alkaloids, which increase the ability to think and facilitate a clearer connection with the spiritual and natural environment. Through

23 Interview to Alfredo in Toribío Territory, April 28, 2025.

24 Interview to Enrique in Toribío Territory, April 28, 2025.

25 Interview to María in Tacueyó Territory, May 01, 2025.

26 “The spirit of dreams tells or advises the thunder what to do”. (Proyecto Nasa, 2017).

27 Interview to Julián in Toribío Territory, April 30, 2025.

28 The stimulating properties of coca leaf derive from an increase in the speed of transmission of nerve impulses based on the flow of electrically charged particles from one neuron to another, which together “produce a subjective awareness of being electrified”. See: (Henman, 2023).

29 Interview to Alfredo in Toribío Territory, April 28, 2025.

this practice, elders “connect with the wind, with water, with the mountain, with fire”³⁰, enabling them to interpret conflicts or needs and provide spiritual or healing guidance to those who consult them. In this way, they receive instructions for healing, balancing, or resolving conflicts.

The *Esh*’s plant is not restricted to major ritual uses but is also present in community spaces, assemblies, and social mobilizations. An interviewee reported that “the Indigenous organization uses large amounts of coca leaf for chewing in institutional strengthening processes”³¹. Another interviewee added that it is also used during mobilizations: “This activity demands a lot of energy”³². To respond to this growing demand, a formal community commercialization mechanism for toasted leaves has been established through the Nasa Project store.

From a spiritual perspective, the use of *Esh*’s requires internal authorization, received through dreams. Elders who train as *Thë Wala*, or traditional doctors, do so under the guidance of the spirit of dreams: “if an elder does not have that connection with dreams, they cannot heal others”³³. The dream, they say, indicates when someone is ready to practice traditional medicine: “While I’m chewing coca, dreams tell me, ‘you can now heal others, you can now help people’”³⁴.

3.4. Pajarita is Planted in Tul and Roasted in Cayana: Cultural Knowledge and Traditional Practices

In Toribío, Cauca, coca leaf are grown mainly for traditional, medicinal, and ritual purposes. The people interviewed emphasize a marked distinction between these ancestral practices and those linked to illegal economies. The *pajarita* variety—identified as native to the Nasa people—and the “leaf by leaf” harvesting method are diametrically different to the Peruvian or Bolivian varieties and the intensive scraping associated with the cocaine market. Similarly, cultivation in the Nasa *Tul*—a diversified agricultural sys-

30 Interview to Alfredo in Toribío Territory, April 28, 2025.

31 Interview to Alfredo in Toribío Territory, April 28, 2025.

32 Interview to Julián in Toribío Territory, April 30, 2025.

33 Interview to Mauricio in San Francisco Territory, April 30, 2025.

34 Interview to Mauricio in San Francisco Territory, April 30, 2025.

tem³⁵—contrasts with commercial monoculture. In the words of an interviewee: “Monoculture no longer serves that [traditional] function; it has turned into production for commercialization, and thus the essence of the leaf’s existence as a sacred plant has been completely lost”³⁶.

Although some crops are intended for the illegal market in the flat areas or on the border with Caloto, these are marginal. In contrast, most coca plants are found on family plots, where they serve medicinal, spiritual, and nutritional purposes. Participants in the community workshop said that “there are plants in all the *veredas*, but they are mostly for medicinal use”³⁷. It is normal for a farm to have between 50 and 70 plants integrated into the *Tul*.

3.4.1. The *Nasa Tul*: A Way of Life in Connection to the Earth

The *Nasa Tul*, or *atx’Tul*³⁸ in Nasa Yuwe, is much more than an agricultural system: it is a cultural strategy for coexistence between Uma Kiwe (Mother Earth) and the family. “This model is not limited to the production of healthy food, but is based on guaranteeing autonomy and confronting various threats” (14), which is considered fundamental to the defense of the territory, “because it is based on the principle of autonomy rather than constituting a form of domination over a space” (14).

There, crops such as mote, arracacha, corn, cassava, beans, citrus fruits, medicinal plants, and domestic animals such as chickens, ducks, and geese coexist in diversity and harmony. In the words of an interviewee: “We don’t plant large quantities, but here we have about two arracacha

35 “A polyculture system that combines food, medicinal, and ritual plants. It is a garden near houses, where a variety of medicinal and food plants are grown, as well as fruit and timber trees, which are planted around the main house. These home gardens are a symbol of protection, sheltering the family unit and representing the heart of the *Nasa Tul*. In Toribío, the *Nasa Tul* covers areas of up to 500 m² according to the conditions indicated by field researchers through surveys”(Sena, 2024).

36 Interview to Alfredo in Toribío Territory, April 28, 2025.

37 Workshop in Toribío, April 29, 2025.

38 Yule and Vitonas (2010) analyze the etymological origin of the word *Tul*, linking it to the concept of *Atx Tul*, which translates as a piece of women’s clothing, specifically a skirt made of sheep’s wool for warmth, derived from “*Atx*”, which means poncho, and “*Tul*”, from *Tel*, which means loom. This conceives the *Tul* as a loom covered by a cloak, where the act of cultivating is likened to weaving, symbolizing care and protection for Mother Earth (Yule & Vitonas, 2010).

plants and five cassava plants³⁹. In this agroecological ecosystem, coca leaf are scattered, “sprinkled here and there⁴⁰, near the house, as a companion and ornamental plant.

Sowing respects natural cycles. Seeds, not seedlings, are sown during the waxing moon, and after preparing the seedbeds. In addition, sowing is done “during the waxing moon at least three or four days [before] the full moon⁴¹. The sprouted plants are carefully selected before transplanting, prioritizing the strongest ones. “Usually coca is not a problem because they are all female⁴², said one interviewee. If a plant gets sick, “they cut it down and it grows back and sprouts again⁴³. This resistance makes coca *pajarita* a long-lived species: some bushes are between 30 and 70 years old and were inherited from grandmothers⁴⁴.

Care is simple and free of agrochemicals. Most of the interviewees said that caring for their crops is easy, as they do not use “poisons or fertilizers; it is done practically ‘at the will of God’”. My mother simply throws whatever leftovers there are from the mote or cooking onto the plants. That’s what feeds them⁴⁵. The fertilizer is entirely organic: “Only chicken feces⁴⁶ or compost⁴⁷. The use of chemicals is avoided for health and respect reasons: “You can use it safely because it’s not harmful⁴⁸.

3.4.2. Risks, Tensions and Community Regulation

The coexistence of traditional and commercial crops—coffee, marijuana, or *sacha inchi* (wild peanut)—on small plots of land leads to indirect exposure to agrochemicals through runoff or drift, a phenomenon that affects the “purity” of traditional crops. For example, one of the elders who sells

39 Interview to Enrique in Toribío Territory, April 28, 2025.

40 Interview to Enrique in Toribío Territory, April 28, 2025.

41 Interview to Julián in Toribío Territory, April 30, 2025.

42 Interview to María in Tacueyó Territory, May 01, 2025.

43 Interview to Jimena in Toribío Territory, April 30, 2025.

44 Interview to Jimena in Toribío Territory, April 30, 2025.

45 Interview to Mauricio in San Francisco Territory, April 30, 2025.

46 Interview to David in Tacueyó Territory, May 13, 2025.

47 Interview to Graciela in Tacueyó Territory, May 13, 2025.

48 Interview to Margarita in Toribío Territory, April 30, 2025.

his coca leaves to the Nasa Project store in Toribío admitted that he had “two coca plants in the middle of his coffee plantation”⁴⁹. Even so, the fundamental principle remains: “The best coca leaf is traditional and organic”⁵⁰.

Regarding the regulation of the crop, several people mentioned a CRIC provision, adopted after 1971, which suggested a limit of 30 plants per family—enough for chewing and ancestral uses. However, this provision is not formally documented, and knowledge of it is limited. Some say the limit is 20 plants⁵¹, others say 50, and many admit that there is no clear rule. “Some families have between 100 and 200 plants, but that is because there is no guideline on how many each family can have. No, there is no set rule”⁵².

The logic behind this regulation is that each family should be self-sufficient with a small number of plants. However, the territorial reality has made this difficult. Land scarcity and the prioritization of profitable crops, such as coffee or marijuana, have reduced the number of households that grow coca in their *Tul*. As a result, there is a shortage of leaves during times of high demand. One interviewee mentioned that she kept only eight plants, “just for [her family’s] *mambeo*, and when they run out [at the Nasa Project store], she roasts them and sells them”⁵³.

The Nasa Project coordinates this production with the Nasa Life Plan healthcare programs, purchasing the leaves from elders for use in rituals and cultural activities. “They channel, buy, and distribute the plants to all the programs that need to advance cultural steps”⁵⁴.

3.4.3. Collection, Transformation and Transmission of Knowledge

The *Pajarita Caucana* variety is recognized as traditional to the Nasa people because of its strength and close connection to spirituality⁵⁵. When asked about harvest volumes, interviewees offered varying estimates:

49 Interview to Julián in Toribío Territory, April 30, 2025.

50 Interview to Alfredo in Toribío Territory, April 28, 2025.

51 Interview to Graciela in Tacueyó Territory, May 13, 2025.

52 Interview to Érika in Toribío Territory, May 13, 2025.

53 Interview to Sandra in Toribío Territory, April 30, 2025.

54 Interview to Alfredo in Toribío Territory, April 28, 2025.

55 Interview to Alfredo in Toribío Territory, April 28, 2025.

some said that a plant can produce between 10 and 16 pounds per harvest⁵⁶, while others claimed that “each plant yields around three or four pounds”⁵⁷. The variation in responses can be explained by local harvesting practices, which do not follow a fixed schedule but are carried out when the weather is dry and according to the specific needs of the family, whether for cultural or medicinal uses or for selling the roasted leaves⁵⁸.

The traditional harvesting method is “leaf by leaf”, which is slower and less profitable than scraping. While a scraper can collect up to 30 *arrobas* (around 960 pounds) per day⁵⁹, the traditional method yields only two or three. Still, the practice persists for symbolic and practical reasons: “When you scrape it, the leaf will have a lot of twigs [...] and traditional doctors don’t like it because it hurts their mouths”⁶⁰. In addition, scraping the leaf damages the buds⁶¹, affecting the plant’s health⁶².

Harvesting is guided by the moon and the leaf’s condition, which must be “*gecha*”⁶³ (dark green and firm). The new moon (“*biche*”)⁶⁴ is completely avoided. “As soon as it ripens, you harvest it so that it doesn’t produce those little twigs”⁶⁵. Once harvested, the leaf is left to “breathe” and then roasted. This process takes place in the home, using clay pots (*cayanas*) over low heat⁶⁶ for “an hour to an hour and a half”. Roasting should never be done in the sun or in metal pots, as this “gives it a different flavor”. “If you cook the product over low heat, it will remain crispy”⁶⁷, added one of the interviewees.

For every three pounds of green leaves, only one pound of roasted leaves is obtained. This, combined with the physical effort required, means that

56 Interview to Julián in Toribío Territory, April 30, 2025.

57 Interview to Mauricio in San Francisco Territory, April 30, 2025.

58 Interview to Lucía in San Francisco Territory, May 13, 2025.

59 Interview to Mauricio in San Francisco Territory, April 30, 2025.

60 Interview to Lucía in San Francisco Territory, May 13, 2025.

61 Interview to Margarita in Toribío Territory, April 30, 2025.

62 Interview to Enrique in Toribío Territory, April 28, 2025.

63 Interview to Julián in Toribío Territory, April 30, 2025.

64 Interview to Alfredo in Toribío Territory, April 28, 2025.

65 Interview to Enrique in Toribío Territory, April 28, 2025.

66 Interview to Juan in Toribío Territory, May 01, 2025.

67 Interview to Juan in Toribío Territory, May 01, 2025.

many families do not consider it profitable. The task falls mainly to women, who stir the leaves by hand or with a spatula (*cagüinga*), taking care not to burn them⁶⁸. “You need a lot of experience in roasting coca leaves so that they don’t overcook and turn bitter. [Just] like with coffee, if you let the coffee sit too long, it goes bad”⁶⁹, they explained. Currently, there is a shortage of *cayanas*, forcing people to use less suitable utensils. “The ideal roasting point is reached when the leaves make a ‘zui zui zui’ sound as they hit the sides of the pot⁷⁰ and begin to crumble”⁷¹.

Once roasted, the leaf is left to cool and stored in dry conditions. Moisture is the biggest threat, as it promotes the growth of fungi. It is advisable to store the leaves in cardboard boxes, paper bags, or burlap sacks. Under these conditions, the leaves can be preserved for up to six months.

3.5. Coca Use Practices: *Mambeo* to Understand, Diagnose, and Cure

In the municipality of Toribío, roasted coca leaves are traditionally used through *mambeo*, a process in which the leaves are chewed together with a catalyst called *mambe*. Unlike other Indigenous communities in Colombia, in Toribío coca flour and yarumo ash are not used as alkalis. Instead, *mambe* is a mineral powder made from limestone (marble) that “sweetens coca”⁷² and enhances the release of its medicinal properties.

The traditional use of coca in this region is characterized by its collective, spiritual and medical dimensions. While in the past it was used daily as an energy booster in agricultural work, today it is mainly used in ritual settings, consultations with elders or healers, and for treating illnesses. In the words of an interviewee: “In everyday life, the coca leaf has been the plant used as energy booster for work through *mambeo*. The elders always used it as a stimulating food plant⁷³. This practice, passed down from grandparents to grandchildren during the working day, has decli-

68 Interview to María in Tacueyó Territory, May 01, 2025.

69 Interview to Alfredo in Toribío Territory, April 28, 2025.

70 Interview to Margarita in Toribío Territory, April 30, 2025.

71 Interview to Enrique in Toribío Territory, April 28, 2025.

72 Interview to Julián in Toribío Territory, April 30, 2025.

73 Interview to Alfredo in Toribío Territory, April 28, 2025.

ned among the younger generations: “The new generation [...] hardly consumes coca leaf. Young people nowadays chew *mambe* when they have a health problem, when an older person tells them, “Look, you need to chew *mambe*”, that’s when they do, but not like us, who chew *mambe* continuously”⁷⁴.

3.5.1. Consultations and Diagnosis through *Mambeo*

Consultations with elders, midwives, or *Kiwe Thë* are considered a fundamental part of spiritual harmonization and healing. It is customary for those who attend to bring roasted coca leaves, tobacco or cigarettes, and a quarter of *chirrincho* (homemade distilled spirit), which are necessary items for facilitating dialogue with the spirits. While practicing *mambeo*, the elder connects with the *Ksxa’w* (the spirit of dreams), and it is through bodily “signs”—what Western medicine would call vibrations or somatic responses—that he diagnoses the situation. As they chew the *mambe*, the body begins to feel it [and] the signs begin to tell [the elder]⁷⁵. These signs are accurately interpreted to determine whether the ailment requires a ritual, a refreshment, or the use of medicinal plants.

In this sense, the coca leaf plays a central role in diagnosis. “Because without coca, one cannot see clearly. If we are surrounded by beings who do not understand each other, [...] using coca is like saying, ‘I need a little help with this.’ [And I offer a drink], I offer it here to the Earth”⁷⁶. Another interviewee explained: “The coca leaf will not encourage you. Chewing *mambe* is a way for the elder to identify what kind of condition I have—What is my spiritual affliction. The coca will serve as a vehicle to find the spiritual affliction that I suffer, [if] it is a natural one caused by me treading on something bad”⁷⁷. The process is based on an energetic reading of the body and the environment, which helps identify the cause of a physical ailment, for example, having crossed a sacred site without proper protection, which causes illnesses known as “*el arco*” or “*el sucio*”. Both conditions re-

74 Interview to Julián in Toribío Territory, April 30, 2025.

75 Interview to Mauricio in San Francisco Territory, April 30, 2025.

76 Interview to Enrique in Toribío Territory, April 28, 2025.

77 Interview to Alfredo in Toribío Territory, April 28, 2025.

quire spiritual assistance through rituals and the use of medicinal plants, in which the coca leaf plays a central role.

Coca, as a vehicle for healing or treatment has specific medical applications and conditions⁷⁸. It can be used as a first line of treatment before going to a Western doctor⁷⁹. According to the information gathered, it is known to be used for injuries, stomach pain, toothaches, and as an energizer. Coca is a very essential substance that gives the body energy⁸⁰.

3.5.2. Coca in Major Rituals

The five most important spiritual rituals of the Nasa people –*lpx Fxixxanxi* (extinguishing the hearth), *Khabu Fxizehnxi* (refreshing the chontas), *Sek Buy* (New Year), *Saakhelu* (awakening of the seeds), and *Çxapuç* (offering to the spirits)—cannot be performed without the coca leaf. During these events, the elder or spiritual guide distributes handfuls of coca to attendees in successive rounds of chewing *mambe*. “Depending on the job at hand, it can be between three or four handfuls [...] or up to seven times”⁸¹, explained one of the interviewees. Sometimes, rituals can last from the afternoon until the early hours of the morning. The coca leaf used in these events comes from the Nasa Project and is distributed through the *cabildo*’s logistics, allowing hundreds or even thousands of people to participate.

This collective use reaffirms the role of coca as a spiritual and social link. Although many people practice *mambeo* in private spaces, one interviewee pointed out that: “[Perhaps] 70 or 80% do not show it openly, because spirituality is more about feeling. The practice of *mambeo* conveys a sense of belonging that only you, as an individual, can feel and experience, because it is not only about seeking your spiritual self, but also about connecting with the natural environment”⁸².

78 An ethnobotanical study on the uses of medicinal plants among the Nasa people showed that there is evidence corroborating the effectiveness of coca leaf in treating ailments such as stomach pain, bloating, headaches, toothaches, parasites, inflammation, and aches and pains. See: (Paz & Montenegro, 2024).

79 Interview to Margarita in Toribío Territory, April 30, 2025.

80 Interview to Juan in Toribío Territory, May 01, 2025.

81 Interview to Juan in Toribío Territory, May 01, 2025.

82 Interview to Juan in Toribío Territory, May 01, 2025.

3.5.3. Traditional Medicine and Intercultural Healthcare

The resurgence of traditional medicine is part of the efforts organized by the Nasa Life Plan. Many people consult traditional healers before going to conventional healthcare centers. Generally, the population turns to the *Thë Wala*, pulse reader, *Kiwe Thë*, elder, midwives, among others, “before going to healthcare centers, the population resorts to ancestral knowledge rather than Western medicine”. (Alcaldía de Toribío, 2024) In this context, the coca leaf plays an essential role as a preventive and diagnostic tool in the SISPI. Its use often precedes, and sometimes replaces, Western medical treatment. The leaf is used in infusions, poultices, or *mambeo* to treat conditions such as stomach pain, diarrhea, toothache, indigestion, and poisoning. The coca leaf is an immediate remedy for loose bowels and diarrhea. Drinking coca water or coca tea [alleviate bloating, [when] someone has eaten too much or [feels sick]]⁸³. For toothaches, it is recommended to boil coca with rue and rinse your mouth with it⁸⁴. Its combined use with moringa to treat anemia was also reported⁸⁵.

In the case of spiritual illnesses, such as “*arco*” or “*sucio*”, coca helps elders identify the hidden cause of the discomfort and guide treatment through the use of plants from the páramo. Personal illnesses are considered events caused by “disharmonies” that arise between people and nature, which are generally not detected by Western medicine (Romero & Muñoz, 2019).

The *arco* is a disharmony or imbalance that stems from coming into contact with or passing through a place inhabited by a spirit, entity, or being without due respect or protection. It can manifest as any physical ailment. It is considered a personal illness because it is based on the connection one has with the worldview of the Nasa People in Toribío. No one knows for certain what the *arco* is; it is like the consequence of being unaware of the presence of some invisible being that manifests in ailments or health problems. us The *arco* is a being that exists around us and has a home: “If you go over that house, then it touches you, [...] and when it touches you, you will get sick, then you will get itchy, you will get pains [or] your skin

83 Interview to Alfredo in Toribío Territory, April 28, 2025.

84 Interview to Margarita in Toribío Territory, April 30, 2025.

85 Interview to Julián in Toribío Territory, April 30, 2025.

will peel, and it can manifest itself in what the West calls leprosy. The *arco* makes you itchy, it bursts like blisters...”⁸⁶.

On the other hand, *Sucio* is a disease, imbalance, or disharmony that can affect both individuals and the community. Its cause can be internal or external. It is the result of negative energies that make the Nasa people sick. The *sucio* is considered a form of contamination caused by poor nutrition, prolonged exposure to cold, ice, heat, contact with deceased persons, access to a cemetery, and other situations (Mosquera, 2023).

Pregnancy and childbirth are times when coca is used to diagnose and monitor more carefully. Although the practice of traditional midwifery among the Nasa people faces enormous challenges to its cultural preservation, coca survives as a tool for identifying what causes difficulties or pain during pregnancy and childbirth. An intercultural care model for childbirth is being developed as part of the SISPI and the healthcare coordination of the Nasa Project, so that they can work together⁸⁷. During childbirth, it is not the woman who chews *mambe*, but rather the elder who is outside the delivery room working with energies: “analyzing, chewing *mambe*, asking his fellow elder how the birth is going, and he tells the midwife what to do”⁸⁸.

3.5.4. Preparing the *Mambe*: Mineral, Plant and Fire

The *mambe* used in Toribío is made from white or blue limestone⁸⁹ from areas such as Puente Quemado or Pilamo. It is cooked for 12 hours over a wood fire until the stone “turns bright red”, at which point it is removed and a few drops of water are sprinkled on it⁹⁰. “The stone turns to dust as if by magic”⁹¹. This powder is stored in a *guasca* gourd (*mambero*) and sold at approximately 15,000 pesos per half pound.

When chewing, using *mambe* stone involves the risk of burning the ton-

86 Interview to Enrique in Toribío Territory, April 28, 2025.

87 Interview to María in Tacueyó Territory, May 01, 2025.

88 Interview to Margarita in Toribío Territory, April 30, 2025.

89 Interview to Mauricio in San Francisco Territory, April 30, 2025.

90 Interview to Margarita in Toribío Territory, April 30, 2025.

91 Workshop in Toribío, April 29, 2025.

gue or inside of the mouth⁹². Therefore, the *mambe* must be placed in the center of the coca so that it does not cause injury. “When you’re chewing, you split the coca with your teeth and tongue [...] and you put the *mambe* right in between, and then you chew it as if trying to wrap it up again. This way it doesn’t hurt you”⁹³. For those who are not used to it, direct contact with the tongue or lips may cause irritation.

Mambe is part of rituals as one of the three fundamental elements for spiritual cleansing or discharge: “The coca leaf, which is the plant; *mambe*, which is the mineral; and *chirrincho*, which is the liquid”⁹⁴. This combination represents a harmony between body, spirit, and territory, and supports a healthcare system deeply rooted in the worldview of the Nasa people.

3.6. Sanitary Safety of the Coca Leaf: Quality, Uses, and Traditional Control

The sanitary safety of the traditional use of coca leaf in the municipality of Toribío is grounded in agricultural, ritual, and social practices deeply embedded in the culture of the Nasa people. These practices—described in the previous sections—ensure standards of quality and care that, although not codified in written rules, respond to cultural criteria for protecting individual and collective health.

The quality of the coca leaf used for *mambeo* is assessed according to the place and method of cultivation (grown in *Tul*), the variety cultivated (mainly *Pajarita Caucana*), the harvesting method (leaf by leaf), the roasting process, and storage conditions. An interviewee explained that quality is determined “by sound, by texture. For example, this coca is good, that coca is fibrous, that one is unripe”⁹⁵. Leaves that smell damp, are poorly preserved, or have been improperly roasted are also discarded, as they can be “very hard and hurt the mouth”⁹⁶.

92 Interview to María in Tacueyó Territory, May 01, 2025.

93 Interview to Margarita in Toribío Territory, April 30, 2025.

94 Interview to Enrique in Toribío Territory, April 28, 2025.

95 Interview to Alfredo in Toribío Territory, April 28, 2025.

96 Interview to Alfredo in Toribío Territory, April 28, 2025.

However, the safety of the leaf is complemented by the context of its use, since *mambeo* takes place in collective spaces, generally in the presence of elders who set the times and quantities and direct its use through ritual or consultation. In other words, the quality of coca leaves is assessed collectively. The roasted leaf is distributed by elders or knowledgeable individuals, who guide the *mambeo*, assess the texture, aroma, and condition of the leaf, and determine the appropriate dose for each person according to their age, health status, and level of participation in the ritual. This cultural and contextual control constitutes a form of community self-care.

3.6.1. Other Forms of Use and Preparation

Although roasted leaves are the most common form of preparation, there are other artisanal uses of coca in Toribío. For example, coca is used in energy drinks (such as lemonade with coca), infusions, flours, ointments, and cookies. A female leader from the Tacueyó territory prepares lemonade with coca, which “tastes like lulo”⁹⁷, and offers it as a revitalizing beverage. Products such as “flours, cookies, and oils” made from ground roasted leaves have been developed in the educational institution in Natalá.

To prepare medicinal ointments, coca leaves are macerated in alcohol and heated over low heat; the concentrate is then extracted and mixed with petroleum jelly, marijuana, or other medicinal plants. As explained by a traditional authority: “We use that extract for ointments”⁹⁸. These preparations are used in the treatment of muscle pain, inflammation and other ailments.

The most commonly reported physical effect of coca leaf use is reduced hunger and increased physical energy. “I started chewing, added a pinch of *mambe* [...] half an hour later, I wasn’t hungry at all”⁹⁹. Its ability to relieve fatigue without causing insomnia is also mentioned.

97 Interview to Mauricio in San Francisco Territory, April 30, 2025.

98 Interview to María in Tacueyó Territory, May 01, 2025.

99 Interview to Julián in Toribío Territory, April 30, 2025.

3.6.2. Consumption Quantities, Frequency and Supervision

The frequency and quantities consumed do not follow a uniform pattern, as they depend on the cultural setting. Since everyday use has declined, most consumption occurs during cultural ceremonies, harmonizations, spiritual consultations, or community rituals. In these settings, the elders decide how much to distribute. “They gauge roughly how much they think you can handle, and that’s what they give you”¹⁰⁰, said an interviewee.

Each round of *mambeo* involves a handful of approximately 5 grams. During a ritual session, between 15 and 35 grams per person may be consumed. For large-scale community rituals attended by more than 30 people, up to 5 pounds, or even an *arroba*, may be required. However, these figures are approximate: “Up to a quarter pound of coca could be used”¹⁰¹, said an interviewee. The amount also varies depending on the type of ritual and the number of participants. For family gatherings, some bring a pound; for community events, three or four pounds.

For uses other than *mambeo*, such as infusions, the dosage is lower. These preparations may require “2 to 3 grams of roasted coca”¹⁰² or up to 15 grams when using green leaves. The interviewees pointed out that prolonged use of the roasted leaf can cause discomfort in the jaw¹⁰³. One interviewee mentioned that it may have affected her teeth¹⁰⁴. But no serious adverse effects were reported.

3.6.3. Perceived Safety and Absence of Restrictions

When asked about unwanted effects, most interviewees agreed that coca leaf, when used traditionally, are harmless. There has never been a reported case of anyone or being harmed intoxicated by coca, “because, as I said, in terms of its use and handling, it is so widespread that today, in the education program being promoted throughout our territories, one of the fundamental principles is to reinforce that principle and revive the

100 Interview to Alfredo in Toribío Territory, April 28, 2025.

101 Interview to Sandra in Toribío Territory, April 30, 2025.

102 Interview to Julián in Toribío Territory, April 30, 2025.

103 Interview to Julián in Toribío Territory, April 30, 2025.

104 Interview to Margarita in Toribío Territory, April 30, 2025.

practice of coca chewing as part of the essence of being Nasa¹⁰⁵. This perception is based on experience gained over generations.

There are no formal restrictions on consumption. Anyone may consume the leaf, regardless of age, gender, medical condition, or health status. "There are no restrictions; coca is for everyone. There are no restrictions whatsoever. It is not allergenic. It is good for everyone. It does not distinguish between races or skin color. So, there are no restrictions on coca; anyone can consume it. No matter if you are diabetic, anyone can use it; anyone can practice *mambeo*"¹⁰⁶, said an interviewee. Not even pregnant women face restrictions: "Pregnant women consume the most because they need to cleanse themselves"¹⁰⁷. In fact, midwives recommend the use of coca during pregnancy as part of spiritual accompaniment and diagnosis.

In the case of children, there is evidence indicating use from a very early age. "In my day, when children attended rituals from the age of three or four, if they were skilled, they liked to chew coca leaf, and the older ones would also do somersaults and all that"¹⁰⁸. In the case of women, "if a woman is menstruating, she can consume and use coca"¹⁰⁹, but it is recommended to do so at home and not in cold places where it is usually practiced, to avoid menstrual pains.

As mentioned above, coca is chewed with *mambe*, but it is also used with other substances. The only situation in which caution is recommended is when the leaf is combined with tobacco or alcohol, as these can cause dizziness or vomiting in sensitive individuals. This is particularly true for tobacco, cigarettes and alcohol. Some "experts say that it causes dizziness because the coca is cleansing impurities; alternatively, it may occur because individuals who are accustomed to tobacco also experience dizziness"¹¹⁰.

Mambe and tobacco are common in rituals, and unwanted effects can oc-

105 Interview to Juan in Toribío Territory, May 01, 2025.

106 Interview to Enrique in Toribío Territory, April 28, 2025.

107 Interview to Alfredo in Toribío Territory, April 28, 2025.

108 Interview to Sandra in Toribío Territory, April 30, 2025.

109 Interview to Alfredo in Toribío Territory, April 28, 2025.

110 Interview to Sandra in Toribío Territory, April 30, 2025.

cur, “they can dry out your glands, all that, and at the very least you have to drink water and eat well”¹¹¹. In some rituals, excessive tobacco use has caused “vomiting due to an excess. We have seen that there are people who are very sensitive to tobacco and that if they try coca in that state, they start vomiting shortly afterwards”¹¹². Honey, brown sugar or sugar is sometimes added to green-leaf coca infusions as sweetener¹¹³.

4. Conclusions

The case study conducted in Toribío, Cauca, confirms that the traditional use of coca leaf by the Nasa people is deeply rooted in a worldview that integrates health, spirituality, nutrition, diagnosis, and care for the land. The Esh’s plant—as the coca plant is called in Nasa Yuwe—is not only considered sacred, but also an essential element for individual and collective life: “There is no Nasa people without coca”.

The findings documented in the San Francisco, Tacueyó, and Toribío territories reveal a complex system of practices associated with the cultivation, harvesting, roasting, storage, processing, and use of coca leaf, which meets specific quality and safety criteria. These practices, although not formalized in written sanitary regulations, are guided by intergenerational knowledge, cultural control mechanisms, and principles of reciprocity and respect for nature.

Coca leaves are mainly roasted and used in ritual, community, or medical settings, and under the guidance of elders, knowledgeable individuals, and midwives. Preparations include *mambe*, infusions, ointments, and food products, and their consumption is subject to community criteria regarding dosage, timing, and spiritual meaning. No cases of poisoning or adverse effects attributable to the traditional consumption of coca leaf were recorded during the fieldwork. On the contrary, the general perception among interviewees is that it is a safe, beneficial product suitable for all members of the community, including children and pregnant women.

111 Interview to Juan in Toribío Territory, May 01, 2025.

112 Interview to Julián in Toribío Territory, April 30, 2025.

113 Interview to Mauricio in San Francisco Territory, April 30, 2025.

This study suggests that, within the context of the Nasa people, there are culturally validated practices that substantiate the safety of the traditional use of the coca leaf as a product for human consumption. Recognizing this knowledge is not only a matter of public health and cultural rights but also an opportunity to advance intercultural and decolonizing approaches to the assessment of natural products with deep ancestral roots.

Chapter 3

Regulatory Framework for the Medicinal Uses of Coca Leaf in Colombia

The Indigenous Peoples of the Andes and the Amazon have used coca leaf since ancient times for ritual, therapeutic, nutritional, and cultural purposes. In the case of Colombia, its traditional use is deeply rooted in the identity of these communities and forms an integral part of their health-care systems.

This chapter presents a review of the Colombian regulatory framework related to the coca leaf, highlighting its dual legal status: as a controlled substance under the Single Convention on Narcotic Drugs, 1961, and as a protected cultural asset. The aim is to provide normative and contextual evidence to support a more balanced approach that respects human rights and is consistent with traditional practices and the public health needs of the peoples and communities that cultivate and use coca leaf.

The coca leaf has a twofold status in Colombian legislation. On the one hand, it is considered a raw material in the illicit processing of narcotics, which means that its cultivation, transformation into coca paste, and conversion into cocaine hydrochloride are subject to control measures and prohibition. On the other hand, the Colombian legal system recognizes the cultural value of the coca leaf, especially in relation to its traditional uses by Indigenous peoples and other rural communities.

This dual dimension has different implications for the Colombian State. In response to illicit use, it must apply the controls established in national and international drug legislation. At the same time, however, it has a duty to protect the coca leaf as an element of the intangible cultural heritage of various Indigenous Peoples, in accordance with Articles 7 and 70 of the Constitution, which enshrine ethnic and cultural diversity as foundational principles of the nation.

This two-pronged approach is key to implementing the National Drug Policy 2023–2033, *Sembrando vida, desterramos el narcotráfico* (Sowing Life to Eradicating Drug Trafficking)¹¹⁴. In particular, the strategic focus on “fair and responsible regulation” promotes research, development, and regulation of the non-psychoactive uses of the coca plant. The goal is to identify and promote legal applications—such as fertilizers, compost, food, textiles, medicines, among others—that contribute to disengaging rural families from the illicit circuit, strengthening legal economies based on ancestral knowledge and the cultural rights of communities (Ministerio de Justicia y del Derecho, 2023). At the same time, this policy promotes the recognition and protection of traditional knowledge associated with controlled plants, particularly those linked to the health and spiritual systems of ethnic peoples (Ministerio de Justicia y del Derecho, 2023).

In the national context, the traditional uses of the coca leaf can be grouped into four widely recognized categories: (i) ritual and spiritual use, (ii) therapeutic use in healthcare, (iii) food and nutritional use, and (iv) identity and cultural use.

Based on the findings of the systematic review and the case study in Toribío, Cauca, the coca leaf can be regarded as a central tool in the healthcare strategies of the Nasa people. Its use is linked to the personal, family, community, and territorial spheres and is integrated into their Life Plans¹¹⁴, the organizational systems of the traditional Indigenous authorities. This type of use reflects a lawful means of accessing coca leaf for medicinal purposes, supported by the powers of self-government recog-

114 These life plans were defined as actions guided by “the right of origin, the Law of Origin or higher law”, for the “investment of the relevant resources from the authorities required for the fulfillment of the assigned competencies, in accordance with the decisions of the Community Assembly or its equivalent, in order to achieve a good community life”, Article 14 of Decree 1953 of 2014.

nized in the Constitution for Indigenous Territories to manage their own education and healthcare systems (Articles 243, 286, 329, and 330), as well as by legal and regulatory developments in the area of legal pluralism and interculturality in public health (Articles 7 and 70).

However, this access is constrained by regulatory tensions arising from the mixed legal status of the coca leaf in national legislation. Although its traditional use is recognized by law, the current legal framework has yet to ensure effective coordination between the powers of Indigenous authorities and State institutions, thereby creating legal uncertainty and barriers to access even for lawful and culturally protected purposes.

In this context, advancing toward regulatory reform that harmonizes existing legal regimes and guarantees safe, legal, and culturally appropriate access to coca leaf and their byproducts is a priority. Such reform would not only benefit Indigenous Peoples but also other sectors of the population that seek integrated health alternatives and the development of natural products based on verified traditional practices. This chapter presents:

- a.** A summary of the constitutional and jurisprudential framework that supports the traditional uses of coca leaf in Colombia, as well as the principle of the primacy of human rights over the obligations derived from international drug control treaties.
- b.** The current regulatory framework governing the medicinal use of coca leaf and their byproducts within the SISPI. With special emphasis on the Nasa People's Life Plan, as the territorial context of the case study presented in this dossier.
- c.** A proposed legal pathway for the use of coca leaf for medicinal purposes outside Indigenous territories, allowing for expanded regulatory options for their safe and controlled use.

1. The Two-fold Status of Coca Leaf in Colombian Legislation

The coca leaf has a two-fold status under Colombian legislation. On the one hand, its classification as a controlled substance is consistent with the international commitments assumed by the Colombian State under the 1961, 1971, and 1988 Conventions on the Control of Narcotic Drugs. Resolution 315 of 2020, issued by the Ministry of Health and Social Protection, maintains the coca leaf as a controlled substance, allowing its use exclusively for medical, scientific, and, exceptionally, industrial purposes, provided that the requirements established by national legislation are met (Law 30 of 1986, Articles 20 and 33; Law 9 of 1979, Articles 461 and 462).

On the other hand, the Constitutional Court has recognized that the coca leaf, when used for traditional and cultural purposes, is an essential element of the identity of Indigenous Peoples and therefore cannot be subject to the same restrictions that apply to psychoactive substances such as cocaine. This distinction is based on article 7 of the Constitution, which recognizes and protects the ethnic and cultural diversity of the nation.

Whether coca leaf is subject to one legal regime or another depends on three factors: the origin of the raw material, the population that cultivates the plant, and the intended use of its byproducts. In practical terms, coca cultivation is considered a crime when it occurs without authorization from the competent authority, except when it is carried out within the framework of traditional uses by Indigenous communities, an exception expressly recognized by constitutional jurisprudence. This regulatory ambiguity has created significant obstacles to the development of lawful medicinal, scientific, food, and industrial uses of the coca leaf, which could benefit not only Indigenous communities but also other rural populations involved in illicit economies associated with drug trafficking.

The international control framework was adopted in Colombia through Law 13 of 1974, which ratified the 1961 Single Convention, and was subsequently expanded through Law 67 of 1993, which ratified the 1988 Convention. In this context, Colombia assumed the obligation to eliminate practices such as coca leaf chewing. However, the Constitutional Court

has held that these obligations must be harmonized with the fundamental rights recognized in the Constitution, as reaffirmed in Ruling C-176 of 1994¹¹⁵. Therefore, by ratifying the 1988 Convention, the Colombian State declared that the criminalization of coca leaf cultivation should be harmonized with alternative development policies, taking into account the rights of Indigenous Peoples and environmental protection.

1.1. Constitutional and Jurisprudential Recognition of Traditional Uses

From this perspective, coca leaf used for traditional purposes is considered an exception to the control regime. The Constitutional Court stated that “coca leaf and their lawful uses cannot be placed on the same level as their use as a raw material for the production of cocaine”¹¹⁶. This position has been consistently upheld in several rulings. In Ruling T-365 of 2020, the Court protected the rights to ethnic and cultural diversity and identity of an Indigenous person detained in a national prison, after he had been denied the possibility of consuming coca leaf inside the detention center. On that occasion, the Court held that the prison administration erred in classifying the coca leaf as a “narcotic, psychotropic, hallucinogenic substance or drug”¹¹⁷ that jeopardized prison security. This conclusion was based on the fact that, for the detainee, the coca leaf is a “sacred plant because of the many benefits it has provided for years”¹¹⁸, which does not pose any risk to detention center protocols.

In Ruling C-882 of 2011, the Court recognized that, beyond constitutional considerations, there is also a practical reason for distinguishing between coca leaf and cocaine. According to the ruling, coca leaf “could have alternative legal forms of trade that could help prevent the spread

115 Ruling that analyzed the constitutionality of Law 67 of 1993 approving the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

116 Constitutional Court of Colombia, Ruling C176 of 1994 (Reporting Justice, Alejandro Martínez Caballero), section 2.b).

117 Constitutional Court of Colombia, Ruling T-365 of 2020 (Reporting Justice, Cristina Pardo Schlesinger), section 3.1.

118 Constitutional Court of Colombia, Ruling T-365 of 2020 (Reporting Justice, Cristina Pardo Schlesinger), section 3.5.

of drug trafficking”¹¹⁹. The Court further acknowledged that the potential economic benefits of coca leaf extend beyond ethnic communities. Similar to the National Drug Policy, the ruling asserts that alternative uses of coca leaf—including food, medicinal, industrial, and agricultural purposes—represent an opportunity to replace illicit economies with licit markets. Such uses, although legitimate, do not necessarily correspond to the traditional practices of Indigenous Peoples, thereby broadening the scope of their potential regulation.

1.2. Protecting Coca Leaf as Cultural Heritage

In the second scenario, coca leaf cultivated by Indigenous Peoples for traditional uses is completely excluded from the effects of control measures, the constitutional prohibition set forth in Article 49, and the application of the Criminal Code. Furthermore, coca cultivated by Indigenous Peoples is recognized as a lawful source of raw materials for medicinal and scientific uses within Indigenous healthcare systems.

This interpretative framework was consolidated by the Constitutional Court in Ruling C-882 of 2011, which established that Article 49 of the Constitution—which prohibits the possession and use of psychoactive substances—is not applicable to the traditional uses of the coca leaf by Indigenous communities¹²⁰. The Court argued that this provision seeks to address public health concerns associated with drug use in the general population and cannot be invoked to restrict cultural practices that constitute legitimate expressions of ethnic identity. Consequently, the traditional use of the coca leaf cannot be considered harmful to public health or used to justify limitations on the fundamental rights of Indigenous Peoples as recognized in the Constitution¹²¹.

119 Constitutional Court of Colombia, Ruling C-176 of 1994 (Reporting Justice, Alejandro Martínez Caballero), section 2.b).

120 “Article 49. The possession and consumption of narcotic or psychotropic substances is prohibited, except when prescribed by a doctor. For preventive and rehabilitation purposes, the law shall establish administrative measures and treatments of an educational, prophylactic, or therapeutic nature for persons who consume such substances. Compliance with these measures and treatments shall require the informed consent of the addict.

121 Constitutional Court of Colombia, Ruling C-882 of 2011 (Reporting Justice, Jorge Ignacio Pretelt Chaljub), section 2.8.

Although not expressly mentioned in the Constitution, the coca leaf is protected by principles such as cultural identity, interculturalism, ethnic diversity, and the protection of cultural heritage¹²². In Ruling C-882 of 2011, the Constitutional Court specified that both the cultivation of the plant and its traditional uses constitute manifestations of the fundamental right to the ethnic and cultural identity of Indigenous Peoples.

In the words of the Court, this right encompasses the protection of “intangible manifestations, products, and representations of culture”¹²³, including languages, “traditions, ancestral knowledge, cultural landscapes, customs, and habits, as well as the tangible and intangible assets attributed to them”¹²⁴. Within this framework, the Colombian State recognizes that Indigenous Peoples have the right to “use and produce their traditional medicines and conserve their medicinal plants, animals, and minerals”, as well as to “preserve and develop their traditional modes of production and economic forms and demand protection of their intellectual property related to works, cultural creations, and other matters”¹²⁵. All these attributes are fully applicable to the coca leaf as a plant with profound symbolic, therapeutic, and productive value within the life systems of Indigenous Peoples.

1.3. Limitations to Regulatory Recognition in Non-Indigenous Contexts

The Constitutional Court examined two landmark cases in which national authorities made decisions related to the coca leaf that sparked debate regarding the protection of the plant and its uses, as well as the barriers to or guarantees for its economic exploitation.

The first case, examined by the Constitutional Court in Ruling T-477 of 2012, arose from the commercial registration of two trademarks that

122 Articles 7 and 70 of the Constitution

123 Constitutional Court of Colombia, Ruling C-882 of 2011 (Reporting Justice, Jorge Ignacio Pretelt Chaljub), section 2.5.1.2.

124 Constitutional Court of Colombia, Ruling C-882 of 2011 (Reporting Justice, Jorge Ignacio Pretelt Chaljub), section 2.5.1.2.

125 Constitutional Court of Colombia, Ruling C-882 of 2011 (Reporting Justice, Jorge Ignacio Pretelt Chaljub), section 2.5.1.9.

included the terms “Indigenous” and “coca”, requested by a person who was not a member of any Indigenous People, with the aim of marketing artisanal products made from coca leaf¹²⁶. The applicant did not have authorization from any traditional authority; therefore, the Court concluded that the registration decision issued by the Superintendence of Industry and Commerce disregarded the unique cultural relationship between Indigenous Peoples and the plant.

In its ruling, the Court held that the use of the coca leaf by Indigenous Peoples stems from a millennial relationship in which they learned about “its benefits, which are currently enjoyed not only by these communities but by all of humanity”¹²⁷. The Court further noted that they embraced the plant “as part of their cultural identity, which is manifested in their relationship with the land and in social and religious aspects”¹²⁸. Consequently, the Court ruled that trademark registrations that “use traditional Indigenous knowledge, manifested, for example, in symbolism, myths, clothing, or songs, in the marketing of products related to the coca leaf by persons outside that social group” are unacceptable¹²⁹.

Furthermore, the Court considered that the fact that a person outside Indigenous communities markets a product as “Indigenous” constitutes “deception of individuals”. Consequently, it suspended the resolution and ordered the Superintendence of Industry and Commerce to refrain from registering trademarks that use the term “Indigenous” without prior consultation. This case demonstrated that the protection of the coca leaf as an expression of the right to cultural identity must also be guaranteed in the areas of trademark law and intellectual property.

The second relevant case was resolved by the Constitutional Court in Ruling T-357 of 2018, in response to a writ of protection (tutela) filed against the Bogotá Health Secretariat by representatives of the Indigenous com-

126 Constitutional Court of Colombia, Ruling T-477 of 2012 (Reporting Justice, Adriana María Guillén Arango), section 13.1.

127 Constitutional Court of Colombia, Ruling T-477 of 2012 (Reporting Justice, Adriana María Guillén Arango), section 12.3.

128 Constitutional Court of Colombia, Ruling T-477 of 2012 (Reporting Justice, Adriana María Guillén Arango), section 12.3.

129 Constitutional Court of Colombia, Ruling T-477 of 2012 (Reporting Justice, Adriana María Guillén Arango), section 13.5. 13.5.

pany Coca Nasa (2), which markets products derived from the coca leaf¹³⁰. Coca Nasa had submitted a request for the Health Secretariat to issue a circular instructing health inspection officials to recognize the validity of health permits and registrations issued by Indigenous authorities—in this case, an association of territories in the department of Cauca—that had authorized these products.

Although the Court reiterated that the coca leaf is an expression of the cultural identity of Indigenous communities, it denied the appeal. The Court held that the manufacture and distribution of products derived from the coca leaf are exempt from compliance with national health regulations only when they are marketed exclusively within Indigenous territories¹³¹.

Ruling T-357 of 2018 held that the resolutions granting permits and health registrations for Coca Nasa products established that coca leaf byproducts should be marketed “in compliance with legal restrictions”¹³². These include the exclusive authority of the Food and Drug Surveillance Institute (Invima) to issue health registrations (marketing permits) nationwide.

This ruling echoes the provisions of Ruling T-477 of 2012: although coca leaf are not formally prohibited, their commercial use outside territories must comply with existing regulatory frameworks¹³³.

1.4. Towards a Human Rights-based Interpretation

Following Ruling T-357 of 2018, the Colombian State has faced tensions between its international obligations regarding drug control and its cons-

130 Resolution No. 001 dated June 29, 2002, published in Official Gazette No. 45.029 authorized the Calderas Territory to use coca leaf grown in indigenous territories to produce infusions. Resolution No. 001 dated March 1, 2005, published in Official Gazette No. 45.854 authorized the Calderas Territory a Special Sanitary Registry to manufacture food and cosmetic products from coca leaf, such as hydrating beverages, baked goods, concoctions of coca leaf with dried fruits and other plants, wine-type alcoholic aperitifs, toothpaste, and bath soap.

131 Constitutional Court of Colombia, Ruling T-357 of 2018 (Reporting Justice, Cristina Pardo Schlesinger), section 10.1.

132 Constitutional Court of Colombia, Ruling T-357 of 2018 (Reporting Justice, Cristina Pardo Schlesinger), section 10.2.1.

133 Constitutional Court of Colombia, Ruling T-357 of 2018 (Reporting Justice, Cristina Pardo Schlesinger), section 6.3.

titutional duty to protect fundamental rights, particularly the cultural rights of Indigenous Peoples and rural communities. Because international obligations on drugs are incorporated into domestic law through ordinary legislation, while fundamental rights have constitutional status, any regulatory conflict must be resolved in favor of the latter.

The strategies implemented under the Single Convention on Narcotic Drugs—particularly those related to eliminating coca leaf chewing, controlling it as a Schedule I substance, and the provisions of Articles 26 and 27—could conflict with the provisions the Constitutional Court has used to define the protection of the coca leaf. A viable solution to this regulatory tension is to frame the regulation of coca leaf from a human rights-based approach, which allows for the interpretation of control obligations in light of international law and so-called “soft law”. This approach would enable the establishment of a regulated market for non-controlled coca leaf products, recognizing both the traditional uses of Indigenous Peoples and alternative uses in rural and community settings.

The International Guidelines on Human Rights and Drug Policy, adopted by multiple United Nations agencies and considered soft law instruments, require States to ensure that their drug control obligations do not violate fundamental rights (ONUSIDA et al., 2019). In other words, the guidelines allow the Colombian State to apply the protection of human rights to the legal and political context of drug control, including the interpretation and application of drug conventions.

Table No. 9 presents the guidelines outlining the obligations, powers, and recommendations for the Colombian State regarding the coca leaf and its traditional uses by Indigenous or peasant communities. According to several guidelines, the religious, medicinal, and traditional uses of the coca leaf, as well as those of other controlled plants or substances, should also be guaranteed beyond Indigenous communities.

Table No. 9. Recommendations and powers of States relating to the coca leaf and its traditional uses by indigenous or peasant communities.

HUMAN RIGHT	STATES SHOULD... (RECOMMENDATIONS)	STATES CAN... (POWERS)
Right to benefit from scientific progress and its applications	Consider reviewing the 1961 and 1971 drug control conventions' schedules of substances under international control in light of recent scientific evidence, and prioritize exploring the medical benefits of controlled substances in accordance with the World Health Organization's scheduling recommendations.	None mentioned.
Freedom of thought, conscience, and religion	Consider exemptions within drug legislation allowing the cultivation and use of controlled substances for religious purposes, including in rituals and ceremonies.	Utilize the available flexibilities in the UN drug control conventions to decriminalize the possession, purchase, or cultivation of controlled substances for personal consumption.
Right to enjoy cultural life	Refrain from discriminatory and otherwise unnecessary or disproportionate interference with the exercise of cultural practices and with access to cultural goods and services on grounds of drug control law and policy.	None mentioned.
	Take necessary measures to ensure the preconditions for participation in, facilitation of, and promotion of cultural life without discrimination, including access to and preservation of cultural goods where these involve controlled plants and substances.	None mentioned.
	Foster a rich and diverse cultural life through the conservation, development, and diffusion of culture and by ensuring the participation of relevant communities in the governance of cultural heritage, including where these involve controlled plants and substances.	None mentioned.

Rights derived from obligations with Indigenous Peoples - Right to enjoy culture and to profess and practice religion	Refrain from interfering with Indigenous Peoples' exercise of their cultural, spiritual, and religious practices, including those involving plants that have psychoactive effects.	None mentioned.
	Adopt appropriate legislative, administrative, and other measures to ensure that drug control efforts do not interfere with Indigenous Peoples' rights to enjoy their culture and to practice their religion, including with members separated by international borders.	None mentioned.
	Take measures to protect indigenous communities from actions by private companies and third parties that deny indigenous people their traditional sources of nutrition, medicines, livelihoods, and ceremonies, including those involving plants that have psychoactive effects.	None mentioned.
	Consider exemptions within drug legislation allowing indigenous peoples to use controlled psychoactive substances for traditional, cultural, and religious purposes.	None mentioned.
Rights derived from obligations with Indigenous Peoples - Right to traditional medicines and health practices	Refrain from depriving indigenous peoples of the right to cultivate and use psychoactive plants that are essential to the overall health and well-being of their communities.	Utilize the available flexibilities in the UN drug control conventions to decriminalize indigenous peoples' possession, purchase, or cultivation of controlled psychoactive substances for personal consumption.
	Repeal, amend, or discontinue laws, policies, and practices that inhibit indigenous peoples' access to controlled psychoactive substances for the purposes of maintaining or increasing the overall health and well-being of their communities, and consider adopting appropriate legislative, administrative, and other measures to guarantee the exercise of the right to traditional medicines and health practices.	Consider taking specific measures to protect the right of indigenous peoples to use psychoactive substances for specially defined purposes, including those related to their right to health.

Source: Prepared by the authors based on (ONUSIDA et al., 2019).

Based on the guidelines, the Colombian State should focus on exploring the medicinal uses of substances such as the coca leaf, while maintaining it on Schedule I of substances under special control and oversight, in accordance with the recommendations outlined in this critical review conducted by the WHO Expert Committee on Drug Dependence and its subse-

quent vote in the Commission on Narcotic Drugs. Even in developing the right to freedom of thought, conscience, and religion, Colombia should “consider exemptions within drug legislation allowing the cultivation and use of controlled substances for religious purposes, including in rituals and ceremonies” (ONUSIDA et al., 2019) Beyond promoting industrial or alternative uses, the critical review process contributes to the adjustment of Colombian regulations on access to coca leaf for medicinal and traditional purposes, as well as to the harmonization of the plant’s dual status.

2. Coca Leaf Within the Indigenous Peoples Healthcare System

The status of the coca leaf as a central element of the cultural identity of Indigenous Peoples links it directly to their healthcare systems, in particular the SISPI. This section presents the legal and operational framework governing SISPI and explains how the coca leaf is integrated into the medical, ritual, and organizational practices of Indigenous Peoples, with a focus on the case of the CRIC.

Currently, the SISPI with the most developed regulations covers the Indigenous Peoples affiliated with the CRIC. However, Decree 480 of 2025 elevated this model to State policy, extending it to 15 other Indigenous Peoples in the country. The decree recognizes ancestral healthcare practices, including the use of medicinal plants, traditional medicine, and harmonization rituals, as well as, although not always explicitly, activities such as the cultivation, roasting, and chewing of coca leaf. Notably, the SISPI regulatory framework recognizes customary law as a legitimate legal basis, meaning that many of its practices are governed by customs and traditions rather than written rules.

The Colombian Constitution recognizes legal pluralism and grants jurisdictional, administrative, and fiscal powers to Indigenous authorities. Several provisions recognize Indigenous territories as territorial entities¹³⁴,

134 Article 286.

and as the “collective and inalienable property”¹³⁵ of the territories with autonomy to govern themselves according to their own rules, exercise their justice systems, and manage resources¹³⁶. Article 330 enables Indigenous councils to design economic and social policies, monitor land use, and redistribute resources, which is key to exercising health sovereignty within the framework of SISPI.

Decree 1088 of 1993¹³⁷ Decree 1088 of 1993 regulated the creation of associations of Indigenous cabildos and traditional authorities, enabling them to manage health projects, administer public resources, and develop economic, industrial, or commercial activities¹³⁸. Subsequently, Law 691 of 2001 integrated Indigenous Peoples into the Sistema General de Seguridad Social en Salud¹³⁹ (SGSSS, in Spanish) under the subsidized regime, recognizing the need to include an ethnic and cultural approach to healthcare¹⁴⁰. The administration of resources allocated to finance services was channeled through the “Indigenous Health Administrators” as an authority body to guide services. This form of participation by ethnic groups in the healthcare system was widely opposed by Indigenous organizations (Urrego-Rodríguez, 2020), leading to demands for a healthcare model of their own, outside the logic of the general healthcare system.

This led to Decree 1953 of 2014, which established a special system for managing Indigenous Peoples’ education and healthcare systems. The decree reinforced principles such as self-determination, cultural identity, ethnic diversity, and the intercultural interpretation of rules¹⁴¹. Within this framework, SISPI is structured into five components: (i) ancestral wis-

135 Article 329.

136 Article 287.

137 Decrees 1088 of 1993 and 1953 of 2014 are regulations with the force of law by virtue of transitional article 56 of the Constitution, which establishes the national government’s power to “issue the necessary fiscal and other regulations relating to the functioning of indigenous territories and their coordination with other territorial entities” while the organic law on territorial organization of Article 329 of the Constitution is enacted. Decree 488 of 2025 was recently issued, updating “the necessary fiscal and other regulations relating to the functioning of indigenous territories and their coordination with other territorial entities”.

138 Article 3 of Decree 1088 of 1993.

139 General Social Security System for Healthcare.

140 Article 21 of Law 691 of 2001.

141 Article 10.

dom; (ii) political and community organization; (iii) training and knowledge generation; (iv) Indigenous and intercultural healthcare; and (v) administration and management.

Its main objective is to guarantee “comprehensive healthcare through Indigenous Peoples’ traditional medicine and that provided by the [SGSSS], including alternative medicines within the latter, in a dynamic of dialogue and mutual respect¹⁴². The SISPI embraces the concept of health as harmony and balance, in accordance with the worldview of Indigenous Peoples, resulting from “the relationships of the individual with themselves, their family, the community, and the territory”¹⁴³. The SISPI can be said to involve mechanisms for “disease prevention rather than care once the disease is already present” (Montero, 2023) In other words, SISPI is a preventive model based “on the ancestral wisdom of the peoples, medicinal and power plants, spirituality, and the ancient knowledge that inhabits the territories” (Montero, 2023).

To allocate resources to healthcare and education, the authorities must draw up life plans based on each community’s vision, needs, and organizational projections¹⁴⁴. The Decree proposes a roadmap for activating the exercise of Indigenous territorial entities’ powers in health and education. First, they must design the life plan; then comply with the special regulations of the health sector together with the Ministry of Finance to enable the receipt of resources from the General National Budget; and finally, design and create the local and regional infrastructure necessary for the provision of services.

Decree 968 of 2024 established specific SISPI standards for the Indigenous territory that comprises the CRIC, reinforcing its general approach, which focuses on “guaranteeing comprehensive care for the individual, the family, nature, and the territory, in accordance with the different stages of the life cycle, based on their ancestral knowledge and practices in health and interculturality”¹⁴⁵.

Although the coca leaf is not explicitly mentioned, its place within the

142 Article 75.

143 Article 76.

144 Article 16.

145 Article 5.

system is clearly inferred from definitions of ancestral medicine, rituality, traditional wisdom, and areas of care. As shown in the case study in Toribío, Cauca, the coca leaf is a sacred plant that plays a role in many stages of the therapeutic process, from cultivation in the *Nasa Tul* to its use in spiritual consultations, harmonization work, major rituals, and family self-care practices.

SISPI recognizes both healthcare professionals and traditional healers, elders, midwives, and *sobanderos* as actors in the system. They can serve as formal or informal caregivers, depending on their involvement in healthcare programs. Within this framework, access to roasted coca leaves—whether through exchange, cultivation, or local sale—is guaranteed as part of the therapeutic and spiritual offering. Article 39 of Decree 968 establishes that healthcare providers may include both ancestral healers and other recognized actors in the system, thus expanding the legitimate forms of care.

In addition, the SISPI conceives intercultural primary healthcare (APSI) as a network strategy that extends beyond hospital settings to include traveling schools, councils of elders, and other community structures. This approach allows practices such as coca chewing to be integrated into prevention, diagnosis, and spiritual strengthening within a holistic healthcare model.

Based on SISPI and the guidelines of the life plans, links exist between formal actors—who are contractually bound or involved in programs financed with healthcare resources—and informal actors—who participate in the management of the system because of their age or their role in family care—through which customs and traditions surrounding the coca leaf can be traced. These include its cultivation, which is promoted in *Nasa Tul* (Proyecto Nasa, 2017); its application in cultural practices throughout the life cycle (Proyecto Nasa, 2017); and its ancestral medicine (Proyecto Nasa, 2017).

Although there is no specific national regulation governing the traditional use of coca leaf within SISPI, a robust legal framework recognizes the validity of these uses and customs and supports their inclusion as an essential part of the Indigenous healthcare system. As outlined in the case study in Toribío, Cauca, the cultivation of the leaf for traditional use is an

integral part of the Nasa healthcare model. From its integration into the family garden (*Nasa Tul*) to its transformation into roasted leaf and its ritual use, the plant circulates legally within the territory and is employed for therapeutic and spiritual purposes.

This right guarantees the availability of roasted coca leaves—through exchange or sale—and provides guidelines for therapeutic uses, which are more or less aligned with the “Western” actors of SISPI. In conclusion, Colombia has a legal market for coca leaf for traditional use that operates within Indigenous communities and their healthcare systems, as evidenced in the case of the Nasa people. Coca leaf and her chewing are not only culturally protected practices but also legally recognized uses from a health perspective.

3. Legal pathway for the coca leaf for medicinal purposes outside the indigenous territories

Today, the rules that allow the use of coca leaf and their byproducts for traditional and medicinal purposes apply only to Indigenous territories, as affirmed by the Constitutional Court in Ruling T-357 of 2018. The cultivation, processing, and commercialization of coca leaf outside these territories exist in a regulatory gray area, creating barriers to the granting of authorizations, manufacturing licenses, and sanitary registrations for coca leaf-based products. In other words, coca leaf is classified as a controlled substance outside Indigenous Territories.

However, Colombian law provides a regulatory pathway that has yet to be fully explored to enable the medicinal use of coca leaf outside Indigenous Territories. In particular, Decree 1156 of 2018 establishes the sanitary registration regime for phytotherapeutic products, which includes medicinal plants containing “metabolites or active ingredients classified as narcotics, psychotropic substances, or controlled substances”¹⁴⁶, such as coca leaf¹⁴⁷.

146 Article 15.

147 Article 5 of the Decree establishes three categories of pharmaceutical preparations. The

In order to authorize coca-based products under the HMP and PFT categories, coca leaf must be included in the list of medicinal plants accepted for therapeutic purposes, and the corresponding registration must be requested. The list of plants is compiled by Invima¹⁴⁸ on the “Colombian Vademecum of Medicinal Plants” and incorporates the monographs of the World Health Organization and the European Medicines Agency (EMA)¹⁴⁹. Currently, the coca leaf is not included in the list (Invima, 2016) or in the Vademecum (Ministerio de la Protección Social, 2008), which prevents its registration as a phytotherapeutic product.

However, the regulatory framework allows for the submission of a formal application to Invima for inclusion, accompanied by documentation supporting the efficacy, safety, indications, traditional uses, and contraindications of the coca leaf-based product. Such applications must comply with the guidelines established by the WHO in its General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine.

The criteria required for a plant to be included in the list of therapeutic uses include:

- a.** Subacute and chronic toxicity studies (in the case of products for systemic use).
- b.** Evidence of efficacy (clinical and/or pharmacological).
- c.** Exhaustive literature review.
- d.** Other relevant evaluation elements according to international guidelines¹⁵⁰.

first refers to herbal medicinal products (HMP), the second refers to traditional phytotherapeutic products (TPP) manufactured in the country (PFT) or imported into the country (IPFT).

148 According to Article 245 of Law 100 of 1993, Invima is “the national reference institution in health matters responsible for implementing the policies formulated by the Ministry of Health and Social Protection in the area of health surveillance and quality control of medicines, biological products, food, beverages, cosmetics, medical devices and elements –surgical, dental, natural homeopathic products and those generated by biotechnology, diagnostic reagents, and others that may have an impact on individual and collective health, and, therefore, is the entity responsible for issuing marketing authorizations for products for human consumption such as medicines”.

149 Article 5.

150 Article 7

Once coca leaf is included in the list, byproducts must meet specific requirements to obtain health registration, including:

- Not being presented in injectable pharmaceutical forms.
- Not requiring sterile conditions, except in the case of ophthalmic preparations.
- Not being combined with chemically defined active substances.

Additionally, given that these medications contain controlled substances, they must be registered with the Fondo Nacional de Narcóticos¹⁵¹, the competent authority for authorizing the medical, scientific, or industrial use of controlled substances.

To date, there are no sanitary registrations in Colombia for medicinal products containing coca leaf or any of its natural alkaloids. However, the critical review process currently led by the WHO Expert Committee on Drug Dependence—and its subsequent consideration by the Commission on Narcotic Drugs—could significantly contribute to paving the regulatory pathway for its inclusion as a recognized medicinal plant, thereby facilitating safe, legal, and controlled access to coca leaf-based products outside Indigenous territories.

4. Conclusion

The coca leaf plays a complex and strategic role in Colombia's regulatory framework. Its dual status—as a controlled substance and as protected cultural heritage—reflects the historical tensions between international drug control commitments and the constitutional rights of Indigenous Peoples. Although the national legal system has expressly recognized the legitimacy and legality of traditional uses of coca leaf within Indigenous healthcare systems, limitations remain on their regulated development outside Indigenous territories, particularly in phytotherapy and food applications.

151 National Narcotics Fund.

Constitutional and jurisprudential analysis shows that the protection of the coca leaf is not limited to its cultural value but also extends to its health and economic potential under conditions of safety and control. This protection has been reinforced by multiple Constitutional Court rulings defending both the right to cultural identity and access to traditional healthcare practices.

However, as evidenced in the cases reviewed and within the current regulatory framework, gaps and gray areas persist that hinder the authorization of coca leaf-derived products in non-Indigenous contexts. This situation not only restricts the development of legal markets based on traditional practices but also limits the expansion of safe access to coca leaf for medicinal, wellness, and comprehensive care purposes.

In this context, the critical review process currently led by the WHO Expert Committee on Drug Dependence represents a key opportunity to advance toward a more balanced and evidence-based regulatory model. The inclusion of the coca leaf in official lists of medicinal plants—such as those recognized by the WHO and Invima—would enable new legal pathways under established quality, safety, and efficacy criteria.

In addition, the International Guidelines on Human Rights and Drug Policy provide a valuable interpretive framework for harmonizing control obligations with the guarantee of fundamental rights. In particular, these guidelines recognize the right of Indigenous Peoples and other rural communities to cultivate and use controlled substances for traditional, medicinal, and spiritual purposes, provided that such use does not pose proven health risks.

As a final observation, Colombia has a solid constitutional and regulatory framework that can serve as a basis for advancing toward a differentiated, rights-based regulation that guarantees fundamental rights. The recognition of the coca leaf as a medicinal plant in the international context—complemented by a clear and coherent national framework—would help consolidate a public policy oriented toward intercultural health, productive inclusion, and territorial sustainability.

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