REGULATORY IMPACTS

Traditional foods

Implications of the EU novel food authorisation process for countries accessing the EU market

July 2026

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List of abbreviations

Agrocalidad	Agencia de Regulación y Control Fito y Zoosanitario
ANDI	Asociación Nacional de Empresarios de Colombia
CBI	Centre for the Promotion of Imports, the Netherlands
CISAA	Centro de Innovación y Soluciones Agrícolas y Ambientales, Ecuador
CONCYTEC	Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica, Peru
EFSA	European Food Safety Authority
EMBRAPA	Empresa Brasileira de Pesquisa Agropecuária
EU	European Union
FCDO	Foreign, Commonwealth and Development Office, UK
FSVO	Federal Food Safety and Veterinary Office, Switzerland
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GPSA	General Pre-Submission Advice
IIAP	Instituto de Investigaciones de la Amazonía Peruana
INABIO	Instituto Nacional de Biodiversidad, Ecuador
INACAL	Instituto Nacional de Calidad, Peru
INIA	Instituto Nacional de Innovación Agraria, Peru
ITC	International Trade Centre
MADR	Ministry of Agriculture and Rural Development, Colombia
MAPA	Ministry of Agriculture and Livestock, Brazil
MINCETUR	Ministry of Foreign Trade and Tourism, Peru
MinCIT	Ministry of Commerce, Industry and Tourism, Colombia
P4F	Partnerships for Forests
PromPerú	Promoción del Perú para la Exportación y el Turismo
SECO	Swiss State Secretariat for Economic Affairs
SINCHI	Instituto Amazónico de Investigaciones Científicas, Colombia
SMEs	small and medium-sized enterprises
TEFOS	Territorios Forestales Sostenibles, Colombia
UMSA	Universidad Mayor de San Andrés
USAID	United States Agency for International Development

Summary

Foods produced in the Amazon and related forest regions have the potential to support sustainable rural development, biodiversity-based livelihoods, and forest conservation. If such foods were not on the European Union (EU) market before 15 May 1997, they are considered under EU law to be “novel foods” (Regulation 2015/2283 on novel foods). All novel foods have to undergo an authorisation procedure before being placed on the EU market to ensure the safety of consumers in the EU. The EU legislation considers foods that can be demonstrated to have been used in customary diets outside the EU for at least 25 years to be “traditional foods”, which are subject to a simplified authorisation procedure.

This creates a potential pathway for introducing EU consumers to products from the Amazon region. However, only a limited number of traditional foods have so far completed authorisation.

This study explores the potential opportunities and challenges for communities seeking EU authorisation of traditional products. For clarity, this study refers primarily to “traditional foods” – the subset of novel foods that are the focus of this research – rather than the broader category of “novel foods”, unless referring to the text of the Regulation.

It examines five cases: kañiwa from Bolivia, roasted baru seeds from Brazil, cacay flour from Colombia, dried guayusa leaf from Ecuador, and sacha inchi from Peru. These cases illustrate how access to the EU market can become a driver of sustainable development by generating stable demand, more predictable incomes, and stronger economic resilience for producers, with particular benefits for indigenous communities and women. Careful development of these value chains can help combat deforestation by creating profitable, environmentally sustainable alternatives to destructive land-use practices – but unlocking these potential benefits can be difficult. The current EU traditional foods authorisation process creates significant scientific, administrative, and financial challenges for those seeking authorisation of traditional foods. Recurring challenges identified in this study include the following.

- *Documenting 25 years of safe use*: oral transmission of traditional knowledge complicates the process of meeting this authorisation requirement, often requiring specific ethnobotanical studies or field surveys.
- *Limited access to accredited laboratories*: a lack of accredited national/regional laboratories that can perform studies according to EU requirements necessitates the use of European or US laboratories, significantly increasing costs and extending project timelines.
- *Language requirements:* although Spanish and Portuguese are official EU languages, novel food applications must be submitted in English, forcing applicants to engage external consultants at additional costs.
- *Complex dossier preparation*: the complexity of the EU traditional food authorisation process, including the volume of documentation and scientific evidence required for a successful submission, was frequently underestimated during the early stages of the application process.
- *High consultancy and testing costs*: the available information suggests that dossier preparation can cost between €111,000 and €190,000, not including substantial in-kind contributions such as staff time, coordination, and technical inputs. These costs are often beyond the capacity of individual small and medium-sized enterprises (SMEs), cooperatives, or producer organisations in the Amazon region.
- *Uncertainty about market potential prior to authorisation*: the decision to initiate a traditional food application requires substantial upfront investment. Clarity on future demand, pricing, or commercial viability is needed to justify these investments. However, opportunities to conduct consumer testing, pilot sales, or small-scale imports are limited prior to authorisation.

This study's findings suggest a structural gap between the demands associated with the EU approval process and the capacities of the majority of applicants from producer regions. The case studies identified several areas where action can significantly enhance the potential for actors to secure traditional food authorisations.

- *More practical and accessible guidance:* applicants would benefit from access to more detailed information that translates existing guidance from the European Food Safety Authority (EFSA) into practical guides. This includes clear explanations of the overall process, expected evidence, timelines, and cost implications in relevant languages (e.g. Spanish and Portuguese for the countries in this study).
- *Access to experienced experts and practical examples*: expertise is crucial to successful traditional food authorisations. Access to examples or annotated summaries of successful applications would help reduce uncertainty and improve efficiency in dossier preparation.
- *Improved analytical infrastructure*: access to accredited laboratories remains a key cost and source of delays. Strengthening regional laboratory capacity, including support for internationally recognised laboratory accreditation, could help reduce reliance on overseas laboratories. Support to access regulatory, scientific, and legal expertise would also be very beneficial.
- *Stronger institutional coordination*: collaboration is crucial to preparing successful applications. Clear national mechanisms that align ministries, research institutions, laboratories, and producer organisations facilitate the organisation of inputs, interpretation of regulatory requirements, and engagement with EFSA throughout the application process.
- *Regional knowledge sharing*: many traditional products span borders. Improved regional collaboration can reduce duplication through shared approaches to data generation, documentation of traditional uses, and laboratory methodologies.
- *Conditions for testing and pre-market validation of traditional foods*: given the considerable investment required in traditional food applications, applicants need reliable ways to assess market potential before committing to a dossier. Controlled environments for testing traditional foods, for example applying the European Commission's proposed "regulatory sandbox" approach, could substantially reduce risk and stimulate more efficient use of limited resources.
- *Targeted technical and financial support*: the resources and expertise required to support traditional food authorisations typically exceed the capacity of SMEs and producer organisations in the countries surveyed. Targeted support mechanisms could facilitate use of the traditional food authorisation process and support the EU's biodiversity and development goals.

1. Introduction

1.1. Context

This study focuses on the export of traditional foods classified as novel within the European Union (EU) regulatory framework. Under the EU's Novel Food Regulation (2015/2283), foods originating from non-EU countries that were not placed on the EU market before May 1997 require prior authorisation before being marketed in the European Union.

While this Regulation introduced a simplified procedure for such products, market access continues to pose challenges, particularly for low- and middle-income countries.[1] The European Food Safety Authority (EFSA) has developed guidance specifying the scientific requirements for applications.[2] Nevertheless, between 2018 and 2025, only 11 traditional foods from non-EU countries were authorised (Figure 1).

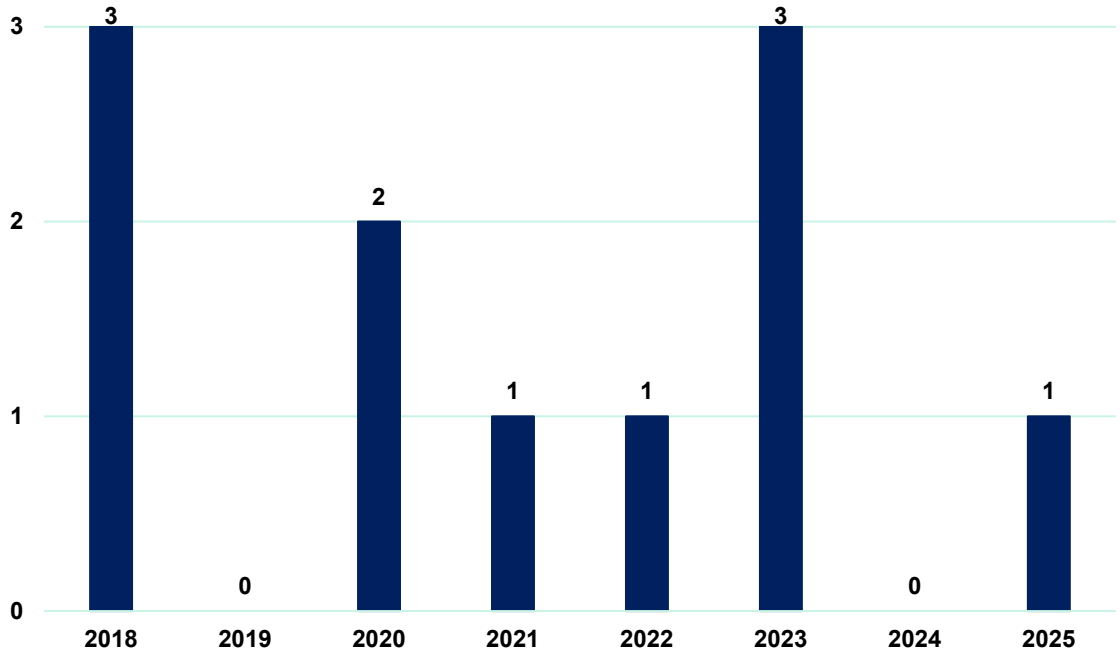


Figure 1. Traditional foods receiving EU approval per year

A region in which there is particular interest in developing exports of traditional foods is the Amazon, where traditional fruits and nuts are seen as contributing to the economic viability and sustainability of the forest. For example, the Amazon is reported to contain over 1,000 different types of edible fruits, many of which grow naturally and in large quantities.[3] The role trade in forest products can play in ensuring sustainability has recently been reaffirmed in the EU and Mercosur Agreement. Both Parties to the agreement "reaffirm(ed) their commitment to encourage trade in products from sustainably managed forests", and noted the

1 WTO (2017) Specific trade concern ID 238. G/SPS/R/86. World Trade Organization.
2 EFSA (2024) Guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283. *EFSA Journal*, 22(9): e8966.
3 Clement, C.R., Pereira, H. dos S., Vieira, I.C.G., and Homma, A.K.O. (2024) Challenges for a Brazilian Amazonian bioeconomy based on forest foods. *Trees, Forests and People*, 16: 100583.

importance of "strengthening the conservation, restoration, sustainable use and management of all types of ecosystems and enhancing the social, economic and environmental benefits of biodiversity for people, especially those in vulnerable situations and those most dependent on biodiversity, including through sustainable biodiversity-based activities, products and services that enhance biodiversity".[4] Although Brazil is the country with the largest share of the Amazon rainforest, interest in utilising the potential of forest foods economically extends to the wider Amazon region, Bolivia, Colombia, Ecuador, and Peru.

While the primary focus of this study is on the Amazon region, one case from the Brazilian Cerrado is also included. This reflects the limited number of successful cases of traditional foods securing approval, and allows the study to draw on relevant experiences. Although the Cerrado is a distinct biome, the challenges and approaches identified are similar.

1.2. Objectives

This impact study aims to provide a better understanding of the potential challenges and support required to facilitate the authorisation of traditional foods from the Amazon region under Regulation 2015/2283.

This study investigates:

- attributes of the application procedure that are poorly known or understood by applicants, where further information and clarification are needed
- scientific and administrative requirements that may create barriers to the completion of traditional food authorisation applications
- detailed costs associated with completing the scientific and administrative requirements for traditional food applications, where possible, putting these costs in a broader economic perspective
- strategies adopted or approaches taken by applicants to manage challenges encountered
- existence of technical, financial, or administrative support services currently available to help the development of traditional food applications
- potential needs for additional support (information, expertise, analytical, administrative) identified by key informants that could help in the development of traditional food applications.

1.3. Methodology

The study applied a qualitative, multi-source approach combining (i) a desk-based review of regulatory, scientific, and contextual documentation; and (ii) semi-structured stakeholder interviews across five Amazon-region countries (Bolivia, Brazil, Colombia, Ecuador, and Peru).

Desk research

The desk research consisted of three parallel components.

- Document check: collection and analysis of relevant background materials, including publicly available guidance, contextual information on value chains and support initiatives, and documentation of previous experiences with traditional foods dossiers.
- Regulatory mapping: review of the EU regulatory documentation for traditional foods under Regulation 2015/2283, including relevant guidance documents, EFSA technical reports on traditional foods notifications, and scientific studies.
- Analytical framework: development of a synthesis framework used to structure the case studies and analysis, covering procedural/administrative hurdles, scientific/technical evidence requirements, costs and resource constraints, and available support services and gaps.

4 EU–Mercosur Partnership Agreement (2026), 35, 38.

Stakeholder interviews

Stakeholders were selected purposively to represent key actors involved in the preparation of traditional food dossiers in the five countries, including applicants, competent authorities, laboratories, technical assistance programmes, industry associations and regulatory advisors.

In total, 20 interviews were conducted resulting in five countries case studies (Table 1). The interviews captured perspectives from both applicants and organisations supporting dossier preparation.

Table 1. Stakeholder interviews conducted by this study

Country	Number of interviews	Stakeholders interviewed
Bolivia	4	Swisscontact La Plataforma ambiental Suecia – Unión Europea-Medio Ambiente (Sweden-EU-Environment platform) Food by Nature Universidad Mayor de San Andrés (UMSA) laboratory
Brazil	4	Palladium (consulting firm) as implementer of UK Government's Partnerships for Forests (P4F) programme Barukas (company) Hogan Lovells (law firm) Amazonia Revive
Colombia	6	Ministry of Commerce, Industry and Tourism (MinCIT) La Asociación Nacional de Empresarios (ANDI) CaryO (company) NIRAS Group (consulting firm) representing the United Kingdom-funded Territorios Forestales Sostenibles (TEFOS) programme[1] Rainforest Alliance Cámaras Binacionales Europeas
Ecuador	4	Wiñak Ami Runa Ecuador (company) Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) (2 persons)
Peru	2	Promoción del Perú para la Exportación y el Turismo (PromPerú) (2 persons)

Note:

1. TEFOS is one programme structured around three pillars: (1) land governance, (2) environmental law enforcement, and (3) sustainable livelihoods and value chains.

Interviews were conducted remotely using semi-structured interview guides adapted to each respondent to capture case-specific information. Interviews were done in the preferred language of the interviewees (Spanish, Portuguese, or English) to facilitate open discussion and accurate capture of their perspectives. Topics covered included awareness and understanding of the EU regulatory pathway, experiences with

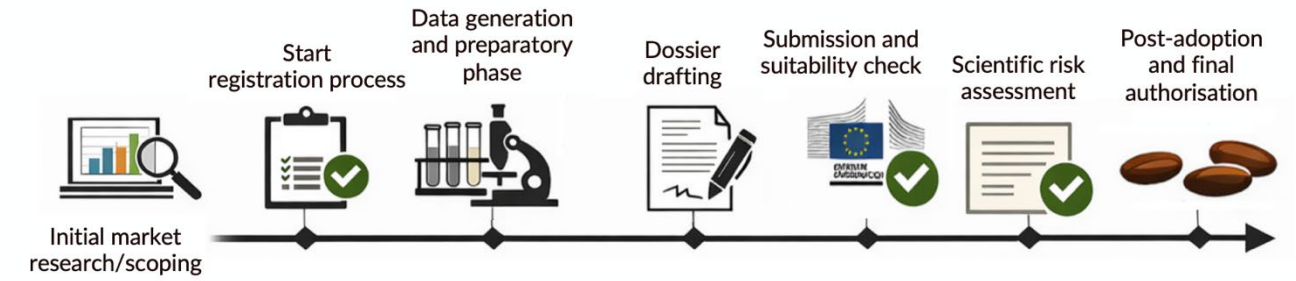
dossier preparation, scientific and administrative challenges, cost drivers, coping strategies, and the availability of technical or financial support.

Notes from the interviews were structured to facilitate comparison across countries and stakeholder categories.

Analysis and validation

The analysis was conducted in two stages. First, evidence collected through desk research and stakeholder interviews was synthesised into five structured case studies (section 2), each representing a specific traditional food product and country context. The case studies were developed using the analytical framework established during the desk research phase, and covered actors and governance structures, awareness and timeline of the application process, scientific and procedural challenges, costs and strategies, and development relevance.

Traditional food applications follow several stages, including initial market research, registration, data generation, dossier preparation, submission and suitability check, scientific risk assessment, and final authorisation. Across the case studies, applications were found to be at different stages: in some cases they were still at an early stage, while in others the products had already been authorised.



Next, findings from the individual case studies were compared through a horizontal analysis to identify recurring barriers, cost drivers, coping strategies, and support needs across countries (section 3). This cross-case analysis allowed for the identification of common patterns and structural constraints.

Where possible, evidence was triangulated across stakeholder interviews, regulatory documentation, EFSA technical reports on traditional food notifications, and available project documentation. Case descriptions and interpretations were shared with interviewees to confirm factual accuracy and clarify any misunderstandings.

Overall, the case studies provide insights into the challenges faced by applicants from the Amazon and Cerrado regions in seeking EU market access for traditional foods under Regulation 2015/2283.

2. Case studies

2.1. Kañiwa from Bolivia

As of April 2026, kañiwa is still at an early exploratory and information-gathering stage for a potential novel food application.

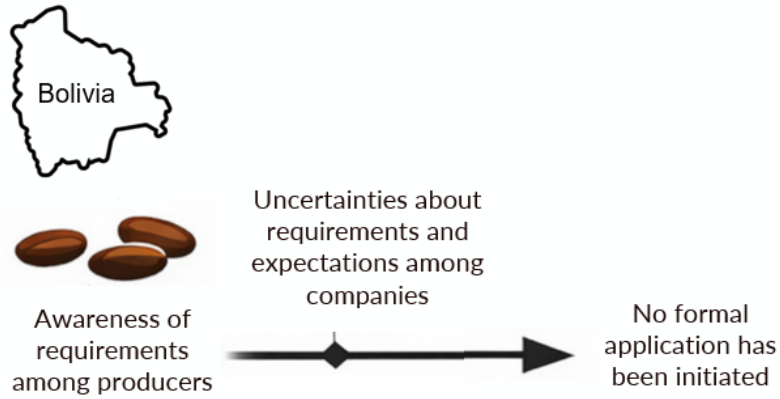


Figure 2. Status of kañiwa as a potential traditional food

Kañiwa (*Chenopodium pallidicaule*), often referred to as "baby quinoa", is a highly nutritious Andean highland seed cultivated by smallholder farmers. Although it has export potential and long-standing traditional consumption in Bolivia, it remains effectively excluded from the EU market due to its novel food status. To date, no novel food dossier has been initiated by Bolivian stakeholders, although Bolivia has been included as a country of traditional use in applications led by potential exporters in other countries (e.g. for coffee cherry pulp).

Actors and governance

In Bolivia, recent ministry closures and mergers (including Environment and Agriculture) have created institutional instability and removed clear governmental counterparts for EU regulatory dialogue. Stakeholders expect the Vice-Ministry of Trade and Logistics to assume this role in the future, but no formal structure is currently in place.

The Universidad Mayor de San Andrés (UMSA) in La Paz has laboratory equipment and internationally trained researchers capable of generating scientific and molecular analyses. However, it does not function as a commercially accredited service laboratory for EU-recognised export testing.

Awareness and timeline

Awareness of EU novel food requirements exists among producers, but expertise and understanding of the technical detail remains limited. Companies are uncertain about the volume of documentation required, the level of scientific evidence expected, and the total time and financial investment involved. As a result, no formal EU traditional food application from a non-EU country has been initiated.

Scientific, administrative, and procedural challenges

The primary barriers are as much structural as technical. SMEs are unable to finance a traditional food dossier independently, while at the outset there is limited clarity on total costs, timelines, and approval prospects. This uncertainty is exacerbated by the absence of a prior market validation study, making it difficult for producers to assess potential returns, and rendering the process too risky for small, resource-constrained actors.

In addition, local technical and regulatory expertise on EU novel food requirements remains limited. Producers lack experience with EFSA standards, and there is insufficient capacity to prepare dossiers in technical English, increasing reliance on external consultants.

EU requirements for food safety, traceability, and documentation are significantly stricter than those within Bolivia'. 'The country's dispersed smallholder production systems, limited aggregation structures, and high internal and international transport costs complicate volume consolidation and increase the financial risk of pursuing EU market entry.

Laboratory capacity presents an additional constraint. Accredited laboratories capable of meeting EU requirements are largely unavailable domestically, meaning that samples would need to be analysed abroad, significantly increasing costs.

Without sustained external support, coordinated multi-stakeholder collaboration, and stable governmental engagement, the initiation of traditional food dossiers for Bolivian niche products under Regulation 2015/2283 remains unlikely.

Costs and strategies

No consolidated cost estimate exists for a Bolivian kañiwa traditional food dossier. However, stakeholders indicate that SMEs would be unable to absorb the necessary investment without substantial external support.

Market validation in the EU is perceived as necessary for initiating a traditional food application. For Bolivian products that are not classified as novel, operators typically test the market through small-scale exports to the EU, generating consumer feedback and assessing demand, product positioning, and willingness to pay.[5] However, for products that fall under the Novel Food Regulation, such testing is not permitted due to regulatory constraints. As a result, there is too much uncertainty regarding the commercial viability of these products, and companies lack the market evidence needed to justify investment in a traditional food application.

Development relevance

Kañiwa represents a traditional highland crop cultivated in low-input systems with strong climate resilience. However, the entry costs associated with an EU novel food prevent the pursuit of traditional food applications for this and similar niche products.

Recent authorisations, such as dried coffee cherry pulp (cascara), show that access to the EU market is possible. However, these processes have typically been led and financed by large international actors, with limited direct involvement from Bolivian stakeholders.

The situation observed for kañiwa reflects broader structural constraints affecting Bolivian biodiversity-based products, including natural sweeteners (e.g. stevia-type products) and other underutilised species. As a result, many of these products remain effectively excluded from EU markets due to regulatory costs, uncertainty, and limited opportunities for pre-market validation.

5 Interview with importer from Denmark with long-standing experience in the Bolivian market (2025).

2.2. Roasted baru seeds from Brazil

Roasted baru seeds were authorised as a traditional food in the EU in 2025.

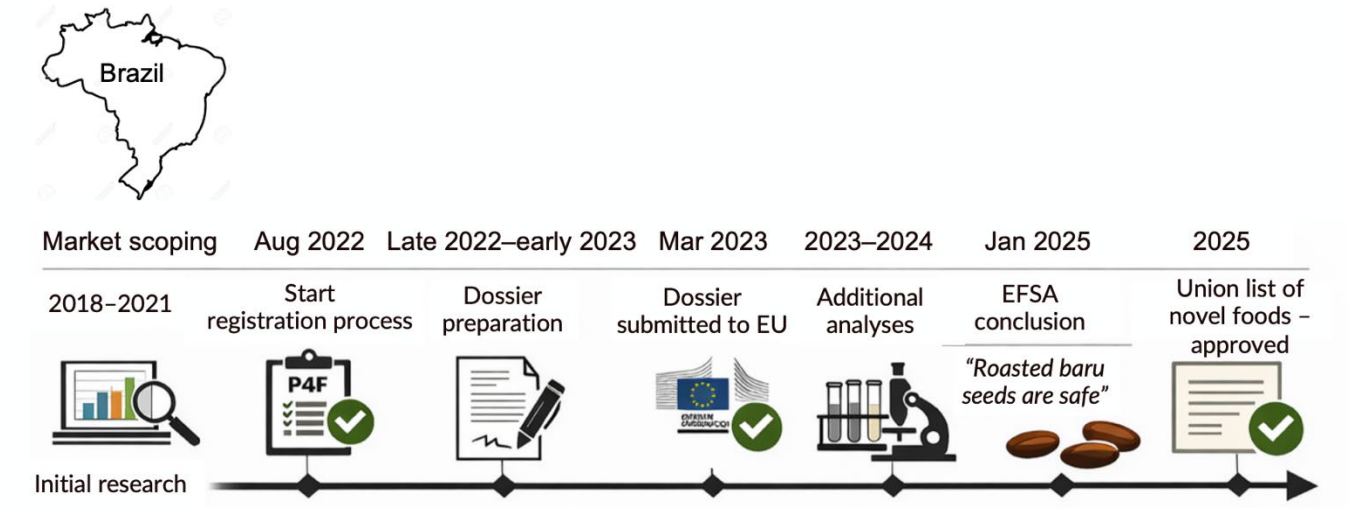


Figure 3. Roasted baru seeds: traditional food authorisation process

Baru seeds (*Dipteryx alata*) are native seeds of the Cerrado, the massive Brazilian savanna, where they are commonly harvested from wild trees. In traditional Brazilian and Bolivian cuisine, baru seeds, generally referred to as "baru", are consumed either raw or roasted, with or without their skins. The EU authorisation process under Regulation 2015/2283 focused specifically on roasted baru. In EU markets, roasted baru is positioned as a "superfood" due to its high protein and antioxidant content. It is primarily marketed as a snack product, as an alternative to nuts such as almonds, peanuts, and cashew nuts.

Actors and governance

The traditional food authorisation process was coordinated by Palladium under the Partnerships for Forests (P4F) programme, funded by the UK Foreign, Commonwealth and Development Office (FCDO). A market assessment conducted by P4F identified strong commercial potential for baru in the UK and EU markets, but also identified the need to submit a traditional food application.

In response, P4F initiated and coordinated the application in collaboration with private sector partners. Specialised legal and scientific expertise was provided by Hogan Lovells, an international law firm with recognised expertise in EU novel food regulation, and by Exponent, a consulting firm which contributed scientific and technical input to support the EFSA submission. The applicant in this dossier was CoopCerrado (Cooperativa Mista dos Agricultores Familiares, Extrativistas, Pescadores, Vazanteiros, Assentados e Indígenas do Cerrado), one of the main cooperatives working with baru in the Cerrado, representing approximately 8,000 households. Technical and scientific data were provided not only by CoopCerrado, but also by Barukas, a company with a controlled roasting facility and prior experience from the Swiss registration of roasted baru. The Brazilian Ministry of Agriculture and Livestock (MAPA) supported the process by issuing an endorsement letter, while EMBRAPA (Empresa Brasileira de Pesquisa Agropecuária), the Brazilian agricultural research corporation, provided data to support evidence of long-term consumption.

Awareness and timeline

Following initial market scoping (2020–2021), the formal P4F-led registration process started in August 2022 with a structured gap analysis that focused on the documented history of consumption and compositional

parameters. Dossier drafting took place in late 2022 to early 2023, leading to the submission of the first version of the dossier to the European Commission in March 2023.

During validation, EFSA raised follow-up questions that primarily focused on compositional variability and shelf-life stability. Additional laboratory analyses and consolidation of Swiss registration data were conducted throughout 2023–2024. In January 2025, EFSA concluded that roasted baru does not raise safety concerns. Therefore, in the absence of any objections from EU Member States, the product was authorised and added to the EU list of novel foods.

Scientific, administrative, and procedural challenges

The main challenge was documenting the required 25-year history of safe food use. Since consumption of baru is primarily based on traditional practices with limited written records, researchers were obliged to compile evidence from multiple sources, including Brazilian school food programme records from the 1980s, and Bolivian historical documentation dating back to the colonial period.

Scientifically, the wild-harvested nature of the product resulted in compositional variability between batches. When EFSA raised questions about variations in protein and fat levels, the applicant explained that the nitrogen-fixing species naturally vary according to rainfall and soil conditions.

Administratively, language requirements posed an additional challenge, as all documentation and correspondence with the European Commission and EFSA had to be conducted in English.

Costs and strategies

The investment in the traditional food authorisation process under the P4F project was approximately €55,000. This amount covered specialised legal and scientific consultancy services required for dossier preparation and submission. However, this figure does not consider the substantial in-kind time investment from P4F staff and participating producers. Two P4F project officers were involved in coordinating the process from August 2022 up to dossier submission in March 2023, translating documentation, and facilitating communication between producers and external experts.

A key preliminary strategy was to validate the market potential of baru before committing to the traditional food application. A dedicated market assessment was conducted to evaluate demand, identify target markets, and assess commercial viability. This pre-validation reduced the risk of investing in a costly and uncertain regulatory process without clear market prospects, and supported the mobilisation of technical and financial resources.

Cost and time efficiency were further improved using pre-existing scientific data. Before the EU application, Barukas had funded compositional and safety analyses for Swiss market approval, estimated at approximately €25,000.[6] These data were reused in the EU dossier, significantly reducing the need for new laboratory testing. Without this, total investment would likely have been closer to €80,000.

Coordinated multi-stakeholder collaboration was another critical enabling factor. The process relied on the combined efforts of public programmes (P4F), private sector actors, producers, and specialised legal and scientific experts. This collaboration helped bridge technical, financial, and knowledge gaps that individual SMEs or cooperatives would not be able to address independently, while also enabling data sharing and distributing costs and risks.

6 For novel foods, Swiss approval appears procedurally simpler, but not scientifically lighter or demonstrably cheaper overall: the Federal Food Safety and Veterinary Office (FSVO) runs a single-authority 12-month process; the EU process involves the European Commission, EFSA, and EU Member States.

The process also benefited from early planning of the data generation strategy. A gap analysis was conducted to identify existing evidence and remaining data requirements, while long-duration studies, such as shelf-life stability tests, were initiated early to avoid delays in dossier preparation.

Finally, proactive engagement with the EU authorities proved essential. Appointed experts maintained continuous communication with responsible officials, responded quickly to follow-up questions, and provided regular updates on progress and expected timelines for additional data. Ensuring adequate English-language capacity throughout the process further facilitated timely and effective interaction with EU authorities. In parallel, laboratory methodologies were verified before initiating supplementary tests on composition and aflatoxins, ensuring compliance with EFSA standards.

Development relevance

The baru value chain contributes to Brazil's socio-biodiversity strategy by supporting rural livelihoods while promoting conservation of the Cerrado. The sector plays an important role in the local economy, as it employs over 16,000 smallholder farmers in Brazil, as recorded in the P4F programme documentation. For these communities, including 8,000 families represented by CoopCerrado, access to EU markets would lead to more stable demand and improved price prospects.

Market assessments carried out as part of the traditional food authorisation process identified significant untapped potential for roasted baru in the EU and the UK. The combined market potential for Germany, the Netherlands, and the UK is estimated at €36 million.[7]

7 P4F (2024) Registering new biodiversity products in international markets. Webinar video.

2.3. Cacay flour from Colombia

At the time of writing, the cacay flour traditional food application was at the submission and suitability check stage, awaiting final technical validation by EFSA.

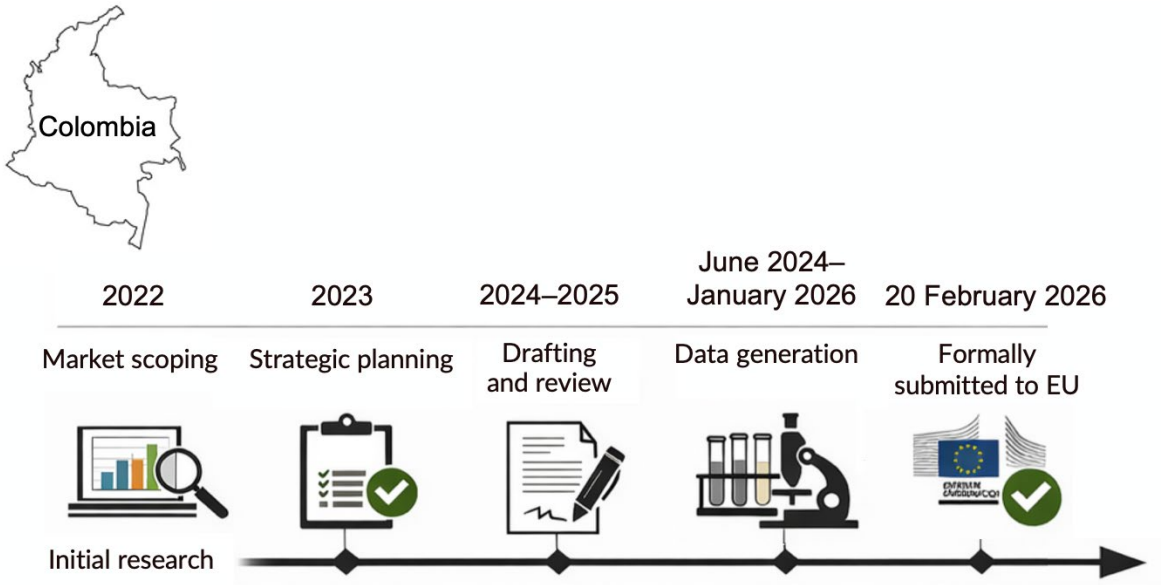


Figure 4. Status of traditional food application for cacay flour

Cacay flour is a by-product of oil extraction from the nuts of *Caryodendron orinocense*. With a protein content between 30 and 40%, it is used in Colombia in shakes, biscuits, and gluten-free bakery products. The cacay nut is native to the Amazon and Orinoquía regions in Colombia, where indigenous communities have consumed it for generations. Traditionally, the nuts are dried, roasted, and eaten similarly to peanuts, or processed into a nutrient-rich milk commonly given to babies. While this knowledge has long existed locally, broader recognition for cacay flour has only emerged recently.

Actors and governance

The initiative was led by Colombia's Ministry of Commerce, Industry and Tourism (MinCIT) and Ministry of Agriculture and Rural Development (MADR), in coordination with the Territorios Forestales Sostenibles (TEFOS) programme of the British Embassy, GIZ, and six Colombian companies linked to the cacay value chain.

An alliance of these six SMEs – CaryO, Kahai, Bioingredientes Amazónicos, L'Oricay, Tacay, and Arlés – was formed under a Memorandum of Understanding allowing cost and data sharing without creating a separate legal entity. CaryO was elected to represent the alliance when communicating with the European Commission and EFSA.

The national business sector played a key role, providing technical information, ensuring the supply of raw materials, validating industrial processes, and demonstrating the feasibility of scaling up production under international standards.

International cooperation played a decisive role in the traditional food authorisation process. GIZ financed the initial roadmap and engaged a German technical consultant with specialised expertise in novel food procedures. In addition, the TEFOS programme (implemented by NIRAS Group Ltd) covered most laboratory analyses and supported a full-time biologist/microbiologist as technical liaison and lead dossier drafter.

Laboratory testing was carried out by Enzipan Laboratories in Bogotá, selected for its expertise in flour analysis and international accreditation.

Awareness and timeline

The development of a traditional food application took on momentum in 2022, when Kahai, a Colombian company that originally exported cacay oil for cosmetics and sought to valorise its protein-rich by-product, approached MinCIT and GIZ. This cooperation triggered the creation of the Novel Food Committee. Initially, SMEs underestimated the demands of the application process: the strictness of EFSA standards, the need for accredited laboratory tests, and the duration and cost of the process.

The preparatory phase spanned approximately 3–4 years: initial market research and scoping (2022), strategic planning (2023), data generation (June 2024–January 2026), and drafting and review (2024–2025). On 20 February 2026, the technical-scientific dossier underpinning the application for cacay flour as a traditional food was formally submitted to the EU, a development that received significant coverage in the Colombian media.[8]

Scientific, administrative, and procedural challenges

One of the most important challenges in preparing the application was documenting the history of safe use. Although long-term consumption was well established in local communities, most of the evidence was oral and/or informal. The consortium worked with indigenous communities, universities [e.g. Universidad de los Llanos Unillanos)], and research institutes [Instituto Amazónico de Investigaciones Científicas (SINCHI) and Humboldt] to translate this knowledge into EFSA-compliant documentation. In addition, it was necessary to demonstrate that the differences between traditional and industrial processing methods did not affect the safety of the product.

EFSA standards require extensive compositional analyses and 12-month real-time stability testing. Limited accredited laboratory capacity was a major bottleneck. Enzipan Laboratories was the only facility within Colombia capable of conducting analyses in line with EFSA requirements. While not all analytical methods were formally accredited according to EFSA standards, procedures were reviewed and validated by the GIZ-appointed expert to ensure equivalence. Stability testing proved to be expensive and time-consuming. Demonstrating the pesticide-free status of cacay nuts also required additional analyses, despite the absence of chemical inputs in production.

Different processors of cacay nuts have developed their own company expertise in the production processes used. Harmonising these processes into a single description, as required in the application, proved difficult. SMEs were initially reluctant to share confidential information, necessitating non-disclosure agreements and the appointment of a neutral technical liaison to build trust. Language was another major barrier. The entire dossier and interaction with the EFSA portal had to be conducted in English, making SMEs dependent on external consultants with the necessary linguistic skills. Finally, logistical issues, such as sample sizes, packaging formats, and transport from remote regions, created additional operational challenges that had to be jointly addressed by the participating SMEs.

Costs and strategies

The total investment in the traditional food authorisation process for cacay flour was estimated at approximately €111,000,[9] largely financed through a combination of international donor programmes and contributions from Colombian public institutions. The largest share of the budget was allocated to scientific and technical consultancy, estimated at around €64,000 (GIZ and TEFOS funds), which covered regulatory

8 Legiscomex, 2025; Agronegocios, 2026; El Productor, 2026; El Tiempo, 2026; Estrella Digital, 2026.
9 This sum is an approximate indication as the technical validation has not yet taken place and the process is not yet finalised.

guidance, dossier drafting, and coordination of the application process. Additional expenditures included approximately €34,000 (MinCIT and Ministry of Agriculture funds) for participation in the steering group, a commercial route study, and awareness-raising activities. Furthermore, approximately €13,000 was allocated to laboratory analyses, 30% of which was covered by SMEs.

Beyond these direct financial contributions, participating actors provided significant in-kind support, including technical data generation, compilation of historical evidence on consumption, and staff time.

Key strategies that were developed to manage costs and risks included:

- conducting an early market study and commercial route analysis to assess demand and define feasible EU entry strategies
- forming an SME alliance
- appointing a trusted third-party technical liaison
- sharing costs across stakeholders
- anchoring the process institutionally through the novel food committee
- securing international expert coaching.

Development relevance

The stakeholders interviewed viewed traditional food authorisation under Regulation 2015/2283 as both a high-risk burden, and a key enabler of a sustainable forest-based bioeconomy. CaryO suggests that EU approval could scale sourcing from hundreds to thousands of Amazonian families, offering a viable alternative to cattle farming, monocultures, or coca production. This could generate significant benefits for remote regions such as Meta, Guaviare, Putumayo, and Caquetá. SMEs like CaryO emphasise that harvesting from wild rainforest trees generates additional income, making standing forests more profitable than cattle farming and thereby supporting conservation and deforestation reduction.

MinCIT highlighted how the cacay flour application is being treated not only as a learning process, but also as a precedent for future applications. The Novel Food Committee sees considerable potential to extend this approach to a wider range of traditional Colombian food products, positioning cacay as an entry point for broader EU market access.

2.4. Dried guayusa leaf from Ecuador

As of April 2026, the traditional food application for dried guayusa leaf is still under preparation and has not yet been submitted to the EU.

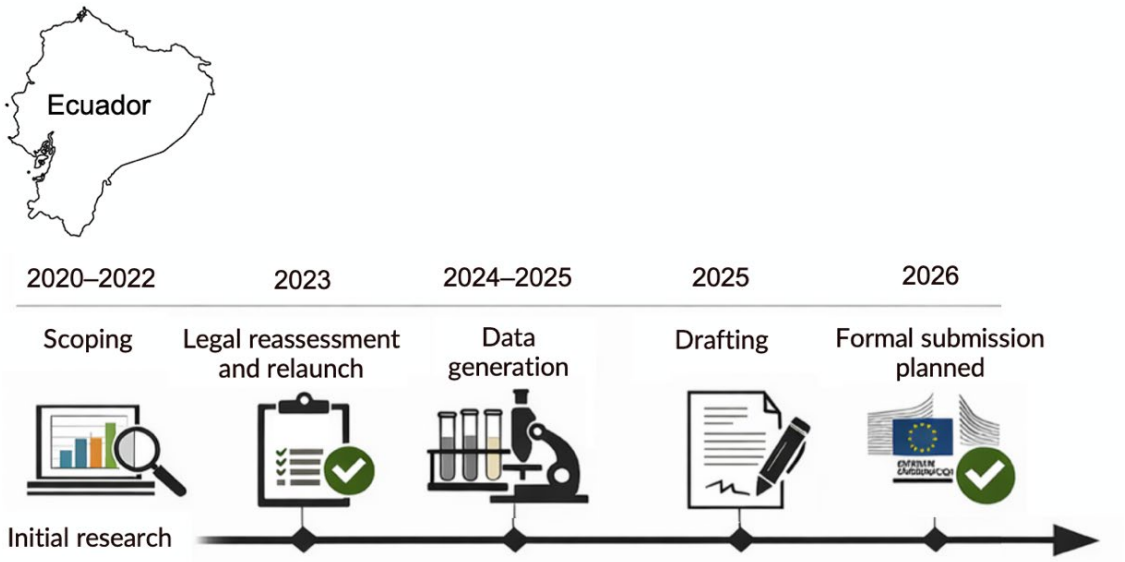


Figure 5. Status of traditional food application for dried guayusa leaf

An aqueous extract of guayusa has already been authorised as a traditional food in the EU. Building on this, producers are now seeking authorisation for dried guayusa leaf, as European buyers have expressed interest in sourcing the raw material directly to develop their own blends, extracts, and beverage formulations.

Guayusa (*Ilex guayusa*) is a native tree of the Ecuadorian Amazon. For over 200 years, indigenous Amazonian communities have prepared their leaves as a nutrient-dense infusion for early-morning ceremonies, valued for their energising and medicinal properties.

Actors and governance

Governance of the guayusa value chain is structured through the institutional platform Guayusa Lab. This platform convenes producer organisations, exporting companies, academic institutions, and public authorities. Participants include provincial and cantonal governments, national ministries, the Instituto Nacional de Biodiversidad (INABIO), and Agencia de Regulación y Control Fito y Zoosanitario (Agrocalidad). Within the framework of this cooperation, stakeholders address strategic issues such as denomination of origin, biodiversity monitoring, and traditional food authorisation.

The EU authorisation process was initially pursued by Jumandipro (Waykana) and the Universidad Regional Amazónica Ikiam, but early attempts were discontinued due to technical and financial constraints. The current application effort is coordinated by GIZ through its BioValor programme.

As the traditional food authorisation process is a matter of national interest, the Republic of Ecuador, represented by its Embassy in Brussels, has been designated as the formal applicant for EFSA. Technical preparation of the dossier and regulatory liaison are carried out with support from GIZ and the Import Promotion Desk initiative, in collaboration with the relevant national stakeholders.

Awareness and timeline

The preparatory phase has spanned several years and can be divided into distinct stages. Initial scoping and early attempts (2020–2022) were followed by a legal reassessment and relaunch in 2023. During this phase, EU-based experts, including a lawyer in Germany, analysed the regulatory distinction between dried leaves and previously authorised guayusa extract, leading to the decision to prepare a new dossier. Data generation (2024–2025) focused on documenting 25 years of safe traditional use and reviewing the existing scientific literature. Drafting (2025) involved technical consolidation of the dossier chapters and English-language editing. Submission is planned for 2026.

Scientific, administrative, and procedural challenges

The primary reported scientific hurdle relates to laboratory accreditation. Although 12 laboratories in Quito and Guayaquil were assessed, national laboratories do not hold accreditation for most of the parameters required under EFSA standards. Where accredited analyses are necessary, samples must be sent to laboratories in the EU, which significantly increases costs. Although the Centro de Innovación y Soluciones Agrícolas y Ambientales (CISAA) could facilitate sample handling, the accredited analyses would still need to be performed in the EU.

In Ecuador, experience with EU traditional food applications remains limited. Consequently, familiarity with the process and the regulatory requirements within the public and private sectors is still developing. A critical procedural hurdle is the requirement that the entire dossier and all portal interactions be conducted in technical English; local producers and organisations lack bilingual technical staff to interpret EFSA guidance or draft scientific sections. Producers have therefore relied on external technical and legal expertise, through GIZ and the Import Promotion Desk, to navigate the EU requirements and prepare the dossier.

Documenting the history of safe use required careful consolidation of available evidence. Although dried guayusa leaves have been consumed for centuries and several scientific studies exist, part of the knowledge remains rooted in traditional practices and is transmitted orally. To complement the existing literature and ensure compliance with EU requirements, GIZ commissioned a field study across the Ecuadorian Amazon to document traditional consumption patterns in a format suitable for regulatory submission.

Costs and strategies

The cost of preparing the dried guayusa leaf dossier is estimated at approximately €74,000. Of this amount, around €28,000, funded by GIZ, has been allocated to preparatory work, including approximately €14,000 for regulatory consultancy services and €14,000 for the field study documenting the history of traditional use in the Ecuadorian Amazon. The remaining €46,000 corresponds to the estimated cost of the laboratory analyses required to complete the dossier; however, funding for these tests has not yet been secured. In addition, GIZ has provided extensive internal technical support over a period of 3–4 years, including regulatory guidance, technical English-language support, and coordination of the application process.

The Guayusa Lab platform has served as a key coordination mechanism, bringing together stakeholders to consolidate data and technical inputs for the dossier.

At the current stage, further progress depends on securing additional funding from both public and private stakeholders to cover the laboratory analyses. Limited financial capacity within the sector to absorb these costs continues to delay final submission of the dossier.

Development relevance

The Ecuadorian Amazon accounts for approximately 95% of global guayusa production, cultivated in ancestral biodiverse agroforestry systems known as Chakra and Aja. These indigenous production systems integrate trees, food crops, and medicinal plants while maintaining soil fertility and biodiversity without synthetic inputs. Around 2,200 hectares are managed by more than 3,500 indigenous families from Kichwa, Shuar, and other indigenous communities. Annual production capacity is estimated at approximately 4,400 metric tons (MT) of dried leaf; however, only about 220 MT are currently processed and commercialised each year. Of this volume, 90% is exported, primarily to the USA, and 10% is sold domestically. EU market access could diversify export destinations and strengthen income stability for Amazonian producers.

2.5. Sacha inchi from Peru

Sacha inchi oil was authorised as a traditional food in the EU in 2014. An application for roasted sacha inchi seeds, submitted in 2018, remains under evaluation due to EFSA safety concerns related to alkaloid content. A separate dossier for sacha inchi flour has been initiated, but has not progressed beyond the draft stage.

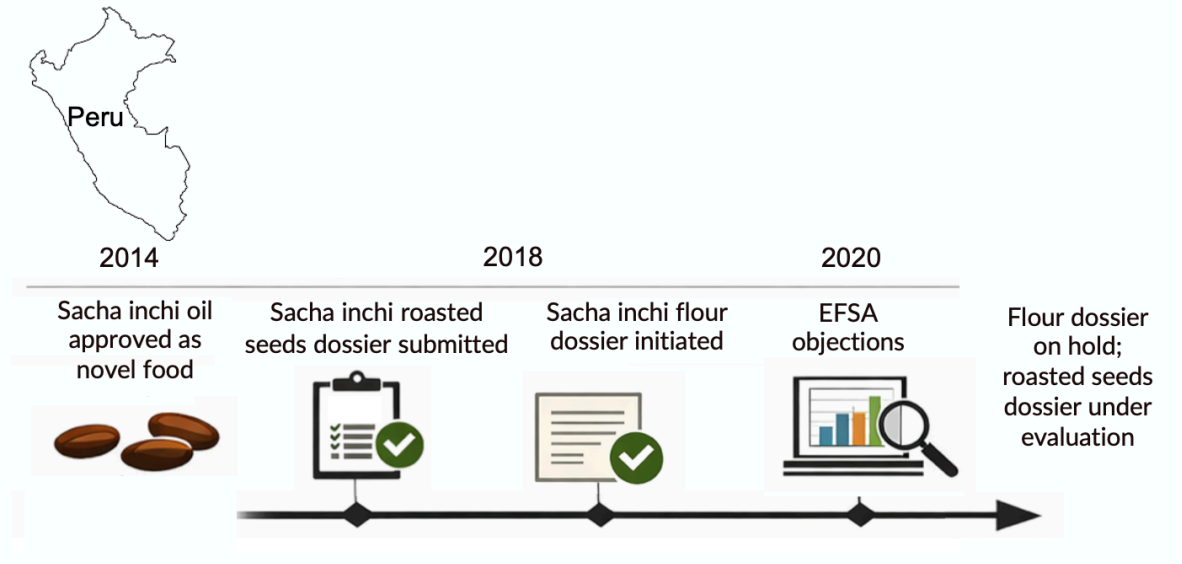


Figure 6. Status of traditional food applications for Sacha inchi

Sacha inchi (*Plukenetia volubilis*), also known as the "Inca peanut", is native to the Peruvian Amazon. It has long been cultivated by smallholder farmers and indigenous communities in regions such as San Martín, Ucayali, and Loreto. Traditionally, the seeds are shelled, washed, roasted, and either consumed directly or incorporated into food preparations.

Rich in protein and omega-3 fatty acids, sacha inchi is marketed as roasted seeds, cold-pressed oil, and flour derived from the press cake. Since 2008, Peruvian companies have exported these products to markets including Japan, USA, Canada, and Australia. Identified as a strategic biotrade product with strong export potential, access to the EU market was pursued to position sacha inchi as a high-value food ingredient.

Actors and governance

The traditional food authorisation process was coordinated by PromPerú, which acted as the representative and lead applicant communicating with EU institutions. The governance structure evolved into a coordinated public–private–academic model.

- Public institutions: the Ministry of Foreign Trade and Tourism (MINCETUR), the Instituto Nacional de Calidad (INACAL), the Instituto Nacional de Innovación Agraria (INIA), the Instituto de Investigaciones de la Amazonía Peruana (IIAP), and the Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica (CONCYTEC) supported standardisation, botanical verification, and research activities.
- Academia: Universidad Nacional Mayor de San Marcos, Universidad Peruana Cayetano Heredia, Universidad Nacional de San Martín, and Universidad Nacional de la Amazonía Peruana contributed scientific expertise, alongside international academic partners from various countries including Brazil, Germany, Japan, and Spain.
- Private companies: Agroindustria Osho, Amazon Health Products, Candela, and Shanantina (among others) contributed technical data, samples, and production histories.

International cooperation played a significant role. Support was provided by GIZ, the Swiss State Secretariat for Economic Affairs (SECO), the International Trade Centre (ITC), the Centre for the Promotion of Imports (CBI) of the Netherlands, Rainforest Alliance, and the United States Agency for International Development (USAID).

Awareness and timeline

Awareness of EU novel food requirements emerged around 2007 and was formalised in 2008 through the Peru Biodiverso project, at a time when EFSA guidance was still limited.

The regulatory pathway was different depending on the type of product. Sacha inchi oil was authorised in 2014 under Regulation (EC) No 258/97 via substantial equivalence with linseed oil. The roasted seeds dossier, submitted in 2018 as a traditional food under Regulation 2015/2283, remains under evaluation due to EFSA safety concerns regarding alkaloids. A draft dossier for sacha inchi flour was also initiated around 2018. However, it has not progressed to submission as it was put on hold pending the outcome of the seed application. Overall, the process has spanned more than a decade.

Scientific, administrative, and procedural challenges

A key technical challenge was the clear taxonomic differentiation of *Plukenetia volubilis* (the species used for sacha inchi products) from other species within the same genus, particularly *Plukenetia huayllabambana*. These species are closely related because they belong to the same genus and share a high degree of genetic similarity, as shown in studies on Amazonian *Plukenetia* species.[10] This distinction is relevant from a regulatory perspective, as EFSA requires that a traditional food application is strictly linked to a single, well-defined species with documented composition, safety profile, and history of use. Even closely related species may differ in chemical composition or levels of naturally occurring compounds, which can affect safety. While *P. huayllabambana* is also reported to produce edible seeds and has been investigated for similar nutritional properties, its history of consumption and safety data are far more limited compared with *P. volubilis*. Therefore it cannot be assumed to be interchangeable, and it was necessary to ensure that all data in the dossier refer specifically to *P. volubilis*. To support this, detailed botanical data sheets were prepared with the involvement of Peruvian and German botanists to ensure accurate species identification and documentation.

Documenting the required history of safe use presented further difficulties. Although traditional consumption is well established, some archival sources were lost due to a fire at Peru's national library. Historical documentation had to be reconstructed using foreign archives and regional records, supported by additional field research to consolidate evidence of long-term consumption.

Laboratory capacity posed another major constraint. Peru lacked accredited facilities capable of conducting certain advanced analyses, including detailed fibre profiling and complex contaminant testing. Samples had to be sent to laboratories in the USA and Germany, significantly increasing costs.

For roasted sacha inchi seeds, EFSA raised concerns based on earlier literature reporting alkaloids that were not clearly identified, and requested clarification of the specific alkaloids involved. Subsequent analyses by the University of Valencia and SGS Germany did not detect alkaloids, and a 2024 study identified a single non-toxic alkaloid (trigonelline). However, these findings did not fully resolve EFSA's concern, as they did not establish whether the compounds previously reported in the literature had been adequately identified and characterised. As a result, EFSA maintained its request for comprehensive identification of relevant alkaloids and their safety, necessitating further specialised research and substantial financial resources.

10 Cachique Huansi, 2015; Fanali et al., 2011; Rodriguez del Castillo et al., 2010.

The sacha inchi oil application avoided many of these challenges, as it was submitted under the former substantial equivalence route, allowing comparison with an already established food category (e.g. linseed oil) with similar composition and intended use. This approach reduced the need for extensive additional toxicological and intake assessments if equivalence in composition, nutritional value, and safety could be demonstrated. However, this pathway was specific to the previous regulatory framework (Regulation (EC) No 258/97). Under Regulation 2015/2283, this formal substantial equivalence route no longer exists. While similarity to an already authorised traditional food may still be practically relevant in shaping the scope of a dossier or supporting amendment applications, it no longer constitutes an independent simplified legal pathway.

Costs and strategies

Total investment across the traditional food dossiers for sacha inchi oil, roasted seed, and flour is estimated at €190,000, largely financed by public institutions and international cooperation programmes rather than individual companies. International laboratory analyses constituted the largest cost component, followed by specialised consultancy for dossier drafting and technical development.

Coping strategies included coordinated public–private–academic collaboration (a “triple helix” model), pooled financing, sharing scientific resources across institutions, conducting preliminary analyses domestically before outsourcing accredited tests abroad, and developing structured product specifications through national voluntary standards (INACAL). Regional cooperation further strengthened methodological alignment and product characterisation, contributing to the development of ISO/DIS 17317 on biodiversity-based products. However, the scientific concerns raised by EFSA regarding the sacha inchi roasted seeds dossier remain unresolved, pending the results of Rainforest Alliance-supported research.

Development relevance

In Peru, sacha inchi is cultivated by several thousand smallholder families, often within diversified or agroforestry production systems. The crop contributes to rural household income, including for women involved in seed collection and primary processing. By utilising the entire plant, ranging from high-value oil to protein-rich press cake and flour, the value chain offers opportunities for product diversification and value addition. Access to international markets, including the EU, could further strengthen these income streams, provided that regulatory requirements can be met.

3. Horizontal analysis of case studies

The five case studies reveal several recurring patterns in the preparation of traditional food applications for traditional Amazonian and Cerrado products. The analysis below synthesises the key barriers, mitigating strategies, and action areas to support trade in traditional foods.

3.1. Traditional foods as a catalyst for sustainable forest economies and livelihoods

It is evident from the cases analysed that stakeholders are confident that traditional foods from the Amazon and the Cerrado, once authorised by the EU, have a potentially important role to play in enabling sustainable rural development and biodiversity-based livelihoods. Improved EU market access was seen as particularly relevant for products derived from forests and agroforestry systems in which forest cover is maintained rather than cleared.

Economic impact

In several cases, stakeholders linked EU market access to direct livelihood benefits for rural and indigenous communities. In Brazil, the baru value chain was reported to involve more than 16,000 smallholder farmers, while guayusa production in Ecuador involves more than 3,500 indigenous families. In Colombia, stakeholders interviewed indicated that EU approval for cacay flour could help scale sourcing from current pilot levels to approximately 2,000 families within 3 years.

In the baru case, a market assessment identified significant untapped commercial potential in the European market. The combined market potential for Germany, the Netherlands, and the UK was estimated at €36 million for roasted baru. Stakeholders involved in this case considered that even limited market capture could generate meaningful export revenues and support the local social bioeconomy.

Environmental impact

Stakeholders also emphasised the environmental benefits associated with these value chains. Wild-harvesting models, such as those associated with cacay and baru, can create income opportunities that reinforce incentives for forest conservation. In Colombia and Peru, value chains based on oil extraction also enable the utilisation of protein-rich by-products such as cacay flour and sacha inchi press cakes, contributing to the circular use of plant materials. In Brazil, the baru value chain is closely linked to agro-extractivist communities and traditional land-use systems, where collection practices support sustainable resource management and the maintenance of forest cover.

Social impact

Social benefits were highlighted across several cases. In Ecuador, interviewees reported that a substantial share of guayusa producers are Kichwa women who manage this income for household needs such as children's health and education. In Peru, women were described as playing an important role in seed collection and the primary processing of sacha inchi. More broadly, stakeholders emphasised that these value chains are embedded in local knowledge systems and traditional production practices, reinforcing their social and cultural significance for indigenous and rural communities.

In this context, understanding the current barriers and exploring solutions to improve access to the EU market for traditional foods is essential.

3.2. Scientific, technical, and administrative barriers (including costs)

Across the cases analysed, applicants reported a combination of scientific, procedural, and financial challenges that slowed or prevented the completion of traditional food applications.

Evidence of traditional use

A recurring hurdle in three of the five cases analysed was documenting the required 25-year history of safe consumption outside the EU. In many instances, traditional knowledge is transmitted orally within indigenous or rural communities and is not documented in formal written sources. Applicants therefore needed to translate cultural and historical practices into scientific and regulatory documentation. This process proved particularly demanding in the cases of cacay flour (Colombia), dried guayusa leaf (Ecuador), and roasted baru (Brazil), where archival research, ethnobotanical studies, or field surveys were required to substantiate evidence of traditional use.

Laboratory capacity and accreditation

In many of these countries, particularly Peru, Ecuador, and Colombia, the existing laboratories lack the necessary accreditation to perform the specific tests required by EFSA. As a result, applicants frequently need to send samples to laboratories in Europe or the USA, increasing costs and extending project timelines.

Scientific variability of biodiversity-based products

Stakeholders in one of the cases analysed also highlighted challenges related to the natural variability of biodiversity-based products. Traditional food requirements assume relatively stable and well-characterised food compositions. However, many Amazonian products originate from biodiverse environments and wild-harvesting systems, where natural variation in composition may occur due to ecological factors such as soil conditions or rainfall. In the roasted baru case (Brazil), differences in protein and fat composition between batches required additional explanation during the EFSA evaluation process.

Language and procedural complexity

Language requirements were reported as an additional barrier in four of the cases analysed (Brazil, Colombia, Ecuador, and Peru). The traditional food application process requires that all documentation and communication be conducted in technical English, even though Spanish and Portuguese, relevant to these case studies, are EU official languages. For many SMEs and producer organisations in the Amazon region, which often lack bilingual technical staff, this requirement increases reliance on external consultants to prepare and manage the dossier. In both the Colombia and Ecuador cases, stakeholders reported that they initially underestimated the rigorous nature of the EU traditional food authorisation process and the volume of data required for a successful submission. Applicants often began with the assumption that the process would be a straightforward task of compiling existing local information on traditional use and product characteristics. However, they encountered extensive requirements for the generation of new data, often necessitating specialised expertise and external technical support to bridge the gap between local capacities and EU regulatory requirements.

Financial costs and resource constraints

Preparing a traditional food dossier requires significant financial investment in all four cases where dossier preparation has progressed (Brazil, Colombia, Ecuador and Peru). Available evidence from the case studies indicates that the investment required varies depending on the product, the availability of existing scientific data, and the level of external technical support. Documented costs range from approximately €111,000 to €190,000. This estimate is based on the Colombian and Peruvian case studies, which are the only ones for which complete information is available (Table 2). In several instances, requests for additional data or objections raised during the EFSA review process further increased the required investments.

The main cost drivers reported across the cases were scientific and technical consultancy services and accredited laboratory analyses. Additional costs arose from field studies documenting the history of traditional use, coordination activities, and institutional support structures.

Due to the varying stages of dossier preparation and the limited availability of detailed financial documentation, cost breakdowns could not be obtained for all case studies. In many instances, the reported figures also **exclude significant in-kind contributions**, such as staff time, coordination efforts, or technical inputs provided by supporting institutions and international cooperation programmes.

Table 2. Overview of available cost estimates for the cases analysed

Case study[1]	Costs (EUR)				
	Total estimated investment	Market/ field study	Laboratory	Scientific/ technical consultancy	Coordination and institutional
Baru (Brazil)	80,000	Not available	Approx. 25,000[a,b][2]	Approx. 55,000[b]	Not available
Cacay (Colombia)	111,000	Approx. 18,000[c]	Approx. 13,000[c,d]	Approx. 64,000[c,e]	Approx. 16,000[c]
Guayusa (Ecuador)	74,000	Approx. 14,000[f]	Approx. 46,000[f]	Approx. 14,000[f]	Not available
Sacha inchi (Peru)	190,000[3]	Not available	Not available[4]	Not available	Not available

Sources: interviews with a, Barukas; b, Palladium (P4F); c, MinCIT; d, CaryO; e, NIRAS Group (TEFOS); f, GIZ.
Notes:
1. The case study for kañiwa from Bolivia is not included here as no traditional food dossier preparation process has started.
2. Includes prior laboratory costs for Swiss market registration.
3. Safety objections by EFSA have been raised in this case.
4. Not specifically quantified, but identified as the largest cost component. Each major laboratory effort costs around €8,600.

Market uncertainty and the need for validation

A cross-cutting barrier identified across several of the cases analysed (Bolivia, Brazil, and Colombia) relates to uncertainty regarding market potential before authorisation. For many SMEs and producer organisations, the decision to initiate a traditional food application requires substantial upfront investment, with no clarity on future demand, pricing, or commercial viability in the EU market. Stakeholders emphasised that market validation is effectively a prerequisite for justifying these investments. However, for products clearly classified as novel foods, opportunities to conduct consumer testing, pilot sales, or small-scale imports are limited by regulatory restrictions.

3.3. Strategies used to mitigate barriers

In each case, applicants developed strategies to try to manage the obstacles they confronted. While each traditional food application faces different challenges in terms of the collection and analysis of data, some of the strategies may be relevant to other applicants to manage the technical complexity and reduce financial risks.

Coordinated multi-stakeholder and institutional support

Across the cases analysed, progress depended on coordinated collaboration between companies, public institutions, research organisations, and international partners. These structures helped pool expertise, spread costs, strengthen institutional anchoring, and facilitate regulatory dialogue. A clear allocation of responsibilities and commitments (e.g. a commitment to data sharing through a Memorandum of Understanding), provides a more stable framework for initiating a traditional food application.

Use of existing scientific data

Reusing existing scientific data, where available, significantly reduced costs and preparation time. The roasted baru application benefited from compositional and safety data previously generated for Swiss market approval, including shelf-life data.

Early planning and proactive communication with EFSA

Early planning proved critical for managing the time and complexity of dossier preparation. Several stakeholders noted that the scale of the evidence required is often underestimated at the outset. Some analytical requirements, such as 12-month real-time stability tests, need to be initiated early in the process to avoid delays. Once a provisional overview of the available evidence and data has been established, early engagement with EFSA is recommended.

Experience from the cases analysed shows that proactive and continuous communication with EFSA can help applicants clarify expectations, anticipate additional information requests, and respond more efficiently during the evaluation phase, as highlighted in the baru case. EFSA is available to provide clarification on its administrative and scientific guidance relevant to the development of traditional food applications.

This interaction with EFSA is referred to as “General Pre-Submission Advice (GPSA)”. Information on how to request it is available on the EFSA website, together with details of the practical arrangements for GPSA (see References and resources).

Market validation

Market validation emerged as an important strategic consideration prior to initiating a traditional food application. Given the substantial financial and technical resources required, stakeholders emphasised the need to assess potential demand, product positioning, and commercial viability in the EU market before committing to dossier preparation. In some cases, early market assessments or exploratory studies were undertaken to evaluate the commercial potential of products and to support investment decisions. For example, in the baru case (Brazil), a market assessment helped demonstrate potential demand and supported the decision to proceed with dossier preparation.

International technical and financial support

International cooperation programmes played a decisive role in enabling progress across several of the cases analysed. Organisations such as GIZ, P4F, FCDO, SECO, CBI, and USAID contributed funding, technical consultancy, translation support, laboratory analyses, and regulatory expertise at different stages of dossier preparation. This support was often essential to compensate for limited technical capacity and financial resources at the level of SMEs and producer organisations. It enabled access to specialised expertise, facilitated compliance with EFSA requirements, and supported coordination among stakeholders.

Given the substantial costs and complexity associated with traditional food applications, such external support mechanisms were key enablers of progress. Without them, most stakeholders indicated that initiating and completing a traditional food application would not have been financially or technically feasible.

3.4. Action areas to support trade in traditional foods

The case studies show that progress in traditional food applications depends on technical expertise, institutional coordination, financial resources, and early market insight – factors that often go beyond the capacity of SMEs and producer organisations, despite their central role in developing traditional food value chains.

In this context, and given increasing policy attention to forest-based bioeconomies and sustainable rural development, the analysis identifies the following priority areas where further action could facilitate access to EU markets for traditional foods.

More accessible and practical guidance

While EFSA provides detailed scientific guidance, applicants require an intermediate level of support that translates these requirements into practical terms. This includes clear explanations of the overall process, expected evidence, timelines, and cost implications. Providing simplified guidance materials, process overviews, and practical tools in relevant languages (e.g. Spanish and Portuguese) would support more informed decision-making at early stages. Allowing applications in these languages, or improving access to EFSA support in these languages, could further reduce translation costs and reliance on specialised consultants.

Access to experienced expertise and practical examples

Progress across the cases analysed relied heavily on specialised external expertise. However, access to individuals or organisations with experience in preparing successful dossiers remains limited and difficult to identify. Facilitating access to applied regulatory, scientific, and legal expertise, as well as to structured examples or annotated summaries of successful applications, would help reduce uncertainty and improve efficiency in dossier preparation.

Improved access to analytical infrastructure

Strengthening regional laboratory capacity, including support for internationally recognised laboratory accreditation, could help reduce reliance on overseas laboratories and the associated costs and delays.

Institutional coordination and support

The cases demonstrate the importance of coordinated institutional involvement. Establishing clear national coordination mechanisms or contact points could support alignment between ministries, research institutions, laboratories, and producer organisations. Such structures can facilitate the organisation of inputs, interpretation of regulatory requirements, and engagement with EFSA throughout the application process.

Regional knowledge sharing

As many biodiversity-based products occur across multiple countries, there is scope to reduce duplication through regional collaboration. Shared approaches to data generation, the documentation of traditional use, and laboratory methodologies could allow knowledge developed in one case to support others, thereby reducing costs and accelerating future applications.

Market validation prior to application

Given the high level of investment required, applicants need reliable ways to assess market potential before committing to a dossier. As direct market testing is often not feasible for products classified as novel foods, stakeholders indicated that limited and controlled forms of market validation, where safety considerations can be ensured, could help reduce uncertainty and support more informed investment decisions.

The European Commission has recently proposed amending the EU General Food Law to allow the creation of “regulatory sandboxes” – controlled environments in which innovative products can be tested prior to

market authorisation.[11] The proposal recognises the role that such environments can play in supporting innovation and product development, and in the generation of evidence. Novel foods are excluded from the scope of this proposal, reflecting broader consumer protection concerns in this area. However, traditional foods from non-EU countries are a distinct category within the Novel Food Regulation (2015/2283), and are subject to a simplified procedure based on evidence of safe use. A complementary and appropriately safeguarded system of regulatory sandboxes could be explored for such products to facilitate limited market validation prior to authorisation.[12]

Targeted technical and financial support

Preparing a traditional food dossier requires resources and expertise that typically exceed the capacity of SMEs and producer organisations. Targeted support mechanisms, including funding, technical assistance, and coordination support, are therefore essential to enable engagement in the authorisation of traditional products, particularly where these products contribute to broader objectives such as forest conservation and rural development.

11 Proposal: Biotech Act
12 AGRINFO (2026) *Biotech Act strengthening the biotechnology sector*.

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European Commission and EFSA resources to support novel foods applications

Regulatory framework & guidance documents	
Legislation	Regulation 2017/2469 on administrative and scientific requirements for novel food applications Regulation 2017/2470 on establishing the Union list of novel foods Regulation 2015/2283 on novel foods European Commission: Novel Food: Authorisations EFSA: Confidentiality and sanitisation
Application procedure	Application procedure for novel foods
Product status overview	EU Novel Food Status Catalogue
Administrative guidance	Administrative guidance for the preparation of novel food applications
Scientific guidance	Guidance on the scientific requirements for an application for authorisation of a novel food Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain
Support initiatives and services	
Services for applicants	EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products
Ask a question	Ask a question The Portal – Account registration and Ask A Question [video] The Portal – Public Access to Documents [video]
Pre-submission advice	General pre-submission advice (GPSA) Renewal pre-submission advice (RPSA) General pre-submission advice – GPSA [video] Pre-application ID and list of intended studies [video]
Clarifications	Clarification teleconference during completeness/suitability check Clarification teleconference during risk assessment Clarification teleconference during Pesticide Peer Review and assessment of MRL application
Post-submission phase	Post-adoption teleconference

IT platforms for application management	
Pre-submission registration	Connect.EFSA (EFSA Toolkit) User Guide Pre-application ID User Guide on Notification of studies
Application dossier-building tools	Food Additives Intake Model R4EU Platform Dietary Exposure tool - DietEx
Submission	E-submission Food Chain platform – ESFC
Progress monitoring	Open.EFSAportal
Post-adoption	EFSA Journal

Annex I. Interview guides

Guide for direct stakeholders

Topic 1. Introduction

1.1 Could you briefly introduce yourself, your organisation, and your role in relation to novel or traditional food applications?

1.2 Introduction to COLEAD study

- Study on the EU market access for novel traditional food products from the Amazon region, commissioned by COLEAD as part of its EU-funded AGRINFO programme. COLEAD, the association behind this study, is a not-for-profit association that implements development programmes in the agri-food sector. The study will be made publicly available and presented to the EU authorities, including the European Commission, to increase their awareness of the difficulties and costs of applying for this authorisation.

1.3 Short introduction, interviewer, and Q-Point

- This study is conducted by Q-Point together with Zeigler Advogados from Brazil.

1.4 Purpose of the study

- Gain deeper insight into the costs, challenges, and support needs related to the authorisation of traditional forest foods from the Amazon region as novel foods, to facilitate their access to the EU market.
- Learn from it, guide others in increasing EU market access for novel traditional food products, and share findings with the European Commission.

1.5 The interview will take about an hour.

1.6 Any questions before we start?

Topic 2. General understanding

2.1 How did you first become aware of the requirements for preparing a traditional novel food dossier for the EU?

- Which sources of information or guidance did you use?

2.2 On what dossiers/applications have you/your company worked, or are working on?

2.3 How was the preparation of the dossier organised within your organisation?

- Who was responsible for coordinating the process?
- Did you rely mainly on internal staff or external expertise (consultants, labs, advisors)?

Topic 3. Application content and data generation

3.1 Content of the application

- Identity of the novel food
  - How did you approach the requirements related to the identity of the product?
  - How did you gather or generate the necessary information?
  - Were there any particular difficulties or uncertainties?
- Production process (description of production and processing steps)
  - How did you understand the requirements?
  - How did you gather or generate the information?
  - Did you encounter any particular challenges when documenting traditional practices or variations in production methods?
  - How did you address these?

- Compositional data
  - How did you obtain compositional data for the product?
  - Which parameters were analysed (moisture, fat, proteins, fibre, contaminants, microbiology)?
  - How many batches were analysed, and which laboratories were used?
  - Were there any practical constraints related to costs, laboratory capacity, or methods?
- Specifications
  - How did you establish product specifications and stability data for the dossier?
  - Were there any aspects that required additional clarification or data?
- History of use of the novel food and/or its source
  - How did you document the history of safe use of the product?
  - What types of sources or evidence were used?
  - Were there any gaps or limitations in the available information?
- Proposed uses and anticipated intake levels
  - How did you define the proposed uses and intake levels for the EU market?
  - Were there any differences between traditional uses and the proposed EU uses?
  - How were intake levels estimated?
- Toxicological and nutritional safety data
  - What types of safety or nutritional data were required for the application?
  - How did you obtain this information?
  - Were additional studies requested during the process?

3.2 Reflections on data and reporting

- Looking back at the process, which requirements required the most time or resources?
- Were there any requirements that you found particularly difficult to interpret or implement?

Topic 4. Process and interaction with authorities

4.1 E-submission portal

- How did you find the portal interface?
- Was it clear which route applied (traditional food notification vs full application)?
- Were instructions and document checklists easy to follow?

4.2 Communication and objections

- Did you receive questions or objections during evaluation?
- How were these communicated?
- Were you able to clarify issues before escalation?
- What were the most common objection topics (composition, safety, contaminants, vulnerable groups, etc.)?

4.3 Unexpected issues

- Were there any positive surprises or challenges that you did not anticipate?

4.4 Outcome and impact

- What was the final result (approved, pending, withdrawn)?
- Is the product now marketed in the EU?
- Did costs or delays affect smallholders, women, or youth in your value chain?

Topic 5. Financial and human resources aspects

5.1 Roughly how many person-months were invested in the process (data gathering, lab work, dossier writing, admin)?

5.2 What type of expertise was needed (regulatory, toxicological, nutritional, analytical)?

5.3 What were the financial costs involved for the entire process?

5.4 What were the main cost components (lab tests, studies, translation, consultancy, admin)?

- Please provide a rough division of costs across the different cost components (e.g. laboratory analysis, consultancy, studies).

5.5 Where were laboratory analyses conducted (locally or abroad)? Follow-up: what were the implications in terms of costs or timelines?
5.6 How were these costs distributed across stages (data generation/ application writing/ EFSA communication)?
5.7 To what extent were there any unexpected or hidden costs?
5.8 Did you access any financial support or technical assistance? From which source(s)?

Topic 6. Support mechanisms and lessons learned

6.1 What types of support or guidance were most useful (formal or informal)?
6.2 In case no support was available, what kind of support would have made the biggest difference (e.g. small grants, shared lab access, expert pool)?
6.3 Which organisations, agencies, or associations were most helpful?
6.4 Have you participated in any training, capacity building, or market access programmes?
- How useful were they?

6.5 What support do you think is missing (technical, financial, institutional)?
6.6 What were the consequences of any support being missing?
6.7 Are there any initiatives that specifically help women- or youth-led producers?

Topic 7. Looking forward

7.1 Are there any initiatives that specifically help women- or youth-led producers?
7.2 What changes or clarifications could make the authorisation process more accessible for traditional foods from the Amazon region?
7.3 What one change would reduce costs or time the most (e.g. model dossier, clearer templates, earlier feedback opportunities)?

Topic 8. Closing

8.1 Is there anything else you would like to add?
8.2 Thank you for your time and valuable contributions to this study.
8.3 The report will be made available and shared with the relevant EU authorities, as well as with the interviewees.

Guide for indirect stakeholders

Topic 1. Introduction

1.1 Could you briefly introduce yourself, your organisation, and your role in supporting companies or producer groups involved in the export or authorisation of traditional food products?
1.2 Introduction to COLEAD study
- Study on the EU market access for novel traditional food products from the Amazon region, commissioned by COLEAD as part of its EU-funded AGRINFO programme. COLEAD, the association behind this study, is a not-for-profit association that implements development programmes in the agri-food sector. The study will be made publicly available and presented to the EU authorities, including the European Commission, to increase their awareness of the difficulties and costs of applying for this authorisation.

1.3 Short introduction, interviewer, and Q-Point
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- Gain deeper insight into the costs, challenges, and support needs related to the authorisation of traditional forest foods from the Amazon region as novel foods, to facilitate their access to the EU market.
- Learn from it, guide others in increasing EU market access for novel traditional food products, and share findings with the European Commission.

1.5 The interview will take about an hour.
1.6 Any questions before we start?

Topic 2. Experience and understanding of the process

2.1 Support experience
- Has your organisation directly supported or advised companies preparing a novel or traditional food dossier?
- If yes: which types of companies or products? (No need to name them if confidential.)
- What kind of support did you provide (technical, financial, regulatory guidance, coordination, promotion)?
- At what stage do producers usually reach out for assistance: before, during, or after starting the dossier?

2.2 General understanding
- How aware are producers and exporters in your country of the EU's novel/traditional food requirements?
- Where do you see the main knowledge or information gaps?
- Which organisations (public or private) are typically involved in helping companies understand these procedures?
- From your experience, to what extent do producers correctly estimate the time or costs involved?

Topic 3. Observed challenges in data generation and documentation

3.1 From your perspective, what are the main challenges producers face in meeting EFSA's scientific requirements, such as nutritional, toxicological, or allergenicity data, or a history of safe use (25 years)?
3.2 Which parts of the dossier preparation process tend to require the most time or resources? (e.g. history of safe use, compositional analysis, toxicology data, documentation of production process)
3.3 Where do most of the costs arise, laboratory analyses, consultancy, or administrative steps?
3.4 Are there local institutions, laboratories, or databases capable of generating or validating this type of evidence?
- If not, how do producers usually obtain or verify the required data?

3.5 How well do EFSA's data requirements align with the type of information typically available in your region?
- E.g. requirements for toxicological studies, validated methods, or long-term consumption data.
- Are there examples where additional studies or analyses were required?

3.6 To what extent do applicants face challenges gathering evidence for the "25 years of safe use"?
- What kind of local or traditional knowledge is hardest to formalise?

3.7 How could data generation or recognition of existing evidence be improved (e.g. regional databases, collaboration with universities, simplified guidance)?
3.8 To what extent have you seen cases where a lack of clear templates or guidance caused extra time or expense?
3.9 How do these requirements affect smaller producers or community-level organisations?

Topic 4. Institutional and procedural challenges

4.1 How do you assess the clarity of EFSA or EU guidance for producers from your country?
4.2 Are there mechanisms for communication or pre-consultation with national authorities or EU bodies?
4.3 Do you see (in)consistencies between national expectations and EU-level requirements that add to costs or confusion?
4.4 To what extent have you seen delays or duplications in communication between companies, ministries, and EFSA?
4.5 Have you observed cases where the "history of safe use" evidence was not accepted, and additional studies were requested?

Topic 5. Financial and resource aspects

5.1 Based on your knowledge, what are the average cost ranges or main cost drivers for applicants from your region (e.g. laboratory testing, dossier drafting, translation, toxicology studies, consultancy fees)?

5.2 Which groups are most affected by these costs: SMEs, cooperatives, community organisations, women- or youth-led groups?

5.3 To what extent do public funds or donor programmes exist to offset part of these costs (e.g. national export agencies, EU programmes, GIZ, IDB)?

5.4 Are these support mechanisms accessible in practice, or too complex or limited in scope?

5.5 Have you seen innovative or cost-sharing approaches (e.g. group applications, shared studies, regional data platforms)?

Topic 6. Support mechanisms and capacity building

6.1 What kinds of technical assistance or training currently exist to help producers navigate the novel food process?

6.2 Which types of support have proven most useful or cost-effective (e.g. guidance materials, coaching, funding)?

6.3 Which organisations are leading such efforts (Ministries, chambers, NGOs, international programmes)?

6.4 What gaps remain: technical, financial, institutional, or language-related?

6.5 Are there support measures specifically targeting women or youth producers?

Topic 7. Lessons learned and looking forward

7.1 Based on your experience, what changes or improvements could make the authorisation process more accessible for producers in your region?

7.2 What one change would most reduce cost or time (e.g. clearer templates, model dossiers, data-sharing mechanisms, local recognition of labs)?

7.3 How could coordination between national authorities and EU institutions be strengthened?

7.4 Are there opportunities for regional collaboration or pooling of resources (e.g. shared databases, common lab infrastructure, regional helpdesks)?

Topic 8. Closing

8.1 Is there anything else you would like to add?

8.2 Thank you for your time and valuable contributions to this study.

8.3 The report will be made available and shared with the relevant EU authorities, as well as with the interviewees.

GROWING PEOPLE

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