



About the project

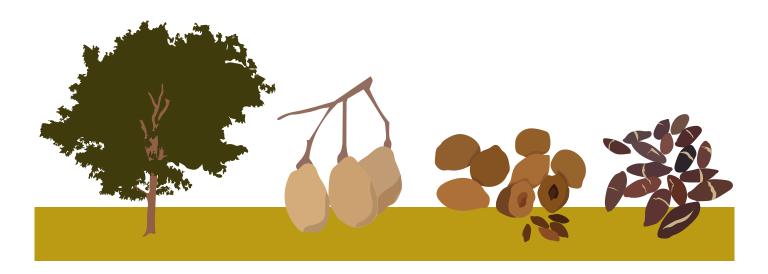
The Baru project aimed to bolster the protection of the Cerrado biome, also known as the Brazilian Savanna. Cerrado plays a crucial role in climate regulation, serving as a significant carbon sink and helping to maintain the ecological balance of the region. Covering approximately 25% of Brazil's territory, the Cerrado biome is considered one of the world's biodiversity hotspots, meaning that it is characterised by exceptionally high levels of species richness and endemism. However, the region also faces significant threats to its ecosystems and biodiversity.

Cerrado is under severe threat from agricultural expansion, mainly from cattle and soya producers. Already, it has lost a staggering 45% of its original vegetation. This rapid deforestation poses a significant risk not only to the

biodiversity of the region, but also to the livelihoods of various traditional and local communities that depend on its natural resources for subsistence.

Moreover, the Cerrado biome provides many NTFPs that are utilized by a diverse range of industries and markets. From agricultural products to medicinal plants, the Cerrado biome offers valuable resources that support economic activities and contribute to the well-being of both local communities and the broader society. One of those NTFPs is the Baru nut, which is collected from the remaining Cerrado areas by local communities. This practice serves as a source of income for these communities, as well as contributing to the conservation of the Cerrado biome by providing economic incentives for its preservation.

Infographic 1: Baru tree, fruits and nuts



The Baru, scientifically known as *Dipteryx alata*, is a fruit species indigenous to the Cerrado biome of Brazil. Renowned for its exceptional nutritional value, the nut serves as a versatile ingredient with various culinary applications. It can be consumed raw, providing a crunchy texture and a rich, nutty flavour, or roasted, to enhance its aroma and flavour profile. Additionally, the Baru nut can be processed into a wide range of products, including flour, cookies, hummus, oil, or protein bars. This versatility makes it a popular ingredient in both traditional and modern cuisine.

The Baru nut value chain holds significant importance within the Brazilian sociobioeconomy, contributing to the local economy and serving as a vital component of regional trade and commerce. Its unique from the Cerrado biome. This exclusivity adds to its value and reinforces its significance as a key bioeconomy product within the Brazilian context.

The Baru nut is known by various names across Brazil, reflecting its cultural diversity and regional variations. Common alternative names for the Baru nut include bajuró, cumaru, cumarurana, and feijão-coco, among others.

¹ ICMBio www.icmbio.gov.br

 $^{^{\}rm 2}$ Brazilian Ministry of the Environment. Souce: https://www.gov.br/mma/pt-brazilian Ministry of the Environment.

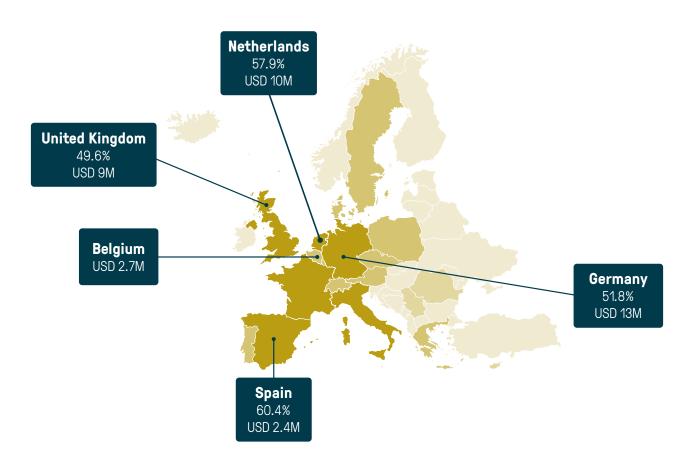
Unlocking international markets for Non-Timber Forest Products

Many NTFPs are not yet registered in international markets such as the UK or EU, where they are classed as 'novel foods'. However, those markets are experiencing a growing demand for sustainable products, and so can be strategic potential markets for bioeconomy products that value the standing forest while creating social benefits for the local communities.

The infographic below looks at the potential of nut exports from Brazil, and demonstrates the relevance of individual markets within Europe. Germany stands out among these, displaying the largest absolute difference between potential and actual exports in value terms. This suggests untapped opportunities for Brazil to increase its nut exports to Germany, with the potential to realize additional exports worth USD 13 million (£11.1 million).

Infographic 2

5 biggest untapped potential markets for nuts from Brazil in the EU and UK (August 2023)



To capitalise on these opportunities, Brazil must strategically position the NTFPs in international markets, emphasising their nutritional benefits, culinary versatility, and sustainable production practices. Additionally, efforts to establish partnerships with distributors, promote product awareness, and meet quality and safety standards are crucial for successfully penetrating and expanding in these lucrative markets.



How can small businesses afford to register NTFPs?

Several avenues exist for small forestry businesses to access financial support to register novel foods in international markets. Government agencies or non-profit organisations that support agricultural or forestry initiatives may offer grants or subsidies to often assist with regulatory compliance costs, including registration fees and laboratory testing expenses. Another option may be to partner with research institutions or universities offering funding for research and development projects related to novel food registration. Crowdfunding platforms and venture capital firms focused on sustainable agriculture and food innovation also offer potential

funding opportunities for small forestry businesses entering international markets with novel food products.

To access those types of fundings, the storytelling presented to those agencies is key. When the proposal for funding shows a concrete rationale that it can unlock investments to sustainable value chains it becomes appealing due to the potential social and environmental positive impacts. On the infographic below it is possible to see the strategy behind the Baru project, that was presented to an internal committee and selected to receive funds from P4F.

Infographic 3: Project strategy







VALUING STANDING FORESTS



INCREASE
IN INCOME
FOR LOCAL
COMMUNITIES

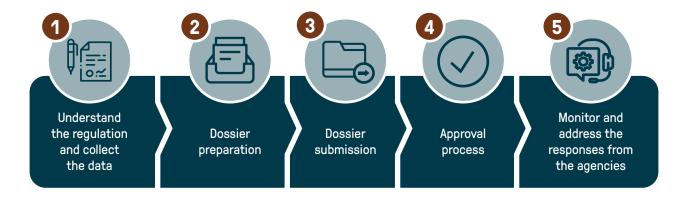
A large portion of non-timber forest products are still not registered in international markets



The registration process

This is a step-by-step guide of the registration process of novel foods in the UK and EU based on the Baru registration experience. Each step is shown in the infographic below and will be described in the following chapters of this material. The specific details of the EU registration process will be used as the primary example, but the UK's registration process operates in a comparable manner, with similar requirements and timeframes.

Infographic 4: Registration process of novel foods





The registration of a novel food has some specific elements that must be understood before starting the process. It is essential to note that the registration is specific to each state of the product being submitted. For instance, if we consider the registration of Baru nuts as an example, only the roasted Baru nut will be registered. This means that other forms of the nut, such as the raw nut, oil derived from it, or products made with Baru nuts, will not be authorised until a separate registration process is completed.

Additionally, once the registration is approved, any producer who adheres to the exportation guidelines can export the product. This means that the authorisation is not exclusive to the original applicant of the registration.





The steps to completing the registration process are as follows:

1 Understand the regulation and collect the data

The first step is to allocate team time or bring the right expertise on board. In our experience with the Baru nut project, we decided to partner with consultants Hogan Lovells and Exponent to complement P4F's skills with strong legislation knowledge and scientific backgrounds respectively.

Novel foods in the EU and the UK refer to foods that originate from various sources such as plants, animals, microorganisms, cell cultures, minerals, and specific categories like insects, vitamins, minerals, and food supplements. These foods may also result from production processes and state-of-the-art technologies, including intentionally modified or newly structured molecules and nanomaterials. However, novel foods do not include items such as enzymes, additives, flavorings, extraction solvents, or genetically modified organisms (GMOs).

Under the novel foods regulation in the EU and the UK, traditional foods from third countries undergo a simplified approval process for foods with a history of safe consumption in their country of origin. For traditional foods from third countries to be approved, they must have been consumed for at least 25 years as part of the customary diet of a significant number of people. The approval process involves submitting a dossier of information supporting the notification, including evidence of consumption history and other relevant data. As such, the starting data research should focus on proving the historical consumption of the NTFP. Scientific papers, books, and supply information from companies are good sources of evidence.

The regulation of novel foods outlines procedures for determining the novel food status of a product when it is not clear, including requesting formal opinions from competent authorities and consulting with EU countries where the food is intended to be marketed.

The Novel Food Catalogue is a historical record of discussions and reviews related to novel foods. It provides information on whether a food has a history of consumption, whether it was previously only used in food supplements, or if there is no consumption history, indicating that it is considered novel. This catalogue should be consulted to better understand the status of the food before starting the registration.

2 Dossier preparation and submission

This phase involves compiling a comprehensive dossier that satisfies regulatory requirements to pave the path for market approval. That often is the most demanding part of the process. Challenges faced in this stage during the Baru registration process included:

- Providing evidence of Baru nuts' traditional use: Regulatory stipulations demanded proof of consumption dating back 25 years, necessitating extensive research efforts. This phase took longer than first anticipated. While some NTFPs like Baru may have been consumed for many years, there is not always accessible evidence of this consumption, which can complicate the process.
- Engaging with specialised laboratories: It is important to find a laboratory that can conduct thorough analyses using validated methods. Search for entities with comprehensive testing protocols.
- The duration of stability testing: This test is essential for assessing the shelf-life and quality of the product. It typically takes around a year to be complete. Starting the stability tests at the beginning of the workplan can reduce overall timelines of the process.

Infographic 5: Dossier structure

Dossier structure



Administrative data

- Identity of the traditional food to be authorised
- Applicant's contact details
- Person responsible for the dossier contact details
- If appropriate, confidentiality requests
- Proposed entry in the Union list (conditions of use, specific labelling requirements)
- Regulatory status outside the EU
- Cover Letter, specifying the content of the submission



Technical dossier

- Pre-application information
- Identity
- Production process
- Compositional data
- Specifications
- Data from experience of continued use
- Proposed conditions of use
- Concluding remarks
- Annexes and references



Public summary

A short summary of the dossier should be provided. This document will be made available to the public and should not contain any confidential information.

In submitting a notification for a traditional food, the applicant must compile essential information, including their name and address, a detailed description of the traditional food, its composition, and the country or countries of origin. Crucially, documented data demonstrating the history of safe food use in a third country must be gathered and presented. Additionally,

a proposal outlining the intended conditions of use and specific labelling requirements, ensuring they do not mislead consumers, is required. Once the notification package is prepared, it is submitted to the relevant regulatory authority in the UK and the EU electronically.

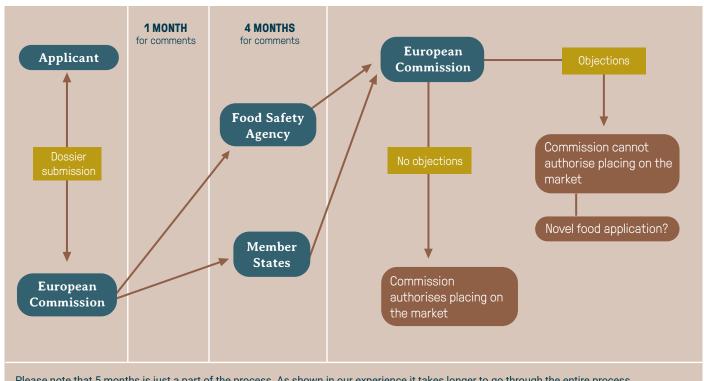
Approval process

The authority then reviews the notification, assessing compliance with regulatory standards before issuing approval for market entry. Throughout the process, prompt responses to any feedback or requests for additional information are essential to facilitate a smooth review process and eventual authorization for commercialisation.

Once the applicant submits the dossier, it goes through a suitability or validity check (to ensure all the required documents are submitted) and following that it goes through the risk assessment process. On the infographic 5 you can see the process of traditional novel food approval in the EU. The process is similar for the UK, with similar timeframes. Once the dossier is submitted, it usually takes at least five months for the assessment to be completed. If the regulatory authority provides the applicant with a request for information during their review, then this timeframe is paused, and the applicant needs to address the requests before the process is continued.

Infographic 6: Approval process of traditional novel foods

Process for traditional food approval in the EU



Please note that 5 months is just a part of the process. As shown in our experience it takes longer to go through the entire process.

Monitor and address the responses from the agencies

Monitoring and addressing responses from regulatory agencies are crucial. Upon submission of a notification, it is essential to remain attentive to any feedback or requests for additional information from the regulatory authorities. Timely and thorough responses to these inquiries are paramount to ensure a smooth review process and eventual authorization for market entry.

Once authorisation is granted, and it is published in the Official Journal, the novel food can be placed on the market. The European Union list of approved novel foods is established

through Commission Implementing Regulation, which includes detailed information on authorized novel foods, such as specific food categories, maximum levels of use, additional labelling requirements, and any other particular requirements. Each time a new novel food is authorized, a new Implementing Regulation is adopted to amend Regulation 2017/2470, reflecting the dynamic nature of novel food approvals and regulatory updates. Authorsations are typically generic, unless the applicant has been granted exclusivity based on proprietary data. In such cases, the applicant may market the novel food exclusively for a period of five years following authorisation.

Project's timeline

The timeline of the Baru registration project is described below. Please note that the project activities of the first phase of P4F ended in February 2024. The applicant is currently tracking the responses of the food safety agencies from the UK and the EU. Based on current timeframes, we expect to have a decision on the authorisation of the Baru nut by September 2024.

Infographic 7: **Project experience**

April

Start of the export of Brazilian NTFPs project which inspired the Baru Register Project

August

Hiring of Hogan Lovells to assist with product registration process in the EU and the UK

• March

Dossier submission to the UK and EU Commission

May

European Commission & UK FSA: follow-up questions

September

Search for additional data: engaging with additional baru nut producer

2020

2022

2023

- Market assessment for Baru nuts in international markets
- Identification of interested European buyers
- Development of Brazilian Baru nut cooperatives' export capacity
- Mapping of the registration process in the EU and the UK

- HL engaged Exponent for scientific and technical expertise
- Data gap analysis
- Baru nuts approved in Switzerland
- Development of notification dossier for Baru nuts registration as a traditional food with the support of the applicant
- The Commission and UK Food Safety Agency assess the validity of the application, its completeness and the presence of the required information
- Additional questions
- Compositional analysis
- Stability Studies shelf-life
- Annexes

September

Close cooperation:

Producers P4F Hogan Lovells Exponent

• January

Finalizing data collection and input

February

Dossier submission to the UK and EU Commission

April

If validated: Notification submission to the Member States and EFSA

September

Best case scenario: Baru is authorised to enter the EU and the UK markets

2023

2024

 Identify laboratory in Brazil to carry out additional testing

- Verification of suitability of methodologies used
- Regular ongoing engagement with producers
- Close contact with EU Comission on expected timeline for feedback
- Review of additional data and finalising notification dossier for baru nuts registration as a traditional novel food
- Reference to Swiss approval

• The Commission and UK FSA assess the validity of the application, its completeness and the presence of the required information

- EFSA suitability check deadline of the 9th April 2024
- Member States or EFSA may submit any "duly reasoned safety objections".
- Where no objections have been submitted, the Commission will authorise the placing on the market of the traditional food and update the Union list



This case study
was developed
by Partnerships
for Forests in
Latin America,
in collaboration
with the External
Relations and
Knowledge global
team

Marcio Sztutman

Regional Director

Iara Basso

Regional Manager

Monica Souza

Results Manager

Isabelle Smith

Monitoring, Evaluation and Learning

Isabella Granero

Monitoring, Evaluation and Learning

Gen McFalls

External Relations and Knowledge Manager

Design

Estúdio Utópika









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