GUIDE TO SUBMITTING PROPOSALS FOR TECHNICAL STANDARDS FOR NATIVE SPECIES PRODUCTS AS DRAFT REGIONAL OR INTERNATIONAL STANDARDS

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ACRONYMS AND ABBREVIATIONS

AACC
American Association of Cereal Chemists

AOAC
Association of Official Analytical Chemist

IAAC
Inter-American Accreditation Cooperation

CAC
Codex Alimentarius Comission

CCLAC
FAO/WHO Coordinating Committee for Latin America and the Caribbean

CBD
Convention on Biological Diversity

CD
Committee Draft

COPANT
Pan-American Commission for Technical Standards

DEVCO
Committee on Developing Country Matters

DIS
Draft International Standard

FAO
Food and Agriculture Organization of the United Nations

FDIS
Final Draft International Standard

IFT
Institute of Food Technologists

ICONTEC
Colombian Institute of Technical Standards and Certification

INACAL
Peruvian National Institute of Quality

INEN
Ecuadorian Standardization Service

INFOSAN
International Food Safety Authorities Network

ISO
International Organization for Standardization

JECFA
Joint FAO / WHO Expert Committee on Food Additives

JMPR
Joint FAO / WHO Meeting on Pesticide Residues

MRL
Maximum Residue Limits for pesticides

MSME
Micro, Small and Medium Enterprise

NCBI
National Center for Biotechnology Information

NMI
National Metrology Institute

NP
New Work Item Proposal (for a draft ISO standard)

NSB
National Standards Body

NWIP
New Work Item Proposal (for an ISO technical committee)

OAS
Organization of American States

PTB
Physikalisch-TechnischexBundesanstalt
German National Metrology Institute

PWI
Preliminary Work Item (of the draft ISO standard)

SDG
Sustainable Development Goals

SIM
Inter-American Metrology System

TMB
Technical Management Board

UNEP
United Nations Environment Program

UNFCCC
United Nations Framework Convention on Climate Change

USDA
US Department of Agriculture

VPP
Vegetable Protein Products

WD
Working Draft (of an ISO standard)

WTO
World Trade Organization

FOREWORD

This guide was developed within the framework of the Regional Quality Infrastructure Fund for Biodiversity and Climate Protection in Latin America and the Caribbean, with the objective of providing guidance for national authorities, national standards bodies, national technical committees on standardization and stakeholders (including exporters or importers of native species products, as well as consumers of such products) on developing standards for native species products, as well as offering technical support for national standards bodies in charge of organizing the submission of draft international standards to the International Organization for Standardization, ISO, and proposals on regional or international standards to the *Codex Alimentarius*.

The aim of this document is to help strengthen the Quality Infrastructure services that support efforts to ensure the conservation and sustainable use of biodiversity in developing countries, and which enable compliance with the obligations entered into as part of biodiversity-related agreements[1].

It also seeks to facilitate and promote greater participation by developing countries in international standardization bodies as proposers and leaders in developing draft international standards on native species products.

This guide is the result of a joint effort by the national standards bodies of Colombia (ICONTEC), Ecuador (INEN) and Peru (INACAL) to systematize their knowledge, experience and processes in order to make proposals to the international standards bodies.

1. Informea. *Treaties and MEAs in Biological diversity* [online]. Available at: https://www.informea.org/en/treaties/biological-diversity

Divided into nine sections, it is organized around two important components:

1. The first is geared towards **identifying a native species of global commercial interest that requires a standardization service to protect its genetic value and encourage sustainable trade in international markets.** Here, the reader will find guidelines and criteria for the proper characterization of products, which serves as a basis for compiling the supporting documentation that must accompany any proposals for draft international standards submitted to ISO, and the *Codex Alimentarius*.

2. As part of the second component, the reader will find **guidelines and templates for beginning the process of submitting draft standards to ISO, or the *Codex Alimentarius***, to ensure that the draft text has the greatest possible chance of being included in the work plan of the corresponding international technical committee. Finally, the reader is presented with three case studies detailing the experience of Colombia, Ecuador and Peru in developing technical standards on native species products and submitting them as draft international standards.

In this regard, it is important to note that this guide has been prepared based on ISO Directive 1 and the *Codex Alimentarius* Procedural Manual in force at the date of publication. In addition, the content of this guide has been supplemented with relevant information gleaned from the technical experience of those who participated in its preparation.

We hope that this guide will prove helpful when characterizing native species products for the purpose of developing draft international standards on product requirements.

1 INTRODUCTION

Latin America and the Caribbean are home to the greatest biodiversity on the planet, and since many of the world's megadiverse countries are found there, the sustainable management of its biodiversity resources is a priority for the region (UNEP, 2016). Its wealth extends to the genetic value of the species native to the region, as well as the value of the ecosystem services provided by its unique biodiversity. Harnessing biodiversity resources and services through sustainable use benefits their conservation, while contributing to equitable social and economic growth (UNEP, 2010).

The conservation of the terrestrial ecosystems that sustain native species with special commercial potential could be accompanied by other actions, such as the recovery of natural surface water sources; respect for traditional knowledge, innovations and practices; and equitable distribution of the benefits arising from their use, which would help meet the Aichi Biodiversity Targets and contribute to collaborative actions designed to mitigate and adapt to climate change.

Globally, consumers are demanding more and more native species products due to their origin and natural properties, which offer nutritional and aesthetic benefits. Native species products cover the spectrum from foodstuffs to body care and beauty treatments, among other goods.

A solid Quality Infrastructure facilitates access to foreign markets through a systematic approach that responds to market demand.

In order to safeguard sustainable commerce that is free from technical barriers to trade in native species products, it is necessary to strengthen Quality Infrastructure services throughout the native species value chain, from raw material harvesting or production, through transformation into end products, up to the final consumption of these products.

In this sense, the Regional Quality Infrastructure Fund for Biodiversity and Climate Protection in Latin America and the Caribbean constitutes an important space for enhancing the Quality Infrastructure. Launched in 2014, this Regional Fund is a project designed to improve Quality Infrastructure services aimed at developing and supplying new and innovative services in the fields of biodiversity and climate in Latin American and Caribbean countries.

The Fund seeks to consolidate the internationally interconnected and recognized components of the Quality Infrastructure, in order to reduce the risks associated with creating isolated solutions, and avoid ending up with structures that would lead to high costs for the users of Quality Infrastructure services (consumers, industry and governments).

Within this framework, by implementing subprojects – including this guide – the Regional Fund is addressing the need for Quality Infrastructure services that benefit the governments of the participating countries, their industries – particularly MSMEs – and consumers. In addition, it is fostering regional cooperation and integration between the countries of Latin America and the Caribbean and, at the global level, contributing to the process of transition towards a green economy on the part of industry and consumers.

In Latin America and the Caribbean, many native species products are harvested by MSMEs, and the processing and transformation stages provide income and economic growth opportunities. Encouraging the participation of MSMEs in the process of developing and submitting standards for native species products to international organizations would enhance their supply chain and increase their share of the final product

value. In this context, contributing, through the standardization service, to the creation of value chains for native species products would support the region's efforts to reduce its poverty rates.

However, the participation of Latin American and the Caribbean countries, and developing countries in general, as proposers and in leadership positions in international standards bodies, remains limited. Furthermore, the countries of the region have very little involvement in compiling and systematizing past experiences and lessons learned when submitting draft international standards, and they have scant access to this information. This guide thus offers an opportunity for developing countries to position themselves in international standards bodies by submitting proposals for regional or international standards for native species products, and to benefit from more active participation, which could have an impact on the conservation and sustainable use of the region's biodiversity, the sustainable economic growth of MSMEs, as well as consumer well-being and support in making better decisions involving native species products in the national and international market.

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PURPOSE AND SCOPE OF THE GUIDE

The main purpose of this document is to guide national authorities, national standards bodies, national technical committees and stakeholders, including exporters or importers of native species products, as well as consumers of these products, in developing technical standards for native species products, including the preliminary study, content and structure of the proposed standards. This guide offers educational and practical guidelines for establishing and standardizing the minimum quality and performance requirements for native species and their by-products. It is intended to provide technical support for the national standards bodies that submit proposals to ISO or the *Codex Alimentarius* as draft international or regional[2] standards, to ensure that they contribute to the conservation and sustainable use of biodiversity, and thus promote greater participation by developing countries in international standards bodies.

This guide offers educational and practical guidelines for establishing and standardizing the minimum quality and performance requirements for native species and their by-products.

2. This only applies to the *Codex Alimentarius*, as its various bodies develop international or regional standards.

This guide can be used by any developing country that is interested in submitting draft standards on native species products to its biodiversity to ISO or the *Codex Alimentarius*.

This guide covers the characterization of native species products that have been cultivated or domesticated, the results of which can serve to develop draft international standards.

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TERMS AND DEFINITIONS

For the purpose of this guide, we have used definitions related to biodiversity, standardization and other terms that are provided here as a reference for the reader.

3.1. General terms

3.1.1. Biodiversity / Biological diversity

The variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

3.1.2. Biological resources

Genetic resources, organisms or parts thereof, populations or any other type of biotic component of ecosystems with actual or potential use or value for humanity.

3.1.3. *Codex Alimentarius*

Set of standards, guidelines and codes of practice adopted by the *Codex Alimentarius Commission*. The Commission, also known as CAC, constitutes the central pillar of the Joint FAO/WHO Food Standards Program and was established by the FAO and the World Health Organization (WHO) with the

aim of protecting the health of consumers and promoting fair practices in the food trade.

3.1.4. Domesticated or cultivated species

Species in which the evolutionary process has been influenced by humans to meet their needs.

3.1.5. International standard

Standard that is adopted by an international standardization organization and made available to the public.

3.1.6. International Standards Body

Standards body of which the national body can be a member.

3.1.7. ISO (International Organization for Standardization)

An independent international non-governmental organization made up of members of the national standards bodies worldwide.

3.1.8. National authority

Body with legal powers and rights.

N.B. *A national authority can be regional or local.*

3.1.9. National standard

Standard that is adopted by a national standardization organization and made available to the public.

3.1.10. National Standards Body (NSB)

Nationally recognized standards body, which has the right to be the national member of the corresponding international and regional standardization organizations.

3.1.11. Native species

Species, subspecies or lower taxon occurring within its natural range (former or present) and dispersal potential, i.e., within the range it occupies naturally or could occupy without direct or indirect introduction or care by humans.

3.1.12. Regional standard

Standard that is adopted by a regional standardization organization and made available to the public.

3.1.13. Regional Standards Body

Standards body of which the national body representing each country can be a member, within the same geographical, political or economic region.

3.1.14. Standard

Document established by consensus and approved by a recognized body, which provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at achieving the optimum degree of order in a given context.

N.B. *Standards should be based on the consolidated results of science, technology and experience, and their objectives should be the promotion of optimal benefits for the community.*

3.1.15. Standards body

Organization that carries out standardization activities, which is recognized at the national, regional or international level, and whose main function is the preparation, approval or adoption of standards that are made available to the public.

N.B. *A standards body may have other main functions as well.*

3.1.16. Stakeholder

Person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity.

3.1.17. Sustainable development

Development that meets the needs of the present without compromising the ability of future generations to meet their own needs.

3.1.18. Sustainable use

The use of an organism, ecosystem or any other renewable resource at a rate within the bounds of its capacity for renewal.

3.2. Statistical terms

3.2.1. Element

Object or person being measured.

3.2.2. Sample

Set of individuals that make up the population of interest, which have been selected using a sample design.

3.2.3.Sampling plan

A sampling plan is a procedure in which a random sample of n units is taken from the batch and inspected to determine the fate of the batch based on the information from the sample.

3.2.4. Sample size

Significant portion of the population that fits the characteristics of the research.

3.2.5. Target population

Set of individuals on which research is carried out and about which it expects to obtain conclusions. It can refer to the total number of productive units in a given location or the total production of each productive unit.

3.3. Metrological terms

3.3.1. Accuracy

Degree of agreement between the reported result and the accepted reference value. Accuracy as a statistical parameter applies to the reported final result of a test.

3.3.2. Calibration

Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties (of the calibrated instrument or secondary standard) and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

3.3.3. Limit of detection

It is defined as the minimum concentration of analyte that can be detected. However, it cannot necessarily be quantified under the established conditions; only a signal from the measuring equipment can be evidenced.

3.3.4. Measurement

Process consisting of experimentally obtaining one or more values that can be reasonably attributed to a quantity.

3.3.5. Measurement uncertainty

Non-negative parameter that characterizes the dispersion of the values attributed to the measurement and based on the information used.

3.3.6. Metrology

Science of measurements and their applications. Metrology includes all the theoretical and practical aspects of measurements, whatever their measurement uncertainty and field of application.

3.3.7. Precision

According to ISO 3534-1 (ISO, 1993) defined as the degree of agreement between the different results of a test obtained under established conditions, and is usually expressed in terms of the standard deviation, relative standard deviation, coefficient of variation or range.

3.3.8. Quantity

Property of a phenomenon, body or substance, which can be expressed quantitatively by means of a number and a reference.

3.3.9. Reliability

Result of the precision and accuracy of the analytical system.

3.3.10. Repeatability (Repetitividad in Spanish)

Results of a test that are obtained when the same method is applied by the same person to identical test items, in the same laboratory, using the same equipment at short intervals of time.

3.3.11. Requirement

Established need or expectation.

3.3.12. Stability

The ability of an instrument to maintain constant metrological characteristics.

3.3.13. Verification

Provision of objective evidence that an item satisfies specific requirements. In regard to measuring equipment, verification provides meaning, by confirming that the deviations between the values indicated by the instrument and the corresponding known value of the measured quantity are consistently less than the maximum permissible error defined in a particular standard, regulation or specification for handling the measuring instrument. The result of the verification leads to a decision either to restore a service, or to carry out adjustments, or else to repair or reduce the rating, or to declare it obsolete.

3.3.14. Traceability

Property of a measurement result or standard whereby the result can be related to certain references, generally international or national standards, through an uninterrupted chain of comparisons, each with its established uncertainties.

In order to guarantee the veracity, reliability, robustness and high quality of the results of the methods offered, laboratories have to validate their analytical techniques. To do so they must use the chemometric and statistical concepts.

3.3.15. Validation

Procedure used to determine the accuracy, precision, linearity, systematic error, robustness/rigor, sensitivity, limit of detection and quantification of an analytical method.

The different methods of analysis are classified into:

- ***Absolute or primary method***
  A measurement that has direct traceability with the international system of units (For example: gravimetry, mass spectrometry with isotopic dilution).

- ***Stoichiometric methods***
  The calibration of a reagent makes it possible to relate the standard quantity to the quantity of the analyte using chemical mechanisms, for example volumetries.

- ***Comparative methods***
  Those in which the values obtained under the same experimental conditions, for a series of standards and samples, are related to each other through a calibration factor or function, as in the majority of instrumental techniques (For example: spectrophotometry, chromatography, etc.).


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METHODOLOGY USED TO DEVELOP THE GUIDE

In order to develop this guide, a study was first conducted of the Quality Infrastructure in Colombia, Ecuador and Peru to understand how the main aspects of the QI function in each country and identify the areas that can contribute to greater regional integration in the field of standardization. The advances made in biodiversity standards in Colombia, Ecuador and Peru were also studied, and an analysis was carried out of the sources of native species products, to collect inputs that would help to determine the commercial potential and requirements of Quality Infrastructure services. In addition, a bibliographic review of biodiversity-related concepts was undertaken to support the consensus on the use of biodiversity terminology used during the preparation of this guide.

Once each country had developed a technical standard for a native species product (lulo in the case of Colombia, amaranto in the case of Ecuador and sacha inchi in the case of Peru), a matrix was created comparing the standards for each product in the different countries in order to standardize the criteria used.

The information contained in this guide includes the contributions submitted by the technical teams from Colombia, Ecuador and Peru. It is also based on information gathered during a consultation process with members of the respective national technical standards committees, national experts, and government authorities.

A technical study on native species was also conducted, and the capabilities of the technical teams from Colombia, Ecuador and Peru on aspects related to accessing international markets, bio trade and creating knowledge and awareness among stakeholders were strengthened. This was achieved through workshops, training delivery and the exchange of experiences. In parallel, a review was conducted of the guides, manuals and directives, among other ISO and *Codex Alimentarius* publications offering guidelines and orientations on how to present draft standards at the international level, which served as input for this guide and provided orientation for the technical studies on the native species products in each country.

The knowledge, experiences, processes and lessons learned that were generated and exchanged during the preparation of this guide are presented in italics as guidelines and recommendation boxes. A summary of the experience of each country is also shared in the annexes to the guide.

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PRIORITIZATION OF THE PRODUCT PROPOSED FOR DEVELOPING AN INTERNATIONAL STANDARD (PRELIMINARY CONSIDERATIONS)

Submitting a proposal for a standard to an international standards body is a challenge that is undertaken at the national level – it is an opportunity to reveal to other countries, and other regions of the world, the products unique to the country's biodiversity, its culture or the degree of technological development in a certain sector.

The existence of normative documents allows a country to broaden the horizons for its products and open doors in a greater number of markets.

Before venturing into the international or regional standardization process, it is essential, therefore, that the country reflect internally on the fundamental aspects involved in the decision to lead a standardization process, be it in ISO or the *Codex Alimentarius*.

The implementation of a standard ensures that the product meets minimum quality parameters and builds greater trust among markets and stakeholders.

In order to draw up a proposal for a standard there should be a national entity responsible for coordinating the work, representing the country before the international standards body and, in turn, representing the interests of the sector affected by the proposal before that body.

It is up to each country to select the international organization in which it will participate, according to the resources it has available, since this participation requires both human and financial resources. The particular issue addressed may also help to determine which body to opt for.

Both ISO and the Codex Alimentarius cover foods. However, if it is a product that is sold fresh, such as fruit or vegetables, then the *Codex Alimentarius* may be the best option.

In the case of processed foods, these international organizations have technical committees whose scope of action covers such products.

If the aim of the country is to achieve a regional standard, then it is recommended that it participate in the Codex Alimentarius, since the commission has regional bodies that can carry out the regulatory process at that level. ISO does not develop regional standards.

On the other hand, if the product in question is not a food and is not related to this sector, it is very likely that it will be examined by ISO, providing that this body has a technical committee dedicated to the matter.

Another important consideration has to do with the topic presented to the international body as a draft standard. The country should know what its strengths are in this respect and what opportunities are offered by the international market. It should also know the products they have available at present and in what type of market they compete, whether it is in the local market only, or whether it has any commercial experience with other countries, and what the consumer preferences are.

The analysis of each industrial sector would allow to identify their particularities and determine the potential for growth and increased production, the behavior of the demand, and whether the country has public policies in place to promote and support the selected sectors, among other related information.

Based on the analysis of this information, the aim is first to obtain a list of products that appeal to the export market and then select and prioritize those that are relevant, determine the topic and prepare the draft standard that will be submitted to the international standards organization.

If the country has carried out a study of each of the industrial sectors and identified the main actors and the products they offer, including native species products, we recommend consulting government institutions linked to trade and export in native species products, as well as national statistical information, among other aspects.

Trade associations also have market studies, they know the sector to which they belong, and they may have carried out studies that show the projection for the sector and which are their needs.

At the international level, there are specialized organizations that may have information about the market for different products, including the FAO, WTO, World Bank and International Trade Centre, among others.

Equally valuable may be an analysis of those sectors that have not performed well in recent years.

The question that the country should ask itself is this: What are the reasons for the sector's condition? The answers may be related to external or internal factors of the country, but whatever the causes may be, they can serve as warning signs for other sectors and help the country to make timely decisions that can promote those sectors and at the same time promote them through normative documents at the international level.

During the information gathering process, it is also important to find out which countries are competitors for the products in question and which has been their commercial behavior. It is useful to have such information because these countries can become allies when championing the issue before an international organization. Furthermore, the supporting documentation for the proposal should show how the product performs in the international market, as will be described in the second step of sub-section 6.1.

The information available to date pertains to the most prominent sectors, such as agro-industry, since they account for a significant proportion of export trade, it is also known that there are public policies in place to promote the production and consumption of certain products and we can find out what the level of supply is. In addition, we can see from this research which are the main target countries for the products associated with promising sectors identified and get to know the trade reality from the perspective of other producing countries. Although not sufficient on its own, this information is essential and is part of the inputs required to decide the priority of topics.

As a result of the above, the initial list of products for which commercially-relevant information is available can be prioritized or readjusted, either because of their high domestic consumption or because production has been scaled up for export, due to their economic importance for the country.

This list forms the starting point to select the topics that are important for a normative document.

In this respect it is important to take into account the following commercial and market-related aspects that should be considered to prepare the documentation for submission to ISO or the *Codex Alimentarius*:

- Trends in the production quantities or volumes of native species;
- Supply and demand for native species in recent years (market evolution);
- Added value of native species (nutritional content, advertising, promotion, packaging, customer service, transportation and prices);
- Countries that produce native species;
- National and international production areas;
- Destination countries with market figures;
- Export quantities;
- Trade behavior (competitor countries);
- Evolution in trade (supply and demand);
- Consumption trend in recent years;
- Potential of the native species product in new markets;
- Estimate or projection of international sales in the native species product;
- Conditioning and marketing infrastructure;
- Risks associated with supply, storage and transportation;
- Level of development of the industry and the production capacity to meet the projected demand;

- Inclusion of a cost benefit analysis of the product to be developed
- Economic aspects (contribution to gross domestic product); and
- Social aspects and environmental impact.

Some topics for potential standardization may have to wait a while if there is not enough information available. Market intelligence and other data can be a good filter to determine which topic is a priority when it comes to standardization at the regional or international level.

An analysis can be carried out of those products that have been identified, in order to reduce the number of topics to be considered for standardization. Although they may all be important and the aim is to submit them to the international standardization organization not all of them will be accepted, given the capacity and number of ongoing proposals under consideration by the technical committees on international standards, so the proponent country will probably be asked to prioritize.

Based on this initial list of products, it is necessary to consider the following points:

- ☑ It should be verified whether there are any existing normative documents covering these products in ISO or the *Codex Alimentarius*; if there are, it does rule out the possibility of proposing them for consideration.
- ☑ Before making any decision, it is necessary to consult the international normative document and determine whether it is technically correct and covers the product in question. If it does not, consider a proposal to update the normative document.
- ☑ If the international document applies to the product in question without having to propose technical adjustments to the standard, then the product can be removed from the list of possible topics requiring standardization, and the international standard may be adopted as

the national standard if there is not a normative reference within the country.

In the case of other topics of interest for standardization that have yet to be defined and for which there is no international standard, it is necessary to check whether there are national standards that apply to these products. The lack of national standards presents a challenge when it comes to developing an international standard; therefore, the application of this criterion can further reduce the list of possible products and their respective topics requiring standardization. If there is no national normative document, this could indicate that there is not a unified position on the product requirements, as the national standardization committees will not have had the corresponding technical discussions that enrich the standard and provide the necessary support to justify its content.

It should not be forgotten that, at the international level, it is not the technical position of a trade association that is presented, but rather the position of the country that is proposing the topic for consideration. Otherwise, it is very likely that when the topic is presented to the international technical committee, the content of the proposed document could be substantially modified due to the lack of strong technical arguments to support the issues under discussion.

Bearing in mind the above, the most favorable situation appears to be one in which there is a national standard covering the product considered for submission at the international level. Nevertheless, it is prudent to review the documentation in light of current trade and technology requirements, as it may be necessary to update the national normative document to ensure that the information presented is current before submitting the issue to ISO or Codex. This is a task carried out by the corresponding national committee and supported by a recognized bibliography, which includes product analysis and, if necessary, comparisons with the national standards of other countries for the same product or similar products.

If there is no national standard on any of the issues remaining on the list, the country should make a decision in this regard, with the best option being to initiate the process of preparing the corresponding national standard. This involves conducting product characterization (see Section 6) in order to determine the corresponding requirements that will be incorporated into a draft normative document, which will serve as the basis for carrying out the standardization process that will lead to its approval as a national reference document. This process can be initiated for several of the topics of interest simultaneously. However, it does not guarantee that they will all be concluded at the same time, as each one will have its own complexities. The first topic to complete the process of being considered as a national standard may therefore be given priority in order to then begin the process of submission as an international standard. If all the selected topics are covered by national standards and these are currently in line with technological and commercial practices, the recommendation is to choose just one topic for submission, which should be the one with the highest priority in the list.

It is hoped that the standard will help promote the consumption of the product outside the country and thus contribute to an increase in demand. There is an associated social component that is important to consider here: namely the number of jobs that can be created, and this may determine which product is of greatest interest. In addition, there are other implications such as the environmental impact of the product during either use or production, which, although not a quality-related issue, may affect the preferences of future customers.

Available tools include normative impact analysis, also known as regulatory impact assessment, which is a methodology that allows the costs and benefits of a mandatory standard or regulation to be systematically evaluated. This tool could be used by a standards body as the basis for assessing voluntary documents such as standards.

Once the product has been prioritized as well as, the topic that will be proposed to the international standards organization, the country should ensure that it has the ongoing participation of experts on the subject, who will provide the necessary support while it is under consideration as an international standard. It is essential that these experts are familiar with the standardization process implemented by the chosen organization to which the proposal will be submitted, to ensure they have a clear understanding of the normative criteria and the limits of the content of the international standard, as well as the good standardization practices established by the WTO (Source: Annex 3 of the Agreement on Technical Barriers to Trade[3]).

5.1. Aspects pertaining to the sustainable management of natural resources

Standards are instruments that facilitate trade in goods and can open up markets, among other aspects that are beneficial to the local, regional and global economy. In the case of standards on native species products, which are goods of incalculable genetic value, it is important to consider their impact on the entire life cycle of the product obtained from a native species, as well as evaluate their environmental and social impact to ensure that any standards developed contribute to the actions designed to safeguard the sustainable use of these products and the quality of the environment.

Some native species products may come from forests. As the planet's natural sinks for CO2 capture, forests are a resource that needs to be conserved through the appreciation and sustainable use of their goods and services. In some cases, forests and their native flora and fauna may be part of a country or region's historical, archaeological, cultural and social heritage. It is important, therefore, to bear in mind the obligations entered

3. Annex 3: Code of Good Practice for the Preparation, Adoption and Application of Standards *https://www.wto.org/spanish/docs_s/legal_s/17-tbt_s.htm#ann3*

into by the country at the international[4] and regional level, in addition to national legal requirements relating to forests.

Good forest management recognizes, maintains and, where possible, increases the value of the ecosystem resources and services (for example, water basins and fishery resources). It strives to strengthen and diversify the local economy by avoiding dependence on a single forestry product.

Forest management takes into consideration the sustainable use of terrestrial and aquatic ecosystem resources and services that the forest can provide, which can include lakes, ponds, rivers and other bodies of water found within the management area.

Aspects pertaining to sustainable forest management are described below and include the application of standards for native species products and, where appropriate, the contexts in which standards might serve as an input for forest management planning. Forest management planning, aimed at safeguarding the health and vitality of ecosystems, allows us to maintain and increase the economic, ecological, cultural and social value of the forest:

5.1.1. Land tenure and rights

In many countries with significant natural heritage, the illegal extraction of forest resources and the pursuit of other illicit activities, such as illegal mining, are constant threats to forest conservation.

The promotion of native species products should therefore be aligned with actions to ensure the sustainable use of forests, including protection of threatened flora and fauna, protection of the environment and its resources, respect for traditional knowledge, and for tenure rights, ownership and use for native

4. Informea. Multilateral environmental treaties and agreements [online]. Available at: *https://www.informea.org/en/treaties*

peoples and communities, equitable distribution of benefits, as well as social, labor and health-related aspects.

5.1.2. Engagement with local communities

Forests are often home to indigenous peoples and native communities that depend on the forest for their livelihood. This is why responsibly managed forest enterprises include a process of consultation and dialogue with the indigenous peoples and native communities that might be affected. The contributions made by these local communities are considered in the design, planning and execution of the venture. The relationship with these communities is maintained by training workers in best practices regarding engagement, dissemination and communication.

5.1.3. Worker health and safety

As mentioned above, illegal activities, some of which are difficult to identify, are a constant threat to forests. One aspect that can facilitate identification is the verification of compliance with mandatory labor requirements, including aspects relating to workplace health and safety, continuous training and inclusion.

5.1.4. Respect for and preservation of traditional knowledge and practices

Indigenous peoples and native communities are an important source of traditional knowledge and technologies for managing forests and their biodiversity and are part of the world's scientific and technological heritage. A responsible enterprise incorporates this knowledge and these technologies when designing and planning the sustainable use of native species products to ensure that operations and activities are compatible with the communities, while respecting the intellectual rights associated with this knowledge.

5.1.5. Sustainable use of primary forest as an area of interest

Primary forests are of vital importance on account of the genetic information they house, and they continue to be a source of discoveries that can benefit humanity. It becomes even more necessary, therefore, to assess environmental impacts[5] and apply a mitigation hierarchy when undertaking any new activity related to a product of a native species originating from a primary forest. This is why the enterprise needs to be designed in such a way as to contribute to the conservation of the primary forest and the development of the communities that live there.

Carrying out an environmental impact assessment that includes a baseline study provides information on the flora and fauna found within the area of influence, which makes it possible to monitor the impacts of the actions undertaken during the life cycle of the venture.

Standards can usually help the organization to implement tried and tested measures to ensure the efficient and environmentally appropriate use of the native species product, maintain a file of the documentation supporting traceability in an environmentally responsible and ethical operation, implement a chain of custody

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5 The CBD defines environmental impact assessment as a process of evaluating the likely environmental impacts of a proposed project or development, taking into account inter-related socio-economic, cultural and human-health impacts, both beneficial and adverse.

Likewise, UNEP defines environmental impact assessment as a tool used to identify the environmental, social and economic impacts of a project prior to decision-making. The aim is to predict environmental impacts at an early stage of the project design and planning; find ways to reduce adverse impacts; adapt the project to the local environment; and present projections and options for decision makers.

Source: *https://www.cbd.int/impact/whatis.shtml#:~:text=Environmental%20Impact%20Assessment%20(EIA)%20is,impacts%2C%20both%20beneficial%20and%20adverse*

process for the product, make the best use of the land on which the forest management plan operates and guide any expansion or modification of the plan.

5.1.6. Traceability

Traceability is essential for producers, since it is the best way to increase consumer trust and demonstrate compliance with legal requirements as well as mandatory compliance with environmental management. Traceability should be ensured from the point of origin of the native species to the end product. The documents required for traceability include the following: the current land register for the forest management unit area; the identification of the native species product within the forest management unit area; identification, protection and management of the stored native species product; and the inventory control record for the native species product.

5.1.7. Changes in land use

In the case of products made from domesticated and/or cultivated native species, it is important that promoting their sale and export does not result in logging, burning or the degradation of forests due to changes in land use[6]. In many countries, the shift from forest to farming is the main source of greenhouse gas emissions. Change in land use can also result in the loss of key species and loss of ecosystem services that are vital to the health of forests and local communities.

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6 The UNFCCC defines land use change as a subsector of the greenhouse gas inventory that covers greenhouse gas emissions and removals resulting from land use change. For example, changing from a forest to a meadow, or from farmland to wetland, among other changes in use.

5.1.8. Water basin conservation

In addition to supplying us with water, water basins provide support for a variety of ecosystem services, particularly hydrobiological ones. Their conservation is vital for the continuity of all industries and services. The characterization of water resources, such as micro-basins, thus provides information used to determine the forest management unit.

This information, along with topographic, soil, climate and community data, also contributes towards better design and maintenance of roads, as well as other means of access and firebreaks, to ensure that they do not affect the services provided by this important resource. The construction of access roads and firebreaks should not cause erosion and has to maintain natural waterways. These types of infrastructure thus become a means to enable the sustainable use of forest resources and the development of the communities that live there.

Water basins are also conserved through proper comprehensive management of solid waste, liquid effluents, discharges and gaseous emissions, the aim of which is to reduce, reuse, recycle and treat, in order to minimize their impact on the environment and on water resources. Additional measures include contingency plans and plans for the prevention of spills and leaks.

5.1.9. Biodiversity conservation

As far as possible, business ventures in forest management areas should contribute to the sustainable use of biodiversity. This is achieved through soil and water conservation measures, as well as measures to improve air quality.

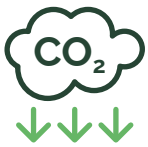
Aspects to consider include:

a. Application of comprehensive pest management, when appropriate, while avoiding the use of chemical pesticides;
b. Prevention of invasive species;
c. Use of fuels with a low toxicity rating;
d. Forest fire fighting management;
e. Good packaging practices;
f. Comprehensive solid waste management;
g. Recovery or remediation of degraded areas;
h. Control and monitoring of the environmental aspects identified in the environmental impact assessment, consistent with the scale of the operations; and
i. Updating of the forest management plan based on the monitoring results, among others.

A forest management plan that is aligned with biodiversity conservation takes into consideration the following elements:

a. Procedures to ensure the conservation of flora and fauna within their natural habitat;
b. Protection of endemic, rare or endangered species;
c. Identification and protection of historical, archaeological, cultural and social sites;
d. Identification of conservation and preservation areas and existing legal reserves; and
e. Management of hunting and fishing activities, among others.

It should be noted that conservation measures should also be applied to the use of non-forest species, such as those from the sea, rivers, lakes, lagoons and other water sources.



5.1.10. Greenhouse gas management

In line with the global commitment to keeping the increase in global temperature to below 2° C to prevent global warming, standards for managing greenhouse gases and related activities[7] should be applied to any enterprise that has an impact on greenhouse gas emissions or behavior in the environment or that impacts sinks and other means of carbon sequestration.

In conclusion, forests provide a range of benefits generated by their natural or cultivated ecosystems, which should be conserved today if they are to be discovered and harnessed by future generations. Particular emphasis should be placed on the conservation of water sources and their runoffs, flora for carbon sequestration and fixation and biodiversity, among other aspects. Forest management activities should promote the efficient and optimized use of multiple products and services to ensure their economic and social viability, thereby ensuring that environmental protection is compatible with economic development.

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7 The aforementioned standards can be found by visiting the ISO/TC 207/SC 7 webpage at *https://www.iso.org/committee/546318/x/catalogue/p/1/u/1/w/0/d/0*

6

PRODUCT CHARACTERIZATION

This section focuses on product characterization, in accordance with the requirements established by ISO and the *Codex Alimentarius* to ensure fair practices in international trade, guarantee compliance with quality standards and, in the case of food, also ensure safety.

This is why the parameters to be taken into account in the standard should be the essential quality-related aspects that the market demands, rather than protectionist parameters that could become a barrier to entry into a particular country. So, once all the aforementioned steps have been completed, the next thing to do is establish what basic characteristics the product should meet to ensure compliance with the requirements of the target market, for example: size (diameter for fruits), iodine value for oils, etc. Before going into detail about the process for determining the quality parameters of the product with a view to proposing a draft standard, it is important to remember that there are clearly established procedures for submitting new topics for standardization to international organizations.

Standardization facilitates the commercialization of products at the national and international level, by including in a standard the essential requirements that ensure products are not rejected in a country with different standards.

The *Codex Alimentarius* includes standards on staple foods, which can be processed, semi-processed, raw or ready to eat, as well as the raw materials used (FAO). It also contains provisions on food hygiene, food additives, pesticide and veterinary drug residues, contaminants, labelling and presentation, analysis and sampling methods, inspection and certification of imports and exports.

The main activity of the International Organization for Standardization (ISO) and its technical committees involves developing international standards in various areas to assist organizations by providing a technical basis for standardization and regulation on issues related to quality, health, safety and the environment. The vast majority of ISO standards are specific to a particular product, material, or process. However, ISO 9000 and ISO 14000 family of standards have a worldwide reputation and are known as "generic management system standards", while ISO 22000 family is specifically designed to guarantee food safety.

These quality and standards bodies have very well-defined and structured standards, and every country or organization wishing to submit a proposal for a standard must comply with the corresponding format. The information that the country should include in this format is covered in this section and is related to the quality parameters for the product, with the respective values that will be taken into account in the international market. These should not act as a barrier to trade and should be easy to apply and evaluate.

6.1. Review and systematization of the literature

This product characterization stage begins with the creation of a "Comprehensive Search Plan" containing the right choice of keywords to be used in electronic databases, manual searches, test records, conference communications (abstracts), grey literature (unconventional, semi-published or invisible research) among other sources. Additional information can be obtained from market intelligence on the participation of companies from the sector in business conferences, trade fair organization, trends, market measurements, and so on, since all new products are created with a focus on demand.

STEP ONE

In the case of products of plant origin, the botanical material is first identified by a specialist (taxonomist) in the botanical family. The provenance of the sample is of utmost importance and can result in material of high economic value, depending on the edaphoclimatic and compositional conditions that characterize samples from different geographical areas. The botanical species may be included in the national inventories or may be a new species. At this initial stage, a search for the species is then carried out in the main databases, such as: *The Plant List* (*http://www.theplantlist.org/*) for ease of reference in publications or product datasheets.

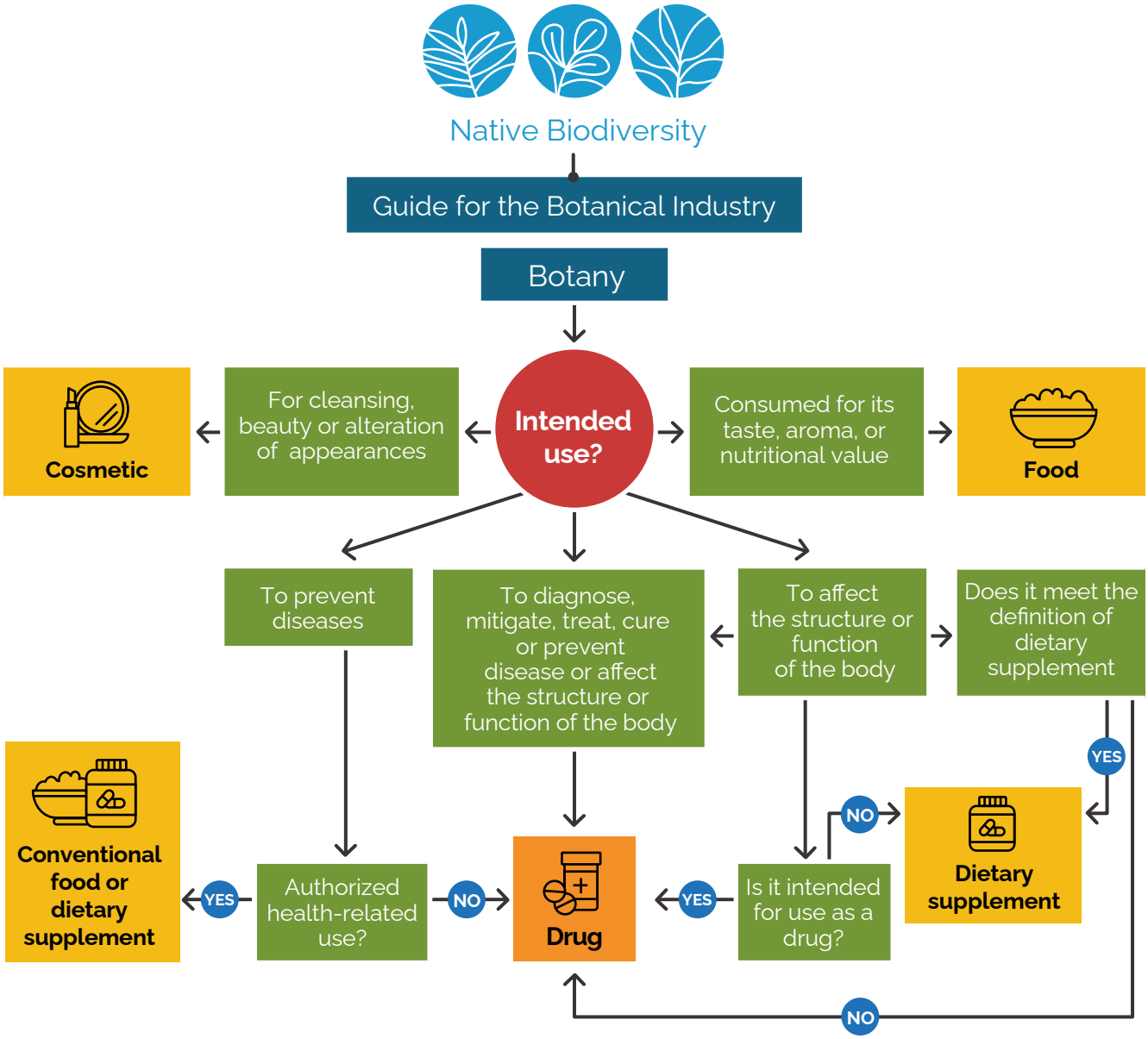
STEP TWO

Market intelligence. The next step that any entrepreneur should take before venturing into business is to conduct a market intelligence study to increase their participation in international trade (see **Figure 1**).

Figure 1. Market intelligence study

Market intelligence entails finding applications for the native species, with the main focus on the environmental, social and economic sustainability of the selected product. At this stage, it can be supported by ethnobotanical information on the species, which can often be found in the "grey literature" and in reports conducted among native communities that may or may not be registered, which includes traditional knowledge, scientific missions involving the collection of native species, institutional reports, universities, community gazettes, local newspapers and national newspapers, fairs, etc.

This study is based on the following question: Where do we aim our research? (see **Figure 2**).



Source: FA Hoffman.

Figure 2. Objective of market intelligence in plant species

STEP THREE

The flow of information provided by market intelligence will make it possible to locate the future product in the different commercial scenarios, while prioritizing and evaluating value chain development according to demand.

An exhaustive search should then be conducted in the main institutional or other databases, mostly accessed through agreements, such as those with national science and technology councils, university repositories or publications at the national and international level, associations such as Chambers of Commerce, export promotion organizations in neighboring countries and free or private virtual libraries. In addition, some results will be recorded as unpublished and belong to the grey literature.

The research may be geared towards one type of prospecting such as:

- **Chemical prospecting**
  Which identifies the main components of the botanical species studied. The data is generally obtained from a first phytochemical run, which provides basic information, before the search is then directed toward the so-called secondary metabolites that give rise to drugs (if this is the focus of the research scientists). However, botanical species also provide sources of food, herbal products, food additives, cosmetics, supplements, etc. Chemical prospecting is the most common method used. If data on the species in question is scarce, information can also be obtained about the composition in the botanical family, which will also provide knowledge about related compounds that might cause some type of toxicity or allergenicity.

- **Genetic prospecting**
  Bioprospecting and the study of genetic variability aimed mainly at examining biological resources in search of active compounds for pharmaceutical, agricultural and industrial use has allowed developing countries to achieve a new competitive advantage. Moreover, recent advances in biotechnology have opened up a new range of possibilities for genetic prospecting. During the initial search, confirming the existence of the same species in different areas of the country provides clues as to the extent of the geographic and demographic use of the products derived from this botanical species.

- **Ecological prospecting**
  Which is the systematic observation of ecological relationships between living beings and their environment. For example, some animals avoid eating certain plants because they cause them discomfort of some kind. Certain plants are used as food – as in the case of camu-camu (*Myrciaria dubia* H.B.K. Mc Vaugh), a fruit with a high vitamin C content that was eaten by fish – or as natural biocides, which has allowed us to discover plant species that contain a large number of essential oils.

In addition, it is important to focus on the following aspects:

- **Identity**
  The first step is to ascertain the botanical identity. Once this is known, the phytochemical characterization is carried out, since it is the plant "actives" that, thanks to their properties, determine the demand, which may be very specific. This "active" is usually the main compound identified as having technical/functional advantages by the formulator during the phytochemical screening of the plant. It is then decided which analysis method will be used to determine the chemical identity of the active ingredient or ingredients that are typical of the species and may serve to detect adulterations. Hence the importance of studying their composition.

- **Composition**

  All composition testing begins with a proximate analysis that involves determining the percentage of moisture, fat, fiber, ash, soluble carbohydrate and protein contained in the foods. One important step is to request or perform a conventional preliminary phytochemical run: extraction, identification and chromatographic separation of secondary metabolites to determine, for example, the presence of alkaloids. Following this initial evaluation, it is necessary to assess the macro and micronutrients, as well as the anti-nutrients present in the botanical extract that will be used to obtain the product. It is advisable to have information about all the parts of the plant due to the possible toxicity that some of them may contain.

  It is necessary to identify the botanical extract to be used and the physicochemical analyses of the main components of the product accompanied by a chromatographic fingerprint analysis. In this group of compounds, anti-nutrients (phytates, saponins, tannins, alkaloids, etc.) may be present in the raw material, which should be eliminated during the production process as they would affect food safety. Also, at the cosmetic level, there may be trace amounts of certain components used in the product production process, which should not be present in the final product and whose presence may cause allergies. In addition, potentially carcinogenic agents that are formed naturally during thermal processing may be a cause for investigation or verification before the product is marketed: for example, acrylamide (in the case of food); hydroxymethylfurfural (HMF), etc.

- **Toxicity and allergenicity**

  In order to guarantee the safety of food or cosmetic products, the legislation currently establishes a series of toxicity and allergenicity-related requirements that must be met by products and the companies responsible for them, particularly in the case of new products. It should be stressed that if the products are foodstuffs rather than cosmetics, the oral intake would be higher,

and therefore the tests requested for cosmetic use could be less stringent. However, countries have created the cosmetovigilance system so that they can receive notifications of adverse reactions to any products sold.

- **Product stability**
  Accelerated and long term.

- **Microbiology**
  According to the microbiological criteria for each product, mycotoxin content: for example, aflatoxins (if required).

  Microbiology-related aspects are generally associated with good practices, such as those on harvesting, storage of the primary product, manufacturing, storage of the finished product and traceability of the product from the raw material, which could lead to contamination of the final product. For example, International Standards for Phytosanitary Measures (ISPMs)[8].

- **Contamination**
  - Heavy metals: The national directive sets the maximum levels of concentration.
  - Pesticides or veterinary residues: Regulations are periodically reviewed and the lists of the maximum permissible limits for pesticides and veterinary residues are updated accordingly.

Once this information has been obtained, the tests are carried out and the methodologies are discussed in the National Technical Committee of each country in order to submit a proposed standard to ISO or Codex.

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8. FAO. Annex 3. International Standards for Phytosanitary Measures (ISPM) [online]. Available at: *http://www.fao.org/3/i2080s/i2080s09.pdf*

6.1.1. Databases

The most widely used and reliable databases for searching for scientific information on the species of interest are:

- **Web of science (WoS)**
  Property of Clarivate Analytics. The WoS (see **Figure 3**) is composed of the basic Core Collection, which includes citation indices for the Sciences, Social Sciences, Arts and Humanities, in addition to Congress proceedings on both the Sciences as well as Social Sciences and Humanities, together with analysis and evaluation tools, such as the *Journal Citation Report and Essential Science Indicators*. Attached to this database is MEDLINE (WoS), which contains medical articles, SciELO and Index Chemicus.

Figure 3. WoS database [9]

- **Scopus**
  Owned by the company Elsevier, it is a database of bibliographic references and citations (see **Figure 4**), covering over 17 500 journals of peer-reviewed literature and quality web content in all fields of knowledge, with research monitoring, analysis and visualization tools. It provides the option of searching by author, affiliation and advanced search. Access to this database is granted through institutions or organizations that have entered into an agreement or have a service contract.

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9. UAM. Web of Science (WOS) [online]. Available at: *https://biblioguias.uam.es/tutoriales/WOS*

Figure 4. Scopus database[10]

- **PubMed**

  Database produced by the U.S. National Library of Medicine containing references and abstracts of articles from around 4 600 biomedical journals indexed by MEDLINE (see **Figure 5**). It allows access to the MESH (Medical Subject Headings) Theasaurus, as well as the full texts of journal articles and e-books. This database provides information on preclinical and clinical trials involving toxicological tests.

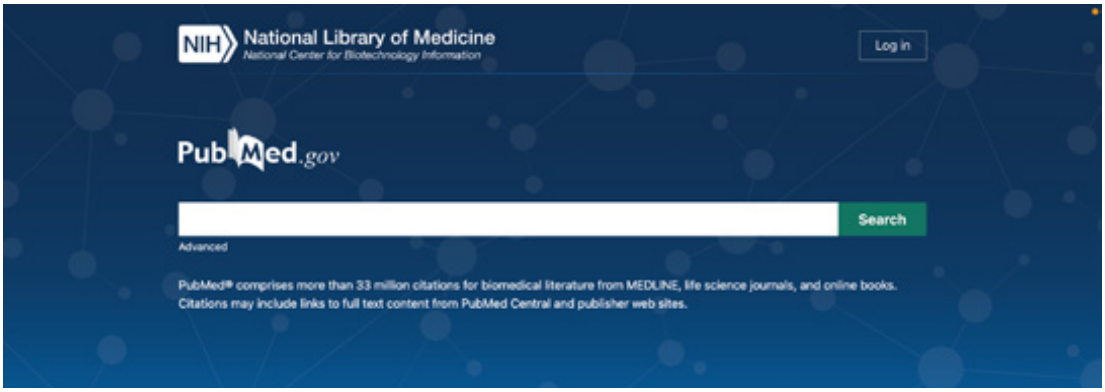

Figure 5. PubMed database[11]

10. Scopus [online]. Available at: *https://www.scopus.com/*

11. National Library of Medicine. PubMed® [online]. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/*

Other important databases include:

- **PAHO BIREME**
  Virtual Health Library (VHL). It is comprised of a large collection of databases such as: LILACS, MEDLINE and the My VHL service. The VHL is coordinated by BIREME in collaboration with a network of libraries mainly from Latin America and the Caribbean (VHL Network). See **Figure 6**.

Figure 6. PAHO BIREME database[12]

6.1.2. Regional databases

- **Latindex**
  (Regional Online Information System for Scientific Journals from Latin America, the Caribbean, Spain and Portugal): A non-profit and free-access academic information system, specialized in academic journals published in Ibero-America. The system is the result of cooperation between different institutions in 23 countries and brings together around 5 000 journals[13].

12. Health information in Latin America and the Caribbean (Lilacs) [online]. Available at: *http://lilacs.bvsalud.org/*

13. Regional online information system for scientific journals from Latin America, the Caribbean, Spain and Portugal [online]. Available at: *https://www.latindex.org/latindex/inicio*

- **Scielo**
  Developed by FAPESP - BIREME of Brazil (Online Electronic Scientific Library), it is a model for the cooperative electronic publication of scientific journals on the Internet. Specially developed to respond to scientific communication needs in developing countries and particularly in Latin America and the Caribbean[14].

- **Redalyc**
  Promoted by the Autonomous University of Mexico. A Network of Scientific Journals from Latin America and the Caribbean, Spain and Portugal. Project promoted by the Autonomous University of the State of Mexico (UAEM), with the aim of contributing to the dissemination of scientific publications produced in and on Latin America[15].

- **Dialnet**
  The Dialnet Foundation was established in 2009 at the University of La Rioja, an institution whose aim is to manage and promote Dialnet as the main database offering Spanish-language content on the internet[16].

- **Dialnet-National Library of Spain**
  This is a library cooperation project in the form of a portal that brings together and provides access to documents published mainly in Spain. It also offers an information alert system and a full-text content platform.

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14. Scientific electronic library online (Scielo) [online]. Available at: *https://www.scielo.org/*

15. Network of non-commercial open access scientific magazines owned by academia (Redalyc) [online]. Available at: *http://www.redalyc.org/home.oa.*

16. DIALNET FOUNDATION [online]. Available at: *https://dialnet.unirioja.es/*

- **Commercial information databases**

  In addition to scientific data, it is important to be aware of commercial trends. This information can be found in specialized journals that can be accessed through university faculties of economics, chambers of commerce, international cooperation organizations, some of which specialize in project-based topics such as the German cooperation (GIZ), Swiss cooperation (SECO), Japanese cooperation (JICA and JETRO), among others, and trade-related institutions, such as the: International Trade Centre (ITC).

Figure 7. International Trade Centre[17]

In recent years, the ITC has developed commercial market information on native biodiversity products[18].

There are different private companies that report on commercially competitive sectors and provide information by market segment. This information can be accessed through trade associations, which acquire the service for their members, such as chambers of commerce, industry societies and promotion organizations that deal with market Intelligence or in university repositories (Faculties of Economic Sciences), reports on trade missions to fairs, and so on.

17. ITC sustainability gateway & ITC market analysis tools [online]. Available at: *https://sustainabilitymap.org/home*

18. International Trade Centre [online]. Available at: *https://intracen.org/*

- **FAO**

  The FAO databases cover a wide range of topics related to food safety and agriculture[19].

  Relevant examples include:

  Fresh fruits and vegetables: Codex standards for fresh fruits and vegetables plus related texts such as the Code of Hygienic Practice for fresh fruits and vegetables are published for use by governments, regulatory authorities, the retail food industry and consumers (*Codex Alimentarius*, 2007a)[20].

  Food Additives: At the international level, the *Joint FAO/WHO Expert Committee on Food Additives* (JECFA) works under the supervision and with the collaboration of the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO). In addition to the Codex standards for foods, the *Codex Alimentarius* provides an online database for food additives[21] (CODEX STAN 192-1995). JECFA acts as an independent scientific committee that conducts risk assessments for food additives and provides advice to FAO, WHO and member countries of both organizations. Requests for scientific advice are mostly channeled through the *Codex Alimentarius* Comission as part of its task of developing international food standards and guidelines under the Joint FAO/WHO Food Standards Program. In Europe, the committee in charge of evaluating the safety of additives is the European Union's Scientific Committee for Food (SCF).

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19. FAO. Data dissemination [online]. Available at: *http://www.fao.org/statistics/databases/en/*

20. FAO. Codex Committee on Fresh Fruits and Vegetables (CCFFV) [online]. Available at: *http://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCFFV*

21. FAO. Online database of the Codex General Standard for Food Additives (GSFA) [online]. Available at: *http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/gsfa/en//*

6.1.3. Examples of databases on regulations

Cosmetic products

- At the European level: (EC) Regulation No 1223/2009 of the European Parliament and Council of November 30, 2009[22].
- In the United States of America: The Federal Drug Administration (FDA) is responsible for cosmetics, as well as for regulating drugs for human and veterinary use, vaccines and other biological products, medical devices, the nation's food supply, dietary supplements and products that emit radiation[23].
- At the Andean Community level: Trade in cosmetic products is regulated by Decisions 516 and 705 and Resolutions 797, 1333, 1418 and 1482 (amendment to Resolution 1418)[24].

6.1.4. Dietary supplements

The FDA regulates both finished dietary supplement products and dietary ingredients, under a set of regulations covering "conventional" foods and pharmaceuticals. Marketers of dietary products and ingredients are responsible for evaluating the safety and labelling of their products prior to sale.

The FDA also regulates herbal supplements, but not as drugs or as foods; instead, they fall into the category of dietary supplements[25].

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22. European Economic Community. Regulation (EC) No 1223/2009 of the European Parliament and Council of November 30, 2009 on cosmetic products [online]. Available at: *https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&from=EN*

23. FDA. Cosmetics Guidance & Regulation [online]. Available at: *https://www.fda.gov/cosmetics/cosmetics-guidance-regulation*

24. Andean community. Cosmetic Products [online]. Available at: *https://www.comunidadandina.org/DocOficialesFiles/Gacetas/GACE771.PDF*

25. FDA. Dietary Supplements [online]. Available at: *https://www.fda.gov/food/dietary-supplements*

Other websites of interest

- World Health Organization (WHO): There are different ways in which countries define medicinal plants or herbs or their products derived, and countries have adopted different approaches to licensing, retailing, manufacturing and marketing to ensure their safety, quality and efficacy. The WHO provides information on herbal medicines[26] (Global strategy on traditional medicine WHO 11-14 April 2000).

- In addition, the FAO databases include regional and national data on food composition programs (FAO, 2019).

- *Food safety:* The aim of the European Union's food safety policy is to protect consumers, while ensuring market functioning[27].

- The comprehensive database of the *European Food Safety Authority* (EFSA) is a unique tool and will greatly improve the accuracy of EFSA's data on global food consumption in Europe[28].

Finally, following an initial search and acquisition of knowledge on the state of the art with regard to the product in question, the next phase involves carrying out a systematic review based on a methodical analysis, which includes the opinion of experts expressed in peer-reviewed articles, a summary of the study data, results and the interpretation of results in order to arrive at conclusions. For example: systematic review principles[29].

It is advisable to put in place a digital repository of the information obtained, where publications can be stored, organized, maintained and disseminated.

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26. WHO. Information Portal - Essential Medicines and Health Products [online]. Available at: *http://apps.who.int/medicinedocs/en/cl/CL10/*

27. EUR-LEX. *Food safety* [online]. Available at: *https://eur-lex.europa.eu/summary/chapter/food_safety.html?root_default=SUM_1_CODED=30*

28. Basque foundation for agri-food security, ELIKA. [online]. Available at: *http://www.elika.net/datos/articulos/Archivo654/EFSA%20Database.pdf*

29. European Food Safety Authority. Application of systematic review methodology to food and feed safety assessments to support decision making [online]. Available at: *https://www.efsa.europa.eu/en/efsajournal/pub/1637*

As an example, **Figure 8** shows a diagram detailing the preparation of a novel food file.

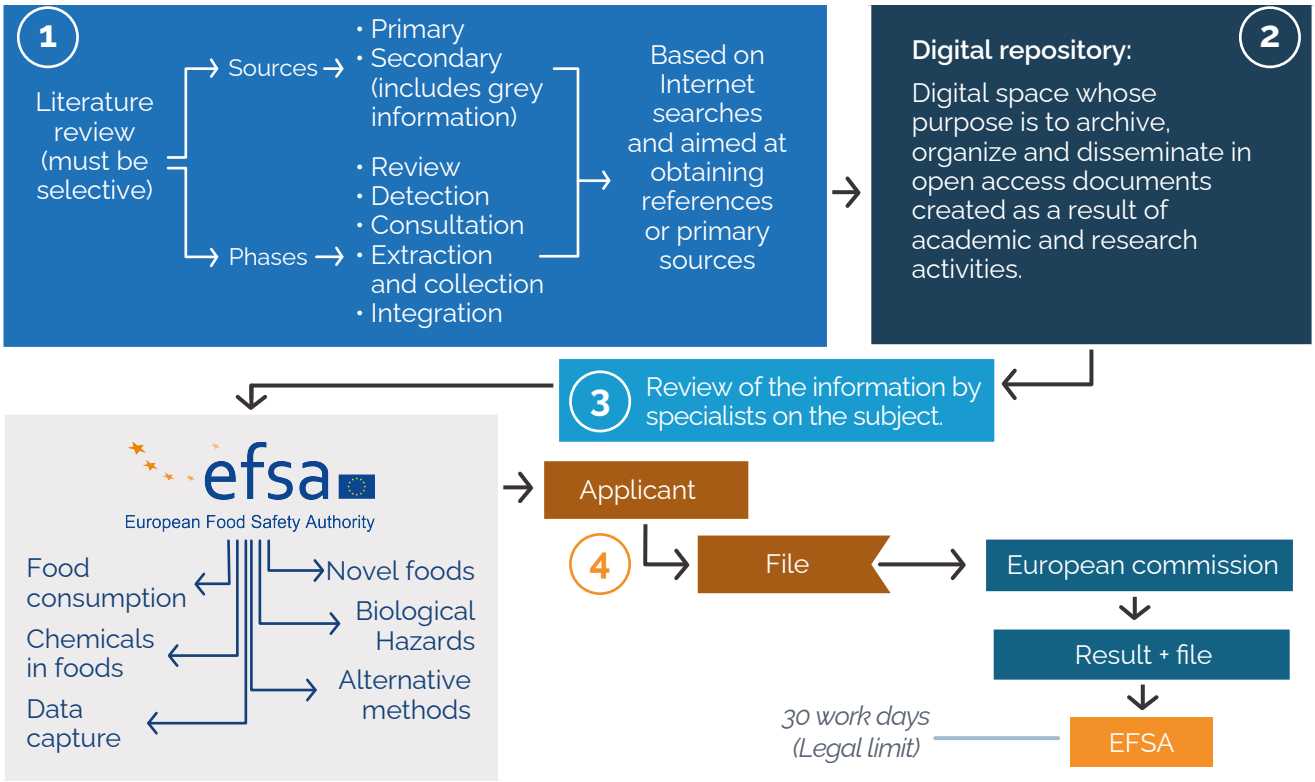

Figure 8. Information flow and evaluation for the preparation of the novel food file and its location in a digital repository

6.2. Product identification

Before beginning the process of development, a draft standard, it is important to define or get to know the product very well. There should be a technical datasheet containing the main product characteristics, as well as the target markets, since this will largely determine the quality parameters that are applied at the international level, or that may be of interest to importing countries without constituting a hindrance or barrier to trade. The general characteristics that it is essential to know about the product include the scientific name, as well as the most common names in both

the supplying and importing countries, along with basic morphological, chemical and safety aspects (in the case of food), as detailed below.

6.2.1. Morphology and physical characteristics

The process begins with the identification of the species by the specialist responsible for registering and cataloguing the preserved specimens according to a specific methodology, using a scientific nomenclature system. One of the benchmark institutions for taxonomic registry is the National Center for Biotechnology Information of the United States (NCBI)[30], another is the Missouri Botanical Garden[31]. However, the national herbaria and botanical gardens in the region have information on local, regional and national plants, which is recorded on datasheets that show the taxonomic key as well as the scientific name.

It is advisable to have the botanical factsheet for the species, which describes the botanical morphology (shape of the plant organs) (Herrera, 2008); vegetative structures (crown, root, stem, bark and leaves); reproductive structures (flowers and fruits); growth habits of the plants (herbs, shrubs, trees, lianas, annual, biennial, perennial); woody, succulent or nutrient reservoir.

One important piece of data is the origin of the seeds, since plants are adapted to the edaphoclimatic conditions, cultural practices, pressure from pests and diseases present in the locality. This endows the individuals in a population with different characteristics, which could result in certain differential characteristics in morphology. For this reason, characterization is now carried out using modern molecular techniques.

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30. National Center for Biotechnology Information. Taxonomy [online]. Available at: *https://www.ncbi.nlm.nih.gov/guide/taxonomy/*

31. Missouri Botanical Garden. Plant Finder [online]. Available at: *http://www.missouribotanicalgarden.org/plantfinder/plantfindersearch.aspx*

6.2.2. Composition

6.2.2.1. Chemical characteristics

In general, it is important to have data not only on the part of the plant that will be used and other organs such as flowers, leaves and stems, but also on the species in the family and their phytochemical characterization. This makes it possible to distinguish the plant in question and establish a similar chemical composition for the species of the genus and family. These data can be obtained from the scientific literature.

In order to sell the product, it is necessary to follow a quality assurance process for the food, which enables any cases of adulteration and/ counterfeiting to be identified and require a chemical analysis to determine which substances are present in the food (proteins, fats, vitamins, minerals, carbohydrates, heavy metal pollutants, pesticide residues, toxins, antioxidants, among others) and in what quantities. This analysis is carried out using both random and representative sampling.

Chemical characteristics offer a better chance of identifying the product application or the market niche in which it should be positioned based on its components. In some cases, this can vary depending on the place of origin and can give the product the desired differentiation; besides the specifications that should be used.

One of these market niches is nutricosmetic. Nutricosmetics are health products that are mainly used for hair treatments, skin imperfections, sun protection and photo-ageing. For example, the omegas 3 fats contained in vegetable oils such as *Plukenetia volubilis L.* or sacha inchi, which have traditionally been used to rejuvenate the skin (anti-ageing), now provide an edge when it comes to marketing.

Cold-pressed oils are preferred by the cosmetics industry on account of their low acidity and peroxide content. In addition, the fruits used to make pulps, juices or healthy, functional beverages, sports drinks, among others, have in the peel (exocarp), (besides seeds) vegetable oils that, when

extracted, are used as ingredients for food or cosmetic use. For instance, the oil of the fruit *Solanum quitoense L*. (known as lulo), which includes 32 volatile components (Suárez et al., 1993), makes an excellent flavoring for ice cream, a very dynamic industry. In the case of oils derived from Andean grains (quinoa, tarwi, *cañihua*, amaranth or kiwicha), these participate in different market segments, since they are considered superfoods. Of particular importance are the essential amino acids they contain, as well as the healthy fats (omega 3).

Essential oils originating from biodiversity have to undergo testing in accordance with international standards for essential oils during which analysis of their physicochemical characteristics is conducted (CD-P-SC, 2016), in addition to microbiological and sensory analysis.

The chemical components present in the food provide us with markers that indicate any adulteration.

6.2.2.2. Nutritional and anti-nutritional properties

Nutritional properties

An analysis is performed of macronutrients such as proteins, fats, (fatty acid profile), carbohydrates (sugars [sugar profile], starch and fiber), micronutrients including minerals (macro and micro minerals) (FAO, 2015) and vitamins (fat-soluble and water-soluble). Micronutrients do not provide the body with energy, unlike macronutrients. An important source of information in this respect is the INFOODS portal, which makes data available on food composition (FAO, 2017). Also, there are databases and food composition tables, some of them offer open access, such as the U.S. Department of Agriculture (USDA) database, which can later be used to calculate the nutrient intake estimates, in the case of foods, and may have other applications, for instance for food ingredient if some components can be differentiate such as dietary fiber[32] (AACC Report, 2001). It is

32. Techpress. (2017). Fibres, a rising market [online]. [Accessed: 06 September 2019]. Available at: *https://techpress.es/fibras-mercado-al-alza/*

convenient to carry out a food composition analysis (Charrondiere *et al.*, 2011), particularly if the substances will later be used as essential nutrients for food, cosmetic or medicinal purposes.

Dietary fiber is part of total carbohydrates. So far there is no exact definition, but the one most widely used is that of the AACC (*American Association of Cereal Chemists)*, which defines dietary fiber as the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with partial or complete fermentation in the large intestine. Dietary fiber includes polysaccharides, oligosaccharides, lignins and other associated plant substances.

The Association of Official Analytical Chemists (AOAC), in line with the new *Codex Alimentarius* definition, established AOAC methods 2009.01 and 2011.25 designed to quantify soluble dietary fiber, insoluble dietary fiber and total dietary fiber.

Anti-nutritional properties

Codex Alimentarius (FAO and WHO, 2007b) to assess the safety and nutritional quality of vegetable protein products (VPP) state that these VPPs could contain toxic or anti-nutritional factors of natural origin, for example, glucosinolates in *Brassica spp.*, gossypol in cottonseed, hemagglutinins and trypsin inhibitors in legumes. Importing countries are becoming increasingly strict in this regard and trade flows are hindered when regulations are not complied with.

In the case of cereals, it is recommended that anti-nutrients be eliminated. These include phytate, tannin and other phenolic substances, lectins and trypsin and chymotrypsin inhibitors, which may reduce the quality and digestibility of proteins. For example:

- Lectins can be reduced using wet-heat treatment.
- Trypsin inhibitory activity can be reduced to acceptable levels by subjecting food to high temperatures or prolonged cooking.
- Phytates can be reduced enzymatically or through maceration or

fermentation.

- Phytoestrogens can be reduced through fermentation.

Other anti-nutrients include saponins, avidin and oxalates.

6.2.3. Sensory characteristics

According to Picallo and Sabljic (n.d.), quality used to be established rather subjectively based on observations related to appearance, smell, taste and texture. The current method of sensory analysis measures, analyses and interprets the reactions to those characteristics of food and other substances that are perceived by the senses of sight, smell, taste and hearing, according to the definition given by the Institute of Food Technologists (IFT). It is also defined as the science of assessment of sensory properties via the senses (ISO 5492:2008 and ISO 5492:2008/ Amd 1:2016). Texture is a sensory property of food that is detected by the senses of touch, sight and hearing. Produced when the food undergoes deformation, it includes three types of attributes: mechanical, geometric and compositional.

In summary, sensory evaluation investigates the attributes perceived by the senses such as appearance, smell, taste, texture and in some cases sound.

6.2.4. Microbiology

- **Microbial agents to be evaluated in foods of plant origin**
  In order to be considered fit for human consumption, foods must fully comply with all the microbiological criteria corresponding to their group or subgroup. In the case of foods, the most important analyses include tests for *Escherichia coli, Salmonella sp.,* molds and yeasts, *E. coli* O157:H7, and *Listeria monocytogenes*.

- **Microbial agents to be evaluated in cosmetic products**
  Total aerobic mesophilic microorganisms, *Pseudomonas*

aeruginosa, Staphylococcus aureus, Escherichia coli, *Salmonella sp*., filamentous fungi and yeasts and *Candida albicans*. The microbial limit will depend on the type of product and the country of destination.

The following methods can be used for the microbiological analysis of non-sterile products:

- United States Pharmacopeia (USP) Chapter <61>,
- British Pharmacopoeia (BP) Appendix XVIB,
- European Pharmacopoeia (EP) Chapters 2.6.2 and 2.6.3,
- United States Food and Drug Administration (FDA). Bacteriological Analytical Manual, Chapter 23,
- Cosmetic, Toiletry and Fragrance Association (CTFA). Microbiology Guidelines, which is currently: The Personal Care Products Council (PCPC). In addition to the 2016 edition, published as the CFTA Microbiology Guidelines 2016, the 2018 edition has a new chapter on investigating microbial data deviations,
- European Cosmetic Toiletry and Perfumery Association (COLIPA). Guidelines on Microbial Quality Management (1997) (Cosmetics Europe 1997).
- International, regional and other standards approved by recognized standards bodies.

6.2.4.1. Microbiological quality

International technical committees participate in ensuring product sustainability by enforcing quality standards. Microbial limits should be adjusted during processing, in accordance with the regulations of the domestic market and international target market, which depends on the positioning of the companies at the national or international level or the trade alliances entered into by the companies, even if the goods are sold as white label products.

Special attention should be paid to cosmetics used around the eyes, on mucous membranes in general, on broken skin, in children under three years of age, in the elderly and in people who exhibit altered immune responses[33] (European Economic Community, 2009). Microbiological limits for cosmetics are detailed in ISO 17516:2014.

6.2.5. Contaminants

The list of contaminants is regularly updated and takes into account the requirements of the destination country. Countries have been concerned with having rapid information exchange systems or alert systems in place, including international systems such as the International Food Safety Authorities Network (INFOSAN)[34].

Contaminants must not exceed the authorized limits for the product. These limits are based on scientific advice from the FAO and WHO and must meet the General Codex Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).

The Codex Committee on Contaminants in Foods (CCCF) establishes and approves maximum permitted levels or reference levels for contaminants and naturally occurring toxic substances in food[35].

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33. EUROPEAN ECONOMIC COMMUNITY. (EC) *Regulation No 1223/2009 of the European Parliament and Council* of November 30, 2009 on cosmetic products [online]. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009R1223

34. FAO. *Early warning and INFOSAN* [online]. Available at: https://www.fao.org/food/food-safety-quality/empres-food-safety/early-warning/en/

35. *Codex Alimentarius*. *Contaminants* [online]. Available at: http://www.fao.org/fao-who-codexalimentarius/themes/contaminants/en/

Where appropriate, a reference to Codex maximum limits for pesticide residues[36] and for veterinary drug residues[37] in food is also included. The Commission of the European Communities, EC Regulation 1881/2006 of December 19, 2006[38] establishes the maximum content of certain contaminants in food products (applicable as of March 1, 2007). Some contaminants may be formed during the production process; hence the importance of periodic monitoring. The agricultural health services of each country are responsible at the national level for the quality of raw materials and food safety. In addition, accreditation bodies accredit the testing laboratories, which provide the list of methods to be used for the analysis of the samples, according to requirements.

When it comes to food, aflatoxins [Aflatoxin B1 and total Aflatoxins B1, B2, G1, G2; Ochratoxin] are also a major public health concern and certain foods contribute to total aflatoxin exposure in many parts of the world.

With regard to cosmetics, phthalates are a class of synthetic chemical contaminants that have the ability to trick the body into believing they are natural hormones when they are not, thus causing health impacts. Phthalates are used as artificial scent fixatives and cosmetic preservatives. Used mainly as plasticizers, they can migrate into the environment, including bodies of water.

They are also contained in some types of plastics used for food and cosmetic packaging.

This is why these and other contaminants are controlled under the regulations of many countries.

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36. FAO. [online]. Codex Pesticides Residues in Food Online Database Available at: *http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/*

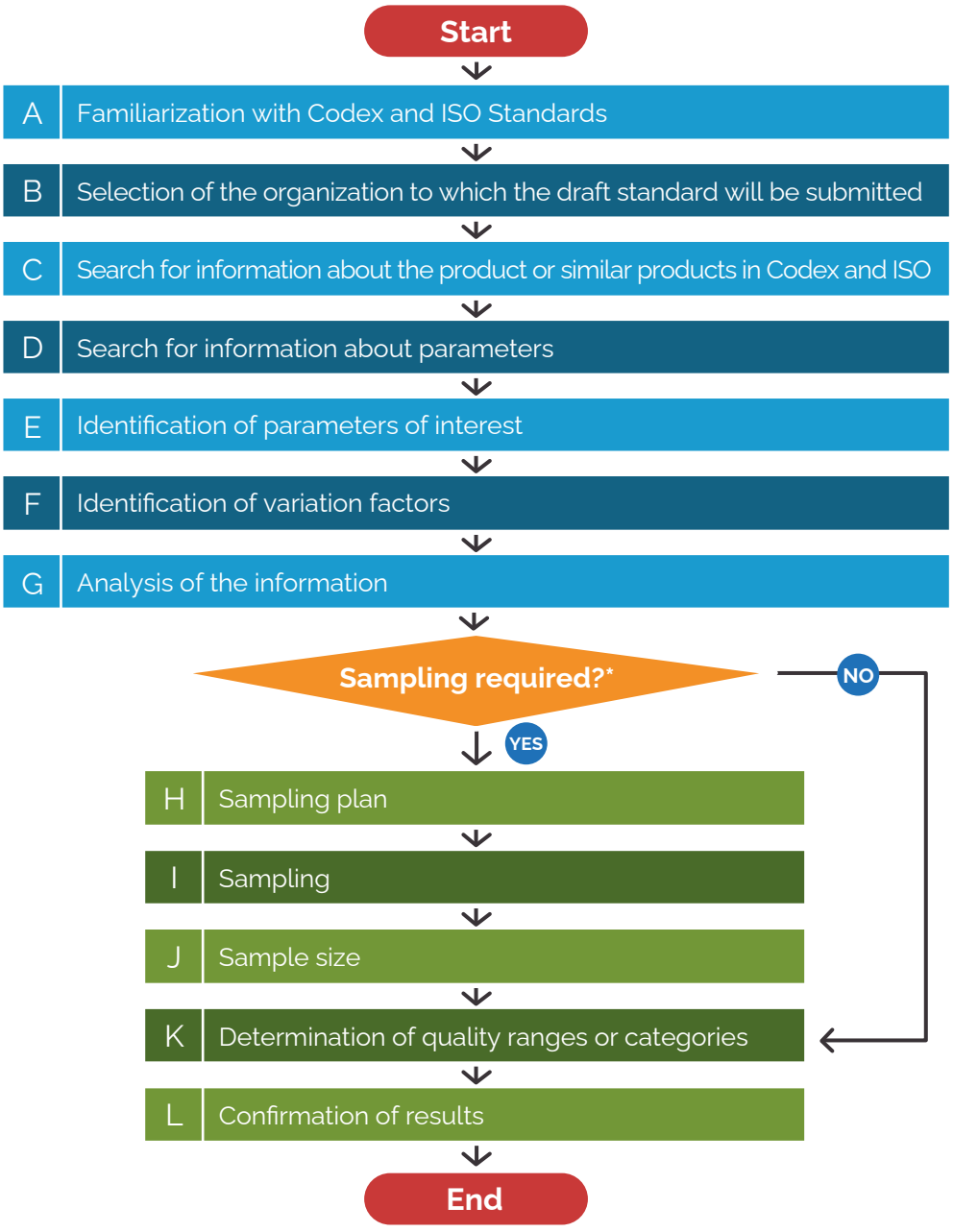
37. FAO. *Index of Veterinary Drugs* [online]. Available at: *http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/vetdrugs/veterinary-drugs/en/*

38. EUROPEAN ECONOMIC COMMUNITY. *EC Regulation No 1881/2006 of December 19, 2006 setting maximum levels for certain contaminants in foodstuffs* [online]. Available at: *https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1881*

6.3. Methodology

6.3.1. Methodological framework for determining quality parameters and their categories

This section describes the step-by-step process used to determine the product quality provisions set out by international organizations. Although basic and general, the focus here is on particular parameters that enable classification into categories, for example fruits classified by sizing. As mentioned previously, these parameters are of course usually associated with the type of product, but also with the target market. For this reason, it is essential to be well-versed in the requirements of the market for which the product is aimed: for example, the access requirements demanded by the American, Asian, and European markets; as well as the Maximum Residue Limits (MRL) for pesticides; niches within a market, such as the ethnic market, the halal market (permitted for Muslims), the kosher market (suitable for the Jewish religion), the large gourmet market with its different variations such as the gourmet market in France, among others. Once the product and target market have been clearly defined, it is necessary to follow a series of steps that are shown in **Figure 9** below.



**Is the information provided sufficient to submit the draft standard or is it necessary to carry out a sampling plan?*

NB: Own elaboration.

Figure 9. Diagram of operations to establish provisions concerning quality and safety-for products to be proposed as an international standard

a. Familiarization with Codex and ISO Standards

It is essential to become acquainted with both organizations' scope of application in order to decide which is the most suitable for the product in question. This can be achieved by consulting the main webpage of the two organizations and looking for information about the product or similar products to identify the scope of the standards in each case and thus obtain more insights to help determine which organization to choose.

b. Selection of the organization to which the draft standard will be submitted

Once the product has been fully identified, along with the target market, it is necessary to select the organization to which the standard will be submitted.

In the case of Codex, a distinction is made between processed food products, fresh fruits and vegetables, milk and dairy products, meat products and their derivatives, fish and their derivatives, cereals, grains, oils and others. Codex is an intergovernmental body focused primarily on food safety.

In contrast, ISO is a private institution in which member countries participate, not an intergovernmental body. It manages specific standards based on the product, material or process within a series of families. Once this selection has been made, the template or a similar standard can be used as a guide for formulating the proposed standard. These organizations have put together templates or models of pre-existing standards designed to ensure that all those of the same type are structured in the same way and include the same information.

c. Search for information about the product or similar products in Codex and ISO

Once the product and its target market have been identified, the next step is to check whether the catalogues of the two organizations already contain a standard or standards covering this product, or similar or related standards with the same scope. It is also important to search the reports issued by each international technical committee, as well as the online ISO platform called "e-ballot" (which can only be accessed by ISO members) to find out which other countries are carrying out standardization initiatives on these issues. This provides good input for identifying the parameters that these organizations have considered important and for becoming familiar with the template, which proves quite useful when it comes to developing the standard. In addition, if there are values or ranges for these parameters in similar products already covered by these standards, they can serve as a good reference point for the proposed standard.

d. Search for information about parameters

A review is then conducted of the information about the product and parameters of interest identified, which is supplemented by any information that may be useful or related. This information should be as complete as possible, mentioning where possible the place of origin, the date, and all the variation factors identified as critical; for example, process conditions (temperature, particle size, unit operations), production conditions (variety, edaphoclimatic conditions) and so on. The information should be filtered, taking into account the reliability of the source, the date, the aspects covered by the information, the quality and reliability as well as the representativeness and validity of the data. It should be provided by recognized institutions such as universities, research centers, government bodies, associations, or companies working in the sector, exporters, among other sources. It is also necessary to review the national standards of producing and importing countries that have standardized the biodiversity product in question to find out the scope of the requirements established in the destination countries. At this point, the decision is taken as to which

laboratory analyses should be performed based on the parameters to be measured for the selected product.

e. Identification of parameters of interest

After having identified the parameters based on the existing reference standards, the market requirements and the experience of the proposing country, the information is then analyzed, and the quality and safety parameters that should be contemplated in the standard are selected. It is important to highlight that the parameters selected are those that allow the products to be classified into categories, according to the product as well the target market.

f. Identification of variation factors

Once parameters of interest have been identified, it is important to identify the factors that affect these parameters; for example, the variety, place of origin, handling conditions, extraction or manufacturing conditions, among others, depending on the product.

g. Analysis of the information

Once the information has been gathered and, according to identified parameters as described above, it should be filtered to determine whether the data obtained is representative and reliable. If it is, the classification criteria arrived at for each of the parameters considered of interest for marketing the product will be incorporated into the draft standard. If not, a suitable sampling plan should be drawn up to characterize the product with regard to these parameters of interest.

The representativeness of the information will be determined by the method selected for obtaining information for each of the sources consulted. This is expected to include criteria associated with the minimum number of observation units established, according to the variability in the target population and the parameters used in the classification, while the reliability will be closely related to the source of information accessed.

Of course, the experience and knowledge of the proposing group is an important factor here in determining the reliability of the information.

h. Sampling plan

Once the quality parameters of interest and the factors that can influence their values have been defined, a sampling plan that includes all these factors is then drawn up in order to be able to establish the values corresponding to each quality parameter. From the literature review of ISO and CODEX standards, the following have been found to be related to sampling for different purposes:

- ISO 2859-1:1999+COR 1:2001+AMD 1:2011, Sampling procedures for inspection by attributes-Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
- ISO 2859-2:2020, Sampling procedures for inspection by attributes-Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.
- ISO 3951-1:2013, Sampling procedures for inspection by variables-Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL.
- ISO 3951-2:2013, Sampling procedures for inspection by variables-Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics.

- ISO 3951-5:2006, Sampling procedures for inspection by variables-Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation).
- ISO 39511:2018, Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation).
- ISO 7002:1986, Agricultural food products-Layout for a standard method of sampling from a lot.
- ISO 5725-1:1994+COR 1:1998, Accuracy (trueness and precision) of measurement methods and results-Part 1: General principles and definitions.
- ISO 28591:2017, Sequential sampling plans for inspection by attributes.
- CXG 50-2004, General guidelines on sampling.

The first thing to do is to construct the distribution curves for each parameter of interest and then proceed to establish quality ranges or categories. When we have "something" we wish to "standardize", we first establish the maximum and minimum levels acceptable (acceptance and rejection criteria). Within these two values, we then establish levels or categories, which will determine the quality categories that are proposed. But to do this, it is necessary to construct the distribution curve for the variable or parameter in question. The criteria for establishing the ranges are explained in item k, since this is done after sampling.

Given the large number of factors that can affect the value of these parameters, one of the most delicate and important points is the definition of the sample size and the sampling itself, to ensure that it is representative of the entire population that may exist or be of interest. A sample can be probabilistic or non-probabilistic, depending on the method by which the sample is selected. When it comes to characterizing the product, the most appropriate method is probabilistic. This type of sampling is the one

recommended for characterization studies and samplings. The elements to be sampled can be selected using simple, systematic or stratified random sampling techniques, with the first being the most suitable, since all the elements have the same probability of being chosen.

i. Sampling

When submitting a draft standard, it is necessary to clarify that the tests conducted are neither experiments nor experimental designs, since the object of study is not subjected to different stimuli or treatments. In such cases, it is more appropriate to talk of observational studies (without external interference), in which the aim is to establish how a product may be influenced by factors (place of production, variety, process conditions, among others) that are not systematically controlled and for which there are no allocation criteria typical of experimental designs. Therefore, in these situations, it is more appropriate to consider the parameterization of a target group (product characterization) based on the identification of representative samples of a population, through the definition and application of suitable sampling methodologies, which can be built around the following criteria:

Purpose: The purpose of any sampling is to make inferences about a population based on the information contained in a selected sample of that population (Scheaffer *et al*., 2007, Vivanco, 2005). It must ensure that the inferences made are valid. If the elements to be sampled are relatively homogeneous, it is recommended that a simple random sampling is carried out in the experimental units, which is equivalent to a completely random design. Now, if the experimental units are not homogeneous and can be grouped together based on certain characteristics that reduce the heterogeneity between the elements, then stratified sampling would be the appropriate method for reducing the variability and would be similar to a block design. Sampling could also be done in stages, and this would be equivalent to a hierarchical or nested design. Thus, a sampling design can be thought of in a similar way to an experiment design and vice versa (Carbonell, 2004).

In practical terms for this guide, the purpose of sampling is to generate reliable, representative and truthful information in order to establish the categorization ranges of the various parameters selected for the product in question, using the most representative output possible. The categorization ranges refer to the different parameters selected for the particular product. It is assumed that there is no national reference standard and it is thus necessary to develop one. Therefore, these categorization ranges refer to the values between which the parameter that we wish to propose as a quality reference of the product varies and, as far as possible, they should take into account all the suppliers of the national market. It is important to note that the product categorization ranges should be capable of meeting international requirements, to ensure that when the proposal is presented at the international level, it is discussed and accepted by the producing countries, which will participate in developing the standard at the international level. The values reported for the selected parameters should be representative of the products produced; they cannot be biased in favor of one supplier, country or producing region or another, since the aim of this guide is to support and encourage the submission of standards at the regional and international level, and it should thus be borne in mind that regional and international standards promote fair trade in safe and quality products. For example, if we wish to characterize a "different" fruit and we want to propose size as a quality parameter, we should be well acquainted with the size distribution curve for the fruit produced in the various exporting countries or those interested in the standard.

Objective: The aim of sampling is to support decision-making through the use of sampling techniques and plans. It is based on determining the value of a population parameter (mean, total, proportion) with an estimation error, so as to be able to make inferences about a population based on information contained in the sample: that is to say, by using a set of measurements rather than having to resort to a census.

From the point of view of product characterization, the objective of sampling is to obtain a reliable, repeatable, truthful and representative frequency distribution for each of the parameters of interest, while taking into account the most important variation factors in the production of the product under analysis. An adequate statistical analysis will make it possible to categorize the parameters (classify them into groups or ranges) and thus provide elements to determine the quality of the product. In this way, it will be possible to develop a well-structured standard that is representative of the characteristics of the product and takes into account the different factors that may affect it.

Good sampling thus results in a reliable characterization of the product at the lowest cost, which is the ultimate objective when carrying out sampling to characterize products for submission as ISO and Codex standards.

j. Sample size

The sample size is directly related to the variability of the relevant product characteristics, and it is therefore recommended that in cases where the aim is to characterize the product for multiple variables, the characteristic with the greatest variability be considered to determine the number of observations to be made as part of the characterization. Furthermore, it is important to consider that the size of the sample influences the cost and the precision of the estimates that will be obtained from the data gathered from the sample. It is thus essential to be clear about the problem under study, the target population, the objectives and the purpose of the study, if we are to properly determine the sample size. In the absence of sufficient resources, a decision should be made about whether to sacrifice precision in order to reduce the sample size.

Now, the sample size can be obtained using international standards or other specialized publications that are applicable to the characterization of the product in question, or by applying the following formulas for the

specific determination of the sample size, usually defined as n, which will be based on the parameter to be estimated from the sample, with the most common being the estimation of the mean and the proportion, which will be calculated using the following formula (García *et al.*, 2013; Kish, 1982):

- Estimation of the mean in a population of unknown size:

$$n = \frac{Z^2_{\alpha/2} * \sigma^2}{\delta^2}$$

- Estimation of the mean in a population of known size:

$$n = \frac{Z^2_{\alpha/2} * N * s^2}{\sigma^2 * Z^2_{\frac{\alpha}{2}} + (N-1) * \delta^2}$$

- Estimation of a proportion in a population of unknown size:

$$n = \frac{Z^2_{\alpha/2} * p * q}{\delta^2}$$

- Estimation of a proportion in a finite known population:

$$n = \frac{Z^2_{\alpha/2} * N * p * q}{Z^2_{\alpha/2} * p * q + (N-1) * \delta^2}$$

where:

$Z_{\alpha/2}$ value of the standard normal function when the accumulated probability is 1 – α (confidence level)

σ standard deviation for the variable of interest

δ estimation error

p estimated proportion of the desired characteristic in the population

q proportion of units in the population that do not have the desired characteristic, corresponds to 1 – *p*

N	population (# production units)	n	sample size

Another alternative that can be used to determine the sample size is to set a level of confidence in advance, which in turn will depend on the degree of rigor and the financial and human resources available. With this level of confidence, it will be possible to achieve the desired interval precision (length). Thus, to estimate the sample size based on the previous assumptions, it will be necessary to solve one of the following formulas (a) or (b) generated from a known or unknown standard deviation, respectively:

a. Sample size calculation based on a **known standard deviation**, known confidence level and established interval length:

$$L=b-a=2z_{\alpha/2}\frac{\sigma}{\sqrt{n}} \quad \text{solving for} \quad n=\frac{4z_{\alpha/2}\sigma^2}{L^2}$$

b. Sample size calculation based on an **unknown standard deviation**, known confidence level and established interval length:

$$L=b-a=2t_{n-1,\,\alpha/2}\frac{\hat{S}}{\sqrt{n}}$$

where:

L	interval length	σ	known standard deviation
b and a	highest and lowest interval respectively within the corresponding confidence level	$\hat{S}$	unknown standard deviation
		n	sample size

$Z_{\alpha/2}$ y $t_{n-1,\,\alpha/2}$	values of the normal distribution and t-student distribution, respectively; based on a defined alpha value

When analyzing formula b) bearing in mind that $\hat{S}$ y $t_{n-1,\alpha/2}$ are unknown before the data is collected, one way to proceed is to assume that the sample size to be determined is large enough to approximate $t_{n-1,\alpha/2}$ by $Z_{\alpha/2}$, and to take a preliminary sample to calculate $\hat{S}$ and find n using formula **b**, as detailed below:

$$L=b-a=2t_{n-1,\,\alpha/2}\frac{\hat{s}}{\sqrt{n}}\ ,\ n=\frac{4z_{\alpha/2}\hat{S}^2}{L^2}$$

It is necessary to clarify that, regardless of the formula chosen, the following precepts should be taken into account:

- The larger the standard deviation σ, the longer the interval length.
- The larger the sample size n, the shorter the interval length.
- The higher the confidence level $1-\alpha$, the longer the interval length.

k. Determination of quality ranges or categories

According to the selected quality parameters and after sampling have been carried out, test methods or measurements required are performed, the information is analyzed to establish the frequency distribution for the values found, which will then be used to establish the quality ranges or categories for each parameter. It is recommended that the categories (confidence intervals) be limited to a maximum of five in order to facilitate the commercialization processes. These will depend on the variability of the data, which is why it is advisable to use one of the data analysis techniques for establishing clusters/groups.

To determine the number of groups, which will be associated with the variables of interest, it is recommended to use the cluster technique as a method for grouping variables. This is a multivariate analysis method that allows groups to be established based on the similarity existing in a set of observations for a set of variables of interest. This technique helps to identify the optimal number of groups and their respective composition, based

on the information obtained for a defined number of cases (observations, producers, productive units, among others).

The ultimate aim of this technique is to aggregate observations into groups (known as clusters), where there is expected to be high homogeneity within the group and the greatest possible difference between clusters (Escobar, 2012).

l. Confirmation of results

Once the characterization has been completed and the groups have been defined by categories, confirmation is obtained from experts on the specific product. In this context, it will be determined whether the characterization of each product reflects reasonable patterns in each of the defined characteristics and, in turn, whether these reflect the desired conditions for positioning the product internationally.

6.3.2. Laboratory Methods and Metrology

6.3.2.1. Laboratory Analysis

The laboratory methods to be applied will depend on the product and the characteristics that are considered decisive in terms of its quality and use. The analytical methods used for foods should be suitable for the purpose in question, which is to say that the methods should have been validated for the significant functional characteristics. The validation study should be based on internationally accepted protocols. Consider that expression form of the requirement should be related with the test method selected.

Codex Standard CXS 234-1999 provides a very complete and well-organized list of food analysis methods classified according to the category of product to be evaluated. This is very useful for the product identification section, where as much information as possible is required to identify the product.

Of course, it is also essential for determining the quality parameters, since methodologies supported by international organizations should be used to ensure that there are no problems between countries when it comes to making decisions regarding the quality that a particular product offers.

These standards include standardized methodologies endorsed by various internationally recognized institutions.

6.3.2.2. Metrology

Metrology has to guarantee the quality of any measurements taken. It is crucial for determining quality parameters and especially for establishing quality ranges or categories. To ensure the measurement quality of the respective magnitudes for the quality parameters, it is necessary to have a metrological assurance system that takes into account aspects such as the measuring instruments or equipment and the measurement methodology. In addition to enabling measurement traceability, this makes it possible to determine whether both the equipment and methodology are appropriate for the magnitude being measured, as well as the level of precision and accuracy required and the corresponding uncertainty. This issue is so important in determining the quality parameters of the product, that the measurements should be carried out by accredited laboratories, or ones that implement the ISO/IEC 17025 standard or Mutual Recognition Arrangement (MRA)[39], which can guarantee compliance with all aspects to ensure the reliability of a measurement.

In summary, metrology integrates data collection and analysis procedures to improve measurements, thus reducing the likelihood of incorrect decisions being taken.

Laboratories that implement the ISO/IEC 17025 standard ensure a high level of reliability in the result obtained. Therefore, when preparing a standard aimed at characterizing or standardizing the quality of a product, access to

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39. BIMP. CIPM Mutual Recognition Arrangement (CIPM MRA) [online]. Available at: *https://www.bipm.org/en/cipm-mra/*

accredited laboratories should be sought; and when evaluating a product, to select an accredited laboratory that guarantees reliable results.

All the parameter measurements that are reported in the draft standard should come from a reliable source, which means seeking out accredited laboratories that can guarantee compliance with all the essential requirements and necessary metrological conditions; or else institutions that have metrological assurance systems in place or that implement the ISO/IEC 17025 standard, thus demonstrating that they have a Quality Management system that enables them to comply with the essential requirements in order to ensure the reliability of the measurements and reported values.

As a general overview, in chapter 3 some basic concepts, relative to definitions related to metrology and quality in laboratories are presented, for all those new to the subject, but that wish to have a basic understanding of the various aspects that those in charge of the measurements or information analysis need to know and apply. However, it should be stressed that the measurements that will form part of the draft standard to be submitted should be entrusted to the NMI or accredited calibration laboratory with experience on the subject that can guarantee the reliability of the information presented to the international organizations so as to avoid subsequent delays. If the product identification parameters include one that is very specific, not widely known or that cannot be performed by an accredited laboratory, then the proposing organizations should reach out to the metrology institute or metrological institutions in their respective country to obtain the necessary guidance regarding its application.

In the case that an accredited laboratory cannot be found to carry out the tests, the selected laboratory should consider requirements 4.1, 4.2, 6 and 7 of the ISO/IEC 17025 standard.

6.4 Documents and Publication of Results

The document provided by the institute or accredited laboratory responsible for determining the values for each parameter should include the details of the methodology as well as the measurement traceability.

The body in charge of submitting the proposal for international standardization should be able to ensure the traceability of the sampling, whether they have carried it out themselves or they have contracted it out, since the laboratory or accredited institution that performs the measurement receives the coded samples detailing the variation factors that were considered; for example, the place of origin, extraction or purification methodologies, cultivation conditions, variety, etc. The institution hired to do the sampling, or the proposing institution itself, can take charge of the statistical analysis of the information provided by the laboratory or entity responsible for the measurements. It is advisable to hire companies or institutions that have experience in sampling the product in question, as well as laboratories that are accredited to determine the measurements, since this ensures that the quality standards for both measurements and sampling are met.

It is very important to reach out to companies that are interested in or will benefit from the application of the standard, such as producers, marketers, carriers, exporters and trade associations, to obtain information or funds to support this work.

7 RECOMMENDATIONS FOR SUBMITTING A PROPOSAL FOR A NATIONAL STANDARD ON A NATIVE SPECIES PRODUCT AT THE INTERNATIONAL LEVEL

To submit a proposal for a national standard at the international or regional level, it is recommended that the following points be taken into account:

7.1 Make sure the product is of interest to the world

Developing countries often make native species products that offer important nutritional and health properties. However, it is not enough to have a good product to propose a draft international or regional standard, the product should be widely known, and there has to be a regional or international market for it. Only then will it be certain that other countries that also produce this type of product and international buyers will accept the proposal; otherwise, it may not be approved. For more details on the evaluation of the product in the international market see Section 5 and the step two of Subsection 6.1 of this guide.

If the product is not well known but is of international interest, increase the visibility of the product! In other words, carry out prior work focused

on efforts to make the product known. To achieve this, you can request support from the trade promotion agencies in your country. It is important, also, to take advantage of international conferences to present the product to peer organizations, so that they in turn can contact the importers of that product when they return to their countries. It may be the case that the representative of the national standards body is not familiar with the product, despite the fact that it is sold by the country. It is your duty to "sow the seed of curiosity" among peer organizations that might investigate the way the product is being marketed upon return to their country of origin.

7.2. Review existing information about the market

Once you have ensured that the product is of interest to the world, consider the following:

- ☑ Identify whether there are any producers in other countries.
- ☑ Identify international buyers.
- ☑ Investigate the type of presentation in which the selected product is being manufactured or bought. In the case of buyer countries investigate the final destination of the product, that is, whether it is purchased as a raw material or end product. If it is as a raw material, try to find out what end product it is made into. This point is important because the requirements for the raw material will be defined according to the end product. In other words, they may increase or decrease in relation to the requirements envisaged initially. Locate the national export promotion agency, which can help you obtain better market intelligence.

7.3. The importance of data (statistical information)

It is recommended that all information such as analysis results, historical information and so on be presented in an orderly and didactic manner as supporting material in face-to-face meetings, or as part of the forms requested by the corresponding international standards body. This information will form part of the technical information that will back up the proposal. For example, statistical charts can be used in several ways to make this presentation.

7.4. Establish contact networks

Since the national standards bodies have already been identified, make sure that they participate in the international or regional standards bodies to which you wish to submit the proposal. If they do, locate the person from the standards body who participates in the specific regional or international committee or subcommittee.

If it is an international organization, find out if there are any regional organizations within the organization. For example, the *Codex Alimentarius*, an international standard-setting body specifically for food, has regional coordinating committees. In the case of Latin America and the Caribbean, the regional technical committee is the CCLAC.

In the case of ISO, if you represent a developing country, contact the Committee on Developing Country Matters (DEVCO). Operating within the framework of this committee is Working group 1. Standardization Areas of Primary Interest to Developing Countries. This reflects ISO's interest in supporting the needs of developing countries in the field of standardization. It is suggested to contact and request support from DEVCO countries participating in ISO international technical committee that is of interest to you.

And what if the regional technical committee or DEVCO does not support you? Do not be discouraged, strengthen your network among the other countries that produce your product or the buyers. Always ensure you have well- founded technical support, since that will prevail in the event of any differences. This is precisely the intention of this guide: to help countries to ensure they have a clear technical justification that supports the submission of a new proposal for an international or regional standard. Review Sections 8 and 9 and the Annex to this guide.

7.5. Be clear about the process implemented by the body and its approval times

Each organization has its own stages and timeframes for developing normative documents. This is why it is important not only to be familiar with the guidelines or manual, but also to pay attention to the virtual tools where this information is made available and thus ensure that you participate by issuing an opinion on the document in question, since the fact of having submitted the proposal does not stop you from voting or expressing a position on it.

It is very important to know and be sure of the type of balloting in which you are going to participate because this determines the percentage of countries that have to approve the proposal. This information should be very clear to everyone involved in the process. In addition, it is recommended to take into account, in particular:

- **The accelerated procedures implemented by each organization**, since this can reduce the timeframe or number of stages.
- **The specific procedures that each international technical committee may have in place for the submission of new work,** including, for example, the development of new standards and the inclusion of new species in existing standards.

7.6. Put together your delegation

The strength of the work of the technical committees lies in the accumulated experience and knowledge possessed by all their members. However, when making an agreement and presenting the country's position at a meeting, all members defend a single position or ballot, which enables them to resolve concerns or answer the unexpected queries that typically arise during discussion at in-person meeting. The sheer number of documents and topics that are reviewed at a meeting means that the responsibilities have to be shared.

Nevertheless, in most cases, developing countries, with great effort, are able to appoint a single representative. This can limit or discourage the participation of the country, which is why it is advisable to encourage the other members of the national technical committee to participate in the international meeting, especially when it is held in the region. Member engagement is suggested, by means of virtual tools used in different international standardization organizations.

Furthermore, it is recommended that the Ministry of Foreign Affairs or a consular representative participate in the international meeting, wherever possible, in the event that a representative of the technical committee or the national standardization body is unable to attend in person.

7.7. Strengthen your position (participate in person in the technical committees)

The best way to present a document or proposal for an international standard is to do it in person. In other words, voting takes place virtually, but before it begins (one year before, on average), it is recommended that the proposal be presented to members to provide information, substantiation and answer any questions. The organization that put together the proposal for the standard is the one best placed to defend it. Sometimes the presentation is delegated to another expert, manager or member of the international

technical committee. But no one will give a better presentation than the proposer. Countries that would not normally vote or might even reject the proposal will be less likely to do so after listening to the justification and hearing about the importance and impact of the draft standard.

7.8. The importance of coffee breaks and spaces for sharing

Each international meeting offers informal spaces (recesses, coffee breaks, dinners, among others) that allow experts from different countries to share, explain or clarify the topic of interest with another member or country. More support can often be achieved at this time than during the meeting, depending on the topic. Moreover, if you can identify the country that is strongest or a leader on an issue of interest to your country, it is advisable to establish contact with them in order to arrange further meetings.

7.9. Be clear about your opportunities to support other countries. How might you support them?

In every type of negotiation, it is important to bear in mind the following:

- Always keep an open mind, listen to the proposals, but do not commit to something that you cannot fulfill.
- How far can I negotiate? A question that is often asked is: Can we live with that? In other words, will that requirement or agreement create any limitations for me in the activity or process under discussion? It is also essential to be clear about how far to give way, as this will allow a range of options to be discussed.
- When you are at the international meeting, it is recommended that you liaise with the standards body you represent to consult on any decision that may come up for discussion at the regional or international committee meeting.

7.10. Thank the countries that supported it

It is important to strengthen ties between our peers and to express thanks for their support for the proposal presented. Not only is this a show of respect and good manners, but it also strengthens ties and opens doors for future efforts.

If the proposal is not approved, thank the countries that supported it and carry out an analysis of what happened so that it can be taken into account the next time a proposal for a regional or international standard is submitted.

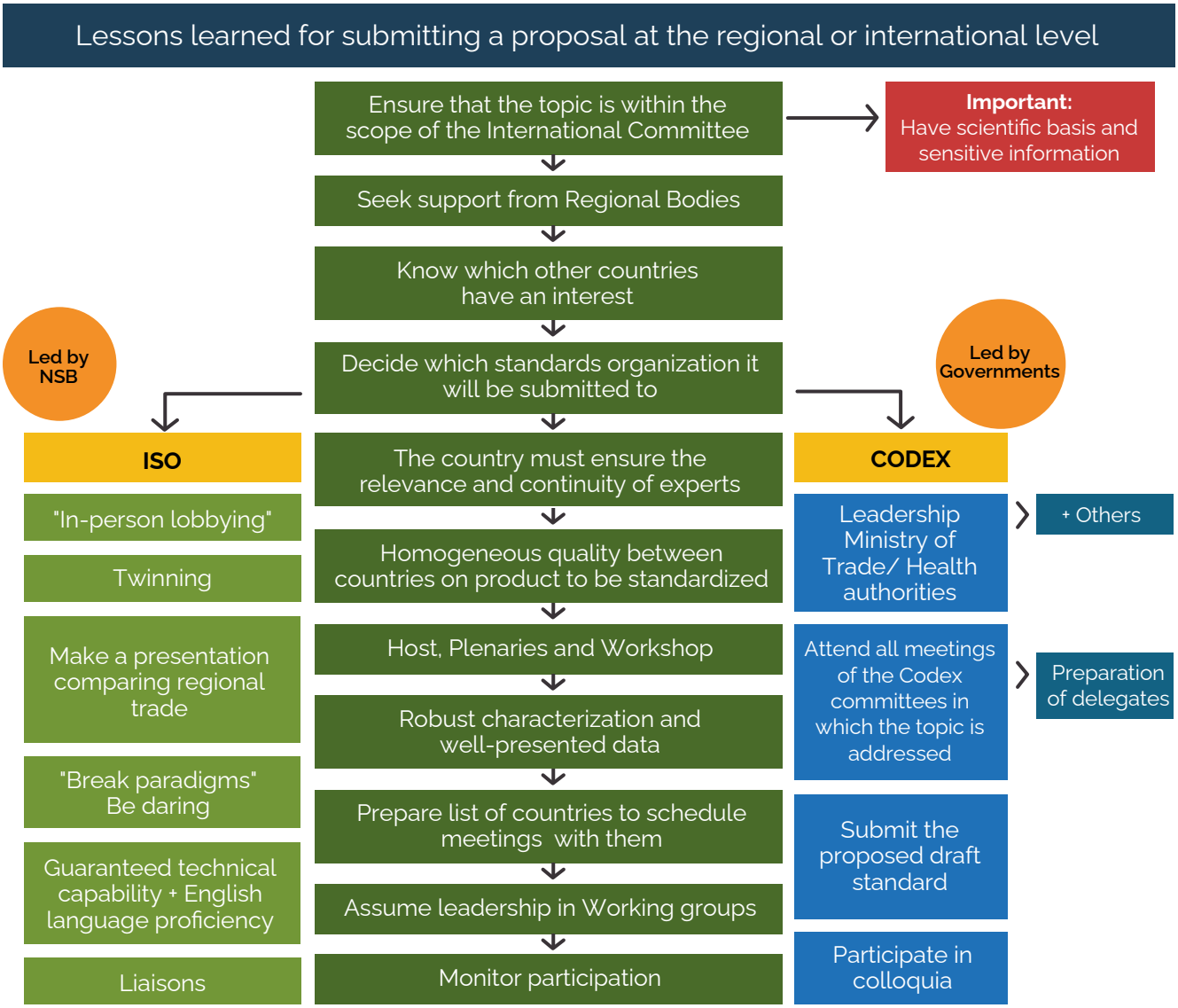

Figure 10. Diagram showing the recommendations for submitting an international proposal on native species products


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PROCEDURE FOR SUBMITTING PROPOSALS FOR TECHNICAL STANDARDS FOR NATIVE SPECIES PRODUCTS AS DRAFT REGIONAL OR INTERNATIONAL STANDARDS TO THE *CODEX ALIMENTARIUS*

8

This section was developed based on the provisions of the *Codex Alimentarius* as of 2020, and we therefore recommend consulting the official Codex portal[40] for the latest recommendations and procedural manuals.

8.1. Procedure for submitting a proposed standard

All *Codex Alimentarius* member countries have the right to put forward new topics as initial proposals to determine whether they meet the requirements for consideration as a draft standard by the committee specializing in the proposed topic.
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40. FAO. *Codex alimentarius* [online]. Available at: http://www.fao.org/fao-who-codexalimentarius/en/

To propose a new topic for consideration by the Codex, it is essential that the product in question has been standardized within the proposing country, which involves having determined the quality and safety characteristics that identify it and other aspects that form part of the structure of the normative documents defined by Codex.

It is recommended that, as far as possible, the country have a national standard for the native species product, which will serve as the basis for the proposal that will be considered by Codex.

The format of Codex standards can be found in the most recent standards approved by the commission on issues related to the product in question, as well as by consulting the *Codex Alimentarius* Procedural Manual.

Below is a summary of the steps that need to be carried out when submitting a new topic to Codex for consideration, from the application made by the country to the international standards body, to the preparation of the corresponding proposal for consideration by the *Codex Alimentarius*.

8.1.1. Request for new proposals

Each of the *Codex Alimentarius* committees sends a circular letter through the Codex Secretariat inviting member countries to submit proposals for new work.

It is worth clarifying that the proposing country should have previously identified the Codex committee related to the topic of interest, since there is more than one committee that could consider standards on products obtained from native species. Therefore, it is necessary to be very clear about the nature and use of the product, and to verify whether, according to the mandate of the selected Codex committee, the topic might be within the purview of the committee in question.

Each Codex committee has a mandate, or a field of action, which defines the issues that it can examine. To mention just a few examples, the following are committees which might examine native species products: Codex Committee on Fresh Fruits and Vegetables, Codex Committee on Processed Fruits and Vegetables, Codex Committee on Spices and Culinary Herbs, Codex Committee on Cereals, Pulses and Legumes, Codex Committee on Sugars and Codex Committee on Additives, among others.

It is also possible to access the report by the most recent meeting of the Codex committee in question and consult the agreements related to new issues under consideration and the deadlines for sending information. These reports can be accessed through the Codex portal:

http://www.fao.org/fao-who-codexalimentarius/en/

In response to the communication, it receives through the Codex Contact Point, or after consulting the reports on the meetings by the committees of interest, the member country proceeds to request the consideration of the standard via the corresponding proposal, which should be sent through the Codex Contact Point to the Codex Secretariat within the stipulated timeframe (see the content of the proposal in sub-section 8.1.4).

The purpose of sending the document for consideration in advance is so that the Codex Secretariat can circulate it among the countries that participate in the Codex committee chosen by the country submitting the proposal. The issue will then be discussed at the plenary meeting of this committee, and a decision will be taken as to whether it reflects the interests of the committee and, of course, the *Codex Alimentarius*. Depending on the origin of the product and its trade coverage, it will be determined whether an international or regional standard should be developed.

When preparing the proposal, it is best to avoid including a detailed analysis of issues that fall within the scope of more than one Codex committee because this requires them to be discussed in each committee, leads to delays in the matter being addressed and to additional costs for the proposing country, since it will have to attend the meetings in which the proposed draft standard is considered, as well as those committees in which parts of it are examined. Do not forget that each committee meets in a different country.

If it is necessary to refer to an issue that is outside the mandate of the committee to which the proposal will be submitted, standards or codes developed by other committees may be cited. This happens in the case of the Codex standards on fruits, which include a chapter on practices related to product preparation and handling, which cites the documents prepared by the committee in charge of that issue rather than describing these practices.

For the purposes of this guide, the topics emphasized are those related to product standards, although Codex develops standards on different issues including codes of practice applied to food, inspection systems and food hygiene.

New topics refer not only to proposals for creating standards on products for which there is no Codex standard, but also to proposals to update an existing standard, or to amend a document due to the need to review or include a particular aspect of that standard.

In the event that the relevant Codex committee is inactive, the requesting country can raise the matter directly at the meeting of the *Codex Alimentarius*, after having sent the proposal through the Codex Contact Point, to ensure that the members of the commission are aware of the information in advance and have the opportunity to submit comments. During the meeting of the commission, a consensus is reached on the steps to be followed, such as the approval of the draft standard, the purpose and scope of application that the standard will have (international or regional), as well as the selection of the country that will lead the committee and the proposal, along with the deadlines for completing the stages of the review process.

8.1.2. Important aspects to take into account when preparing the proposal for a standard for native species products

In the case of native species products that are considered part of the biodiversity of a country or a region, it is important to take into account certain basic aspects that are of great interest to the *Codex Alimentarius* and can significantly affect the acceptance of the issue. The proposal or discussion paper that is sent to the *Codex Alimentarius* es fundamental should include the following information:

- Description of the product in question, preferably accompanied by an image or images of both the part that is sold, as well of the species from which it is obtained; and which may include:
  - Coverage of main issues related to consumer protection and trade by existing or proposed general standards;
  - Number of products that would need separate standards, detailing whether they are raw, semi processed, or processed, including information on the justification of such needs;
  - Information on work already undertaken by other international organizations in this field and/or suggested by relevant international intergovernmental body(ies), including an analysis of areas of possible complementarity, gaps, duplication, or conflict with previous activities are not provided in the project document, as required in the Procedural Manual: Criteria for Work Priorities;
  - Proof that the product will be presented in satisfactory condition for human consumption; and/or
  - Level of difference with respect to other products.
- The nutritional composition of the proposed product;
- How it is prepared, where relevant, and how it is consumed;

- Commercial impact of the product, as evidenced by statistics of volume of production and consumption and trade patterns between countries showing the level of demand and supply;
- The main producers and destinations of the product (with figures and graphs);
- Figures showing how trade in the product has evolved in recent years in the country proposing the topic; and
- A report on the national area of production and the trend over recent years.

The aforementioned aspects may vary according to the nature of the product and some of these points may not apply in all cases. The information given above may apply to products such as fruits, vegetables and tubers. In other cases, such as that of a native product that is used as a condiment, a description of its nutritional value is unlikely to be required. However, it may be necessary to describe the different forms in which it is sold.

Once the Codex Secretariat has received the information within the established timeframe, it circulates it to the member countries, which will have the opportunity to submit comments on the matter or present them at the plenary meeting of the corresponding International Committee.

8.1.3. Attendance at the meeting of the *Codex Alimentarius* Committee

The country proposing the standard should attend the meeting of the International Committee to present the project proposal – that is to say, the information submitted as the discussion document – to the delegates of the countries and to respond to any concerns that are raised at the meeting or are submitted in advance. Registration for meetings is carried out through the country's *Codex Alimentarius* Contact Point. The result of the presentation will be the decision taken on the proposal by the plenary session attendees, which may be either to endorse the issue as it was presented, modify its scope in order to add products for consideration or remove some of those contemplated, or else not accept it for consideration due to a lack of relevant information, or reformulate the proposal to be presented at the next sessions, or another result.

As part of the preparation for attending the meeting of the Codex Committee, the proposing country should select a delegate or delegates with sufficient autonomy to make decisions or reach agreements on any topics of debate that may arise during the meeting. Failing that, the country should define in advance the appropriate communication channels to enable the delegate to be in permanent contact with the national authority in charge, in order to ascertain the country's position and convey it to the plenary committee.

Furthermore, the Codex Committee in which the presentation was made may decide that the issue should be put before a Regional Codex Committee to address aspects related to trade, supply and knowledge of the product. Consequently, the final document will be identified as a regional product standard and not as an international Codex standard. However, it should be noted that the document approved as a regional standard may later be submitted to Codex for consideration as an international standard once trade in the product evolves and it becomes more well known worldwide.

If the intention of the country is for the product in question to achieve international status, it is very important that the information about its commercial impact, as well as production and destinations (see sub-section 8.1.2), clearly convey the relevance of the issue for different countries in various regions of the world. If this information is restricted to a group of countries in a particular region, the decision will likely be to examine it as a regional Codex standard.

Since presenting the new topic for consideration to the Codex committee is crucial to completing the remaining steps and securing its recommendation by the Executive Committee, it is essential to take into account the following aspects to ensure the support of the other members of the committee and prevent it from being rejected:

Continued on next page.

• In advance of the presentation, contact the delegates of the countries that may be interested in the topic, either because they are producers or consumers of the product. This contact can be made prior to the international meeting through the Codex Coordinating Committee for Latin America (CCLAC). This meeting could be virtual. It is also possible that a face-to-face meeting may be scheduled prior to the start of the International Committee through the CCLAC on the same day or the day before.

• Find out the opinions of the delegates regarding the topic in question, their interest in the future document and its usefulness for trade in the product, and at the same time express your point of view to them on these aspects. If there are any explanatory brochures on the subject, it is important to have them to hand and send them on to the delegates you have contacted. In some cases, depending on the circumstances, a number of proposers have distributed samples of the product under consideration.

• Prepare a very concise but illustrative presentation highlighting parts of the information that was previously circulated through the Codex Secretariat, such as the sections related to the product characteristics (accompanied by images), producing countries, product destinations, trends in production and trade (which can be in graphic form). Also explain the importance of having a standard (a useful tactic here may be to pick up on points made during the initial contact with delegates from other countries).

• As an expert on the topic, set aside any information that may be needed if questions arise about the product under consideration, such as production data, export volumes, differences between this and similar products regardless

Continued on next page.

of whether they are covered by a standard, aspects related to its production and its impact on the environment, ways in which it is used or consumed, and so on.

- The proposing country should pay close attention to any comments made during the presentation of the topic to the committee because they may give rise to ideas that can enrich the future document that will be submitted for critical review by the Codex Executive Committee (see sub-sections 8.1 .4 and 8.1.5).

- The proposing country should be prepared to assume the chairmanship of the electronic working group where the work will be reviewed, to suggest the working languages, and be logistically prepared for the work to be undertaken (for example, translation costs, trips to committees, etc.).

The conversion of the standard from a regional to an international one can be requested as soon as the regional standard has completed the consideration process. Such a request is preferably made through the committee related to the topic in question and should undergo critical review by the Executive Committee, which will recommend to the *Codex Alimentarius* what the next step should be. Since these are standards that have been extensively debated in the process that culminates in a regional standard, the Commission may agree to consider the conversion through a uniform accelerated procedure, which is described below (see sub-section 8.3).

8.1.4. Preparation of the proposal for the *Codex Alimentarius* Executive Committee

Once the issue has been given the go-ahead by the International Codex Committee to which the proposal was presented (see 8.1.3), the proposing country proceeds to make the adjustments required and send documentation to Codex Secretary, in order to be submitted for consideration by the *Codex Alimentarius*, Executive Committee, the body responsible for recommending to the *Codex Alimentarius* Commission which topics should be officially approved for consideration as a Codex standard.

It should be remembered that the proposal was prepared and sent in advance to the Codex Secretariat, which circulated it to the countries, and it was later discussed by the Codex Committee at a meeting attended by the proposing country. (See sub-section 8.1.3)

It is on that basis that any necessary adjustments resulting from the debate in the Codex Committee are then made.

The project document that will undergo critical review by the Executive Committee should include the information detailed below:

8.1.4.1. Purpose and scope of the standard

This information should be aligned with the scope agreed at the International Committee meeting during which the presentation of the proposed standard was made.

When it comes to native species products, such as fruits and other food products sold fresh, it is a good idea to include the scientific name (name of the species), the botanical family to which the product in question belongs and, if necessary, the alternative names used in other countries, including in different languages, in order to avoid any confusion regarding the product in question.

The end use of the product should also be specified in the purpose, such as, for example, for fresh consumption and industrial use or just one of these alternatives.

If it is a manufactured product, it is necessary to specify the raw material from which it is made. It may also be important to state the scientific name of the source material, which will prevent the manufactured product from being confused with similar ones, although the relevance of specific details about the source material should be evaluated.

In the purpose and scope of the standards for this type of products, the above paragraph on the use of the product is also applicable, except that in this case it would be for direct or industrial consumption.

It is also a good idea to mention whether the standard will be international or regional in scope, depending on the results of the Codex Committee meeting. In the case of amendments to standards, their inclusion needs to be justified within the scope of the standard and with proof that the product will be presented in satisfactory conditions for human consumption.

8.1.4.2. Relevance and timeliness

This can include the origin of the standard, which is to say the decision made by the Codex Committee to which the proposal was submitted. It is also advisable to mention its commercial importance based on the statistics presented to the committee, as well as information on the area of cultivation and any recent changes in these data.

With regard to the product itself, information can be included about its origin and how widely it is consumed.

The data provided as evidence should be accompanied by the bibliographic sources consulted, which constitute the support needed to back up the information presented. It is therefore recommended that recognized national and international sources be used.

8.1.4.3. Main aspects to be covered

This part of the report refers to the aspects contemplated by the standard. Based on the structure of the draft standard prepared by the proposing country, it thus details the topics covered in the chapters that will make up the future international or regional standard. The information requested here will help to establish whether the proposed topic is amenable to standardization; in other words, whether the specific characteristics of the product have been identified. As these may vary from one country to another, they should be included in a normative document that covers the range of possibilities.

As part of the work carried out prior to the preparation of the proposal, the country can consider the regulations relating to the native product that are in place in different countries. Neighboring countries will probably be able to pool data on the product characterization, which will help save time later, because if the proposed standard already covers products from different origins, the discussions needed to include such products in the standard will not be necessary.

To support this information, it is important to attach the proposal in the Codex standard format, which establishes the structure and approximate content of the future international or regional standard. Of course, this content may undergo some modifications as a result of the agreements reached in the committee meetings.

8.1.4.4. Evaluation of the criteria for establishing work priorities

It is important for the Codex Executive Committee to know the reason why it should undertake work on a standard. So, in addition to the information mentioned in sub-section 8.1.4.2, it is important to include the trade characteristics of the product, the production and consumption volumes in different countries, as well as the trend in these data and the product's potential to enter new markets. It is also necessary to explain the risks associated with the lack of a standard, which may be risks for both the consumer as well as trade, and how these risks can be mitigated through the elaboration of the normative document.

This information can include an explanation of the importance of having a document that covers commercial practices and consumer needs. Furthermore, since it is a standard focused on quality and safety (Codex principles), it would also ensure that the health of consumers is protected.

8.1.4.5. Relevance to the Codex Strategic Objectives

All work undertaken by Codex must abide by the guidelines set out in its strategic objectives. These objectives can currently be found in the *Codex Procedural Manual* and are essentially focused on protecting the health of consumers, ensuring fair practices in the food trade, encouraging coordination with other international organizations, prioritizing and directing the work of preparing standards and amending any published standards as required. There is also a CODEX Strategic Plan[41], which is updated every five years. This document includes the goals and objectives of CODEX, which are aligned with the SDGs. When submitting the discussion document, this information can be used as support.

Thus, the elaboration of a standard on issues related to biodiversity can have a direct impact, for example, on the protection of people's health and the protection of the environment because it contemplates aspects that, if not addressed, will negatively affect consumers of the product. Moreover, inappropriate exploitation or cultivation affects the environment and, although the standard does not explicitly cover these practices, it is an underlying aspect that is associated with requirements such as limits on

41. The Strategic Plan for the 2020-2025 period can be downloaded from the following link: *http://www.fao.org/fao-who-codexalimentarius/publications/en/*

contaminants. The standard can positively affect trade by making it more equitable between countries, since it considers requirements that serve as the reference point for establishing trade agreements, irrespective of the countries involved.

Although environmental protection is not part of the Codex objectives, the country should bear in mind that when dealing with native species products, the necessary measures should be taken to protect the habitat and ecosystems associated with the product in question. It is important, therefore, to consider the environment and its protection, as well the sustainability of the resource, during both the cultivation stage as well as the handling and packaging of the product for sale.

8.1.4.6. Information on the relation between the proposal and other existing *Codex Alimentarius*, as well as other ongoing Codex work

If there are existing documents that have any connection with the proposed topic, whether it is within the same committee or in different committees, it is essential to make this information known. It is important to identify any complementarity between documents, which can provide an additional argument to justify the work. If this is not the case, it is sufficient to indicate the committee in which the proposed work will be carried out.

It should be clarified that complementarity does not mean duplication of work, but rather that the working document may refer to other documents developed by Codex that should be taken into account for the correct and complete application of the future standard.

There are Codex standards that could be deemed cross-cutting in nature due to their scope of application, which is to say that their content can be applied to a large number of products and even committees. These documents, which include standards and related texts, as Codex calls the codes of practice and other documents developed, can be cited where appropriate within the Codex product standards.

Thanks to this, when describing packaging characteristics in a standard on a fruit, in addition to including the usual texts established by Codex, reference can be made to the Code of Practice for the packaging and transport of fresh fruits and vegetables (CXC 44-1995), meaning that the details of the activity will be found in this code. For this reason, when putting together the proposed standard, it is essential to take into account the provisions set out in the Procedural Manual and consult the Codex product standards developed by the same committee.

If there is already a Codex standard on a topic very similar to the one addressed in the proposal and there are common elements in the two documents or there are gaps in the existing standard, it is important to explain to the Executive Committee the reason for preparing the new document, and why it is not sufficient to update the existing standard to cover the new topic proposed.

8.1.4.7. Identification of any requirement for and availability of expert scientific advice

When a country takes on the responsibility of proposing a topic to Codex, it is because there is a body of technical and scientific literature to support the information contemplated in the proposed standard, and the country should therefore ensure that the experts responsible for the studies have committed in advance to participating, if required, when the standard is developed. The availability of these experts should be stated in this sub-section of the report.

All the information generated on the product characterization is what really constitutes the scientific backing for the work performed. This information should therefore be made available in case it is needed to answer any concerns that may later be expressed either by the Codex Executive Committee during the critical review, or during the debates that take place in the Codex Committee.

The country should ensure that it has the experts and the infrastructure needed to carry out additional analysis or measurements that may be required to supplement the draft standard.

When it comes to the consideration of specific topics such as requirements on contaminant limits, the use of additives or other particular issues, it is important to bear in mind that Codex has experts on these topics who belong to the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Joint

FAO/WHO Expert Committee on Nutrition (JEMNU). If the participation of these experts is required, the Executive Committee should be informed.

8.1.4.8. Identification of any need for technical input on a standard from external bodies

If, depending on the nature of the document, input is needed from documents developed by other organizations, notification should be given of this need. If not required, this fact should be recorded in the report submitted for critical review.

The analysis of this information should include the review of work carried out by other international organizations on the topic in question. The aim is to avoid duplication in the work undertaken by Codex, and to detect overlaps and gaps between documents. If any of these situations should occur, the proposing country should provide substantiation for the proposed standard.

8.1.4.9. Proposed time-line for the completion of the new work

As indicated in the Codex Procedural Manual, the elaboration period should not normally exceed five years. Sub-section 8.2 explains each of the steps or procedures in which the country can submit the information requested, taking into account the activities described and also the complexity of the document to be developed. The main milestones that the new work schedule should consider are: the work start date, the proposed date for endorsement at Step 5, and the proposed date for adoption by the *Codex Alimentarius* Comission.

To determine these timeframes, in addition to considering the number of steps or procedures and the frequency of the Codex Committee meetings, it may also be important to consider the debate generated when the proposal was presented to the committee, since difficulty in reaching agreement on the consideration of the topic and the product or products covered can mean that a longer timeframe will be required to develop the standard.

However, according to Codex policies, if the total time required for consideration is very long, objections are likely to be raised. In this case, it is advisable to adhere to the maximum times established by Codex, which can be accomplished by ensuring that the project document is well prepared and backed up by technical support, anticipating any potential difficulties, and creating strategic alliances to push forward the proposal.

Finally, this report must be submitted by the Codex Contact Point of the country proposing the standard to the Codex Secretariat, which in turn will send it to the Executive Committee for critical review.

8.1.5. Critical review by the Codex Executive Committee of the submitted proposal

It should be borne in mind that the decision made by the *Codex Alimentarius* Commission to undertake the work or not is based on the critical review of the proposal by the Executive Committee.

To carry out this review, the Executive Committee takes into account the guidelines established by the Codex Commission, understood as the *Criteria for the establishment of work priorities*. It also assesses the

standardization needs of developing countries, which are set out in the report submitted by the proposing country.

As part of the critical review, the Executive Committee considers whether the work proposal requires the participation of other competent subsidiary bodies of the Codex Alimentarius; in other words, other committees that, due to their scope of work, have information that can complement the proposed work. This review also determines whether specific expert advice is needed from the FAO or WHO or from other bodies of scientific experts related to the topic in question.

The result of the critical review will be taken into account by the *Codex Alimentarius* Commission, which will decide whether it can undertake work on the proposed standard.

Depending on the standard, the information presented and the result of the critical review, the Commission may decide to do one of the following:

- Undertake work on developing the Codex document;
- Undertake work on updating a Codex document; or
- Make an amendment to a Codex document.

The fundamental difference between an update and an amendment is that the former makes additions or adjustments to technical aspects of a published Codex document, while the latter makes corrections or other editorial changes to a published Codex document.

The Commission is unlikely to decide not to accept the proposal for consideration due to deficiencies in the report presented to the Executive Committee because, in this case, the document will be returned to the proposer, who can then make the corresponding adjustments and resubmit it to the Executive Committee through the regular channel indicated above.

Therefore, it is essential that the report submitted is as complete as possible and covers each of the items included in sub-section 8.1.4. Although this does not guarantee that the proposal will be fully accepted, it does largely ensure that it will not be rejected.

8.2. Uniform procedure for the elaboration of Codex standards

The standard procedure that is followed by the *Codex Alimentarius* for developing a proposed standard once it has been approved by the *Codex Alimentarius* Commission for development by the corresponding committee consists of the steps explained below.

Step 1

This stage includes the approval of the proposal for new work by the *Codex Alimentarius* Commission (CAC) based on the opinion issued by the Executive Committee. In this regard, the CAC also decides which body will undertake the work and whether it will be an international or regional document. In the case of Codex Regional Standards, the Commission will base its decision on the proposal of the majority of members belonging to the region.

Step 2

Depending on the specific topic, the Codex Secretariat arranges for the preparation of the draft standard or refers the matter to JMPR or JECFA or other panels of experts mentioned in the section on the critical review by the Executive Committee (see sub-section 8.1.4.7).

Step 3

The proposed draft standard is sent by the Codex Secretariat to the members of the CAC for comment on the possible implications of the proposed text (the document is circulated internationally with a deadline for comments).

Step 4

The comments received are sent by the Secretariat to the relevant body (committee or other subsidiary body) to consider such comments and to amend the proposed draft standard. At this stage, it is essential that the proposing country participate in the international or regional committee, depending on where the work is undertaken, so that it can address the comments submitted by the other countries and present the necessary arguments.

A good strategy to ensure that the document advances may be to seek alliances with other countries that have a common interest in the product in order to reach agreements prior to the meeting.

In the event that the document under consideration has not made significant progress at the meeting, the committee may recommend to the CAC that the draft standard remain at the same step, that is Step 3, to continue being debated at the next meeting. This can significantly affect the schedule proposed by the country (see sub-section 8.1.4.9).

In such circumstances, Codex committees have chosen to establish working groups that work between sessions, meeting in person, virtually, or using both modalities, which allows progress to be made on the document before the next meeting of the committee, thus speeding up the process and enabling the group leader to present the results of the work undertaken and the group's analysis of any issues that were pending from the previous committee meeting. The conclusions of the working group are submitted to the other members of the Codex committee for consideration.

It is a good idea for the country that proposed the topic for consideration to offer to lead the working group, since it has in-depth knowledge of the issue and the reasons that led it to submit the proposal. It is likely that other countries will apply to co-lead the working group, in which case the schedule for submitting documents, the deadlines for receiving comments, and the languages in which the group will work will have to be coordinated with them.

The working group is set up on a voluntary basis with other countries interested in the topic that register within the established deadlines.

Continued on the next page.

Although the working group is formally established at the committee meeting and several countries may apply to join it, it is here that the decisions will be taken as to who will lead and coordinate it, in which languages it will work, and which aspects of the document should be submitted for consideration by the working group.

Following the committee meeting, those countries that wish to do so are invited via e-mail to join the electronic working group. Codex has set up a platform for this purpose, where delegates can log on to the topic of interest and register using a username and password to access the documents under consideration and submit comments. Along with the document, they will also find the deadlines for submitting comments, which will be analyzed internally by the coordinating country or countries.

In contrast, if significant progress is made on the proposed draft standard, the committee recommends that it advance to the next step.

Step 5

The proposal is submitted through the Codex Secretariat to the Executive Committee for critical review and then to the CAC for approval as a draft standard. If it is a regional standard, although all CAC members participate in the debate, the final decision is taken only by those from the region.

The adjusted draft is circulated internationally by the Codex Secretariat with a deadline for comments.

Step 6

The draft standard is sent by the Codex Secretariat to all members and international organizations for comment (circulated internationally with a deadline for comments).

Step 7

The comments received by the Codex Secretariat are sent to the committee or subsidiary body to consider such comments and adjust the draft standard.

The comments received are examined at the meeting of the corresponding international or regional committee, so it is also very important at this stage that the country proposing the standard is present to answer any concerns raised and has the necessary arguments and expertise to address the comments received.

Both for this committee meeting as well as the other meetings required to consider the draft standard, it is essential to be aware in advance of the comments submitted by the countries in order to gather the necessary support and respond to each of them at the meeting.

It is important that the debate held at the national level is organized through the corresponding technical committee to ensure that the response offered reflects the unified position of the country.

Continued on the next page.

During the Codex committee meeting, additional comments may be delivered on-site, which should be gathered together as soon as possible to determine how they will be addressed before the discussion begins. This prevents the discussion from stalling due to the lack of an adequate response to a particular comment and thus speeds up the progress made on the topic.

In some circumstances, a non-negotiable position should be maintained with respect to changes to the proposed standard, particularly if these changes negatively affect the quality or safety of the product in question. On the other hand, concessions should sometimes be made, providing this does not affect the aspects mentioned above and it can help the proposal to progress.

Step 8

The adjusted draft standard is submitted by the Secretariat to the Executive Committee for critical review and to the CAC for adoption as a standard. It is submitted together with any comments sent by the Codex member states and other organizations (this means that once the draft standard was adjusted by the committee, it was circulated internationally, prior to the CAC meeting).

8.3. Uniform accelerated procedure for the elaboration of Codex standards

This procedure, as its name indicates, is an alternative that can speed up the process of adoption of a draft document as a CODEX standard.

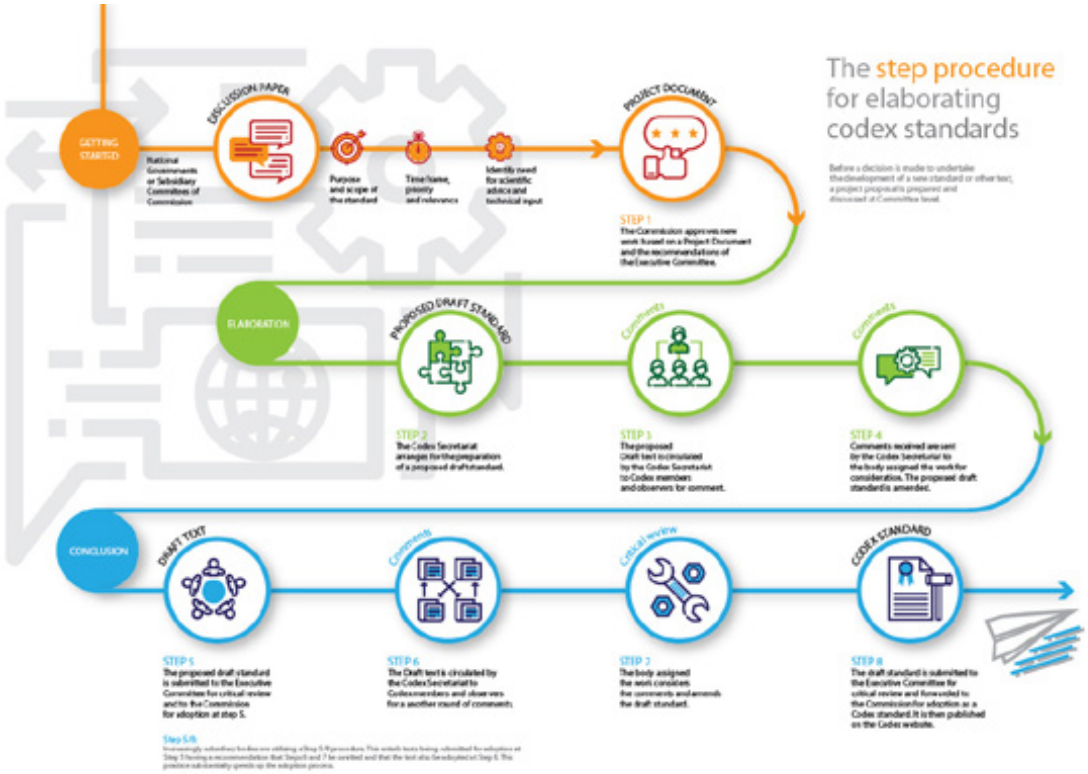
Unlike the normal procedure explained in sub-section 8.2, the recommendation issued at the meeting may be to propose the accelerated procedure (Step 5/8), providing that the documents submitted for consideration by the committee in Step 4 did not encounter any problems regarding a lack of consensus or lack of information that might hinder their progress. This step involves sending the document approved at Step 5 to the CAC for final approval and adoption (Step 8).

If this is the situation, the Codex Secretariat will submit the draft standard to the Executive Committee for critical review, which will then forward it to the CAC for approval of the standard by its members, this will depend on the result of the report presented by the Executive Committee.

If approval is not given for the accelerated procedure, the document under consideration will be sent back to the step from which it came from to continue the uniform procedure as indicated in sub-section 8.2.

8.4. Subsequent procedure concerning publication and acceptance of Codex standards

The standard adopted by the CAC is published and issued to members of FAO and WHO and other international organizations concerned. This publication is part of the *Codex Alimentarius* and can be consulted free of charge through the CODEX website: *http://www.fao.org/fao-who-codexalimentarius/en/*



Source: The Food and Agriculture Organization (FAO)

Figure 11. Process diagram[42]

42 Available on: *http://www.fao.org/fileadmin/user_upload/codexalimentarius/photo-archive/Infographics/Grafico_3_step.jpg*


Belarus

PROCEDURE FOR SUBMITTING PROPOSALS FOR STANDARDS FOR NATIVE SPECIES PRODUCTS AS DRAFT REGIONAL OR INTERNATIONAL STANDARDS TO THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, ISO

9

This section was put together based on ISO provisions as of 2020, and so it is recommended that the official ISO portal[43] be consulted for the latest directives, forms and guides.

9.1. Identifying the appropriate ISO committee

The first key step when embarking on the process of submitting a draft standard for native species products to ISO is to identify the ISO committee concerned. In order to do so, it is necessary to review the scope of potential committees, as well as their respective business plans. Below is a list of the most common scenarios encountered:

1 There is no corresponding committee. In this case, the NSB has two options depending on the resources it has available.

43. ISO. *Directives and policies* [online]. Available at: *https://www.iso.org/directives-and-policies.html* ISO. *ISO Forms, model agendas, standard letters* [online]. Available at: Forms: *https://www.iso.org/iso-forms-model-agendas-standard-letters.html*

a. Propose a new area of standardization. In this case, ISO would be responsible for encouraging the creation of a new committee that could accept the proposed standard.

b. Propose a new field of technical activity. In this case, the NSB would be responsible for the process of setting up a new committee that would accept the proposed standard.

2 There is a corresponding committee, but the subject of the proposed standard is not covered by its business plan. If this is the case, the NSB would proceed to follow the steps in the Preliminary Stage, in line with Part 1 of the ISO/IEC Directive.

3 There is a corresponding committee and the subject of the proposed standard proposal is covered by its business plan. In this scenario, the NSB would follow the steps established for the Proposal Stage, in accordance with the aforementioned directive.

9.2. Participation in the ISO committee

To ensure that the proposed standard has a better chance of being accepted by the committee, it is recommended that the proposing NSB join the committee as a P-member. A P-member is one that actively participates in the development of ISO standards. In addition, if the NSB has the opportunity to gain experience by participating at the working group level, this will strengthen its capacity to lead the development of its proposed standard.

Such participation will also help the proposing NSB to become familiar with the different stages of the ISO standardization process, which are shown in Table 1. Each stage of the proposed project is given a ***code*** associated with the name of the document. This facilitates monitoring the development of the draft standard.

Table 1. Project stages and related documents

Process stage	Code	Name of the document	Abbreviation (acronym)
Preliminary stage	00	Preliminary work item	PWI
Proposal stage	10	New work item proposal	NP
Preparatory stage	20	Working draft	WD
Committee stage	30	Committee draft	CD
Enquiry stage	40	Draft international standard	DIS
Approval stage	50	Final draft international standard	FDIS
Publication stage	60	International standard	ISO

Source: ISO/IEC Directives, Part 1:2021 2.1.3.1

The proposing NSB should take the necessary actions to create a scenario in which there is a corresponding committee, the subject of the proposed standard is covered by the committee's business plan and the NSB has been participating in the committee as a P-member. Such a scenario would provide the necessary elements to begin the Proposal Stage, which will be the focus of this section.

9.3. Recommendations on twinning[44]

The following description will focus on the **document**, not on the committee:

44. *Twinning* is a voluntary collaboration agreement between two ISO members aimed at developing competencies at the national standards body level to enable successful participation in international standardization work.

9.3.1. Resource assessment

The series of activities involved in the provision of resources by the country submitting the proposal are described below.

- Resources should be considered not only for the project, if it is approved, but also for the country's engagement. In other words, it is important for the country to participate in the prior meetings to propose and present the project idea, to ensure that once the NWIP is launched, there is sufficient knowledge within the committee about the document and that it is approved.

- Meetings can be attended using participants' own means or with the help of sponsorship. If the country uses its own resources, it can implement national strategies to obtain funds (sponsorships from associations, companies, paid short courses on the topic, among other alternatives). If the country uses sponsorship, it is recommended that it not consider that of the NSB alone, as the country can also submit the project with the sponsorship of an expert on the document.

- Host work group meetings and ensure the availability of all channels. Sometimes participating in a meeting outside the country can be less burdensome. However, hosting work group meetings is a good way to attract the attention of other countries and consolidate the leadership position on the project.

- Technical experts on the project available with their own resources. Even if other means of financing the development of the project are sought, it is essential that national experts have their own resources. This can be achieved by raising awareness of the importance of the project for the country and the world.

In conclusion, the aim is for the country to implement a *twinning* partnership based on recognition and leadership position; however, the proposers of the draft standard are encouraged to have their own resources and not depend on sponsorships or the resources of the other country.

9.3.2. Identifying the country based on the available technical documentation

Does the country submitting the proposal have a national document based on:

- **Information provided by its national experts and that may serve as a draft for the NWIP**. Engagement should also be sought with countries involved in the matter to be standardized, preferably, with those experienced in presenting proposal.
- **The adoption of documents from other countries that may serve as a draft for the NWIP**: the best-case scenario is to set up a twinning arrangement with the country whose document was adopted.

If the proposing country does not have a national document that can serve as a draft for the NWIP, it should approach a country that does have such a document and establish ties. It is recommended that the countries discuss the document beforehand so that it can be presented as the proposed draft.

9.3.3. Other recommendations on identifying the country

It used to be believed that the ideal scenario was to enter into a twinning agreement with a developed country, but it has been shown that these countries are not necessarily interested in this type of partnership or tend to end up leading the project. The guidelines now allow twinning between two countries regardless of their economic development. So, it may be more advantageous for two developing countries to partner up, as recognition is likely to be mutual and probably easier.

It is useful to take into account the experience of the country with which the twinning arrangement is established.

9.3.4. Decide what role will be played once the twinning arrangement is agreed

Consider the following roles for agreements involving:

Project leader and committee manager: One country leads the process and the other is the committee manager,

Convenor and co-convenor: Both countries lead the project.

If it is the first time and it is the other country that is proposing the technical documentation as described in point two, the role of co-convenor is recommended. If additional resources are available, the role of committee manager is recommended. If the country already has experience, has the resources and wishes to consolidate its leadership role, then the positions of project leader and convenor are recommended.

9.4. Proposal stage (10) - New work item proposal (NP)

The Proposal Stage involves the submission of proposals for new standards. Although the proposal may be submitted by the committee or subcommittee secretariat, in addition to the proposing NSB, it may also be presented by another committee or subcommittee, a category A liaison organization, the Technical Management Board (TMB) or its advisory groups, or the Secretary General of ISO. To increase the likelihood of success, it is recommended that the proposed standard be submitted by the NSB.

Each new work item proposal (NP) must be submitted via the corresponding ISO *Form* with its justification. Prior to this, it is recommended that the NSB follow the guidelines set out in Section 7 of this guide. This means that the NSB will have a working draft of the standard, a designated project leader, and will have identified other NSBs interested in the proposal. With these elements in place, the NSB should contact the manager and the chair of

the committee to discuss the proposal and coordinate details of the process, such as the right form to submit; the required timeframe for developing the proposed standard; and the project plan, including key milestones, and the date of the first work meeting.

The dates established in each committee are under constant review based on the progress made, which is permanently monitored.

Once the details of the process for developing the proposed standard have been agreed, the NSB can proceed to submit the form, which will usually be Form 4. Form 4 is submitted to the committee secretariat, as previously arranged. The secretariat will evaluate the submission then circulate it among the members of the committee or subcommittee to be voted on by the P-members and to inform the O-members and liaison organizations.

Approval by a 2/3 majority of the P-members, not counting abstentions, is required for the approval of the proposed standard as a new work item for the committee or subcommittee. Approval is also subject to the commitment of members to actively participate in its development. In the case of committees or subcommittees with 16 or fewer P-members, at least four P-members are required to have appointed experts; and in the case of committees or subcommittees with 17 or more members, at least five P-members are required to have appointed experts[45].

45. There are exceptions to the minimum number of experts, which are detailed in the ISO/IEC Directive, Part 1.

That is why it is important to follow the guidelines in Section 7, in order to ensure that the NSBs are P-members of the committee or subcommittee interested in working on developing the proposed standard prior to voting. Furthermore, during the voting period, ISO provides facilities for the proposing NSB to generate greater interest in and commitment to the proposed standard among ISO members.

It is important that prior to submitting the new proposal, that it has been disseminated through bilateral, regional or international forums. This may be done through the activities carried out in COPANT to involve stakeholders interested in native species products.

9.4.1. General considerations for filling out ISO Form 4 New Work Item Proposal (NP)

Below are some guidelines on filling out form 4 in its 2019 version. However, it is recommended that you consult the ISO page for the current version[46].

Title of the proposed deliverable

This title must be stated clearly and concisely in English and French.

Scope of the proposed deliverable

It is necessary to specify the intended aim of the proposed standard. As far as possible, the limits and scope of the standard should be defined, including the corresponding exclusions.

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46. ISO. ISO Forms, model agendas, standard letters [online]. Available at: Forms: *https://www.iso.org/iso-forms-model-agendas-standard-letters.html*

Purpose and justification of the proposal

This covers the aspects necessary to justify the new proposal, such as: Is there a market need? What problem will this document solve? What value does it bring to end-users? The more well-supported the proposal, the better it will be received.

The type of information that might be included in the justification is detailed below:

- Simple and concise description of the commercial, technological, social or environmental aspects that the proposal intends to address and their link with the committee or subcommittee business plan;
- Documentation containing global statistics relating to the commercial, technological, social and environmental aspects or new markets. This can include an estimate of potential sales as an important indicator for the product;
- Technological benefit – description of the technological impact of the proposal, aimed at supporting emerging technological systems, future innovation technologies and competition, and technologies relating to the diffusion and operational capacity of a system or operational component;
- Economic benefit – description of the proposal's potential to remove barriers to trade, improve access to international markets, support public procurement, improve the commercial efficiency of a wide range of companies, including small and medium-sized enterprises. This can include a cost-benefit analysis of the product to be developed;
- Social benefits – description of the social benefits expected from the new proposal;
- Environmental benefits – description of the environmental or sustainability benefits expected from the new proposal;

- Intended use of the standard to be developed, including for conformity assessment, regulation, guidance, best practices, etc.;
- Data on its market relevance, which can help evaluate the benefits for stakeholders;
- Statement explaining how it relates to ISO's *Global Relevance Policy* and ISO/TMB recommendations;
- Statement on the proposal's compliance with the principles for developing ISO standards.

UN Sustainable Development Goals (SDGs) that the document will support

You are asked to select one or more United Nations Sustainable Development Goals towards which the standard proposal will contribute. Information on these goals is available on the ISO website: *www.iso.org/SDGs*.

Preparatory work

If a proposed standard is available, the option indicating that a draft is being attached should be ticked. Also, it should be indicated that the proposing NSB is prepared to undertake the leadership.

The proposed standard is drawn up in English, in line with Part 2 of the ISO/IEC Directives Principles and Rules for the structure and drafting of ISO and IEC documents.

To assist the user of this guide on the rules for drafting, the following document is available at https://www.iso.org/iso/how-to-write-standards.pdf. A model manuscript of a draft international standard (known as "The Rice Model") is available at https://www.iso.org/iso/model_document-rice_model.pdf and the simple template for a standard at https://www.iso.org/iso-templates.html.

If a draft is attached to this proposal

Based on the coordination between the NSB and the manager and chair of the committee or subcommittee, one of the options listed below must be marked:

- Draft document can be registered as a Working Draft (WD – stage 20.00);
- Draft document can be registered as a Committee Draft (CD – stage 30.00);
- Draft document can be registered as a Draft International Standard (DIS – stage 40.00).

If the attached document is copyrighted or includes copyrighted content, the proposer must ensure that ISO has permission to use it.

Is this a Management Systems Standard (MSS)?

In this case tick "No".

Indication of the preferred type to be developed

Choose the option of "International Standard".

Proposed Standard Development Track (SDT)

The alternatives given are 18, 24, and 36 months[47]. When choosing one of these options, it is important to consider that, although the timeframes are reviewed, it is essential to meet the established deadline and a maximum of nine months is the only extension that can be granted. The choice of timeframe will depend on how complex the proposer of the standard considers the issue to be, as well as the stage proposed for beginning the work.

47. Based on the 2020 provisions.

Draft project plan

The project plan which has been agreed upon with the manager and chair of the committee is presented, and it should include the date for the first meeting, as well as the dates for the circulation of the drafts at its various stages.

Known patented items

It is necessary to indicate whether or not there is any relationship with patented items. If so, the relevant information should be attached to Form 4.

Coordination of work

To the best of one's knowledge, if a document has been submitted to another standards organization, such as the *Codex Alimentarius*, this should be declared, and the organization(s) should be specified.

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables

This is a summary of how the proposal may impact or relate to existing ISO projects or deliverables. It is important to clearly state that there is no duplication or that the work differs from apparently similar work carried out by the committee. Where relevant, it is necessary to explain how any conflict or risk of duplication will be minimized.

A listing of relevant existing documents at the international, regional and national levels

Any document that is related and relevant to the proposed work should be included, such as works by other standards bodies, as well as supporting documentation.

Please fill out the relevant parts of the table below to identify relevant affected stakeholder categories and how they will each benefit from or be impacted by the proposed deliverable

This information should have been collected according to the guidelines provided in Section 7, prior to filling out the form. It is necessary to detail the potential benefits and impacts, and include examples of organizations or companies to be contacted.

Liaisons

List the international organizations or internal parties (ISO committees or subcommittees) to be engaged as liaisons in the development of the draft standard.

Joint / parallel work

If joint work with another regional or international standards body is warranted, this must be specified.

A listing of relevant countries which are not already P-members of the committee

During the gathering of information and dissemination of the proposal, the existence of related standards may be identified in the countries of the region. If these countries are not P-members of the committee, then they should be listed together with other relevant countries.

Proposed Project Leader

Include the full name and email of the project leader.

When the proposing countries do not have the resources and the experience to undertake the preparatory work necessary to submit a new proposal to a specific ISO committee, *twinning* an facilitate the development of the proposal by improving the standardization infrastructure and capacities of the twinned member, in optimizing the use of resources and their long-term strategic development.

Name of the Proposer

Include the contact information of the proposing NSB and the contact person.

This proposal will be developed by

The response should have been previously coordinated with the manager and chair of the committee or subcommittee.

Supplementary information relating to the proposal

In most cases, the option chosen should be "This proposal relates to a new ISO document".

Maintenance agencies (MA) and registration authorities (RA)

If the standard will require frequent modifications, then a maintenance agency should be chosen.

However, if the proposed standard includes registration provisions, then opt to appoint a registration authority.

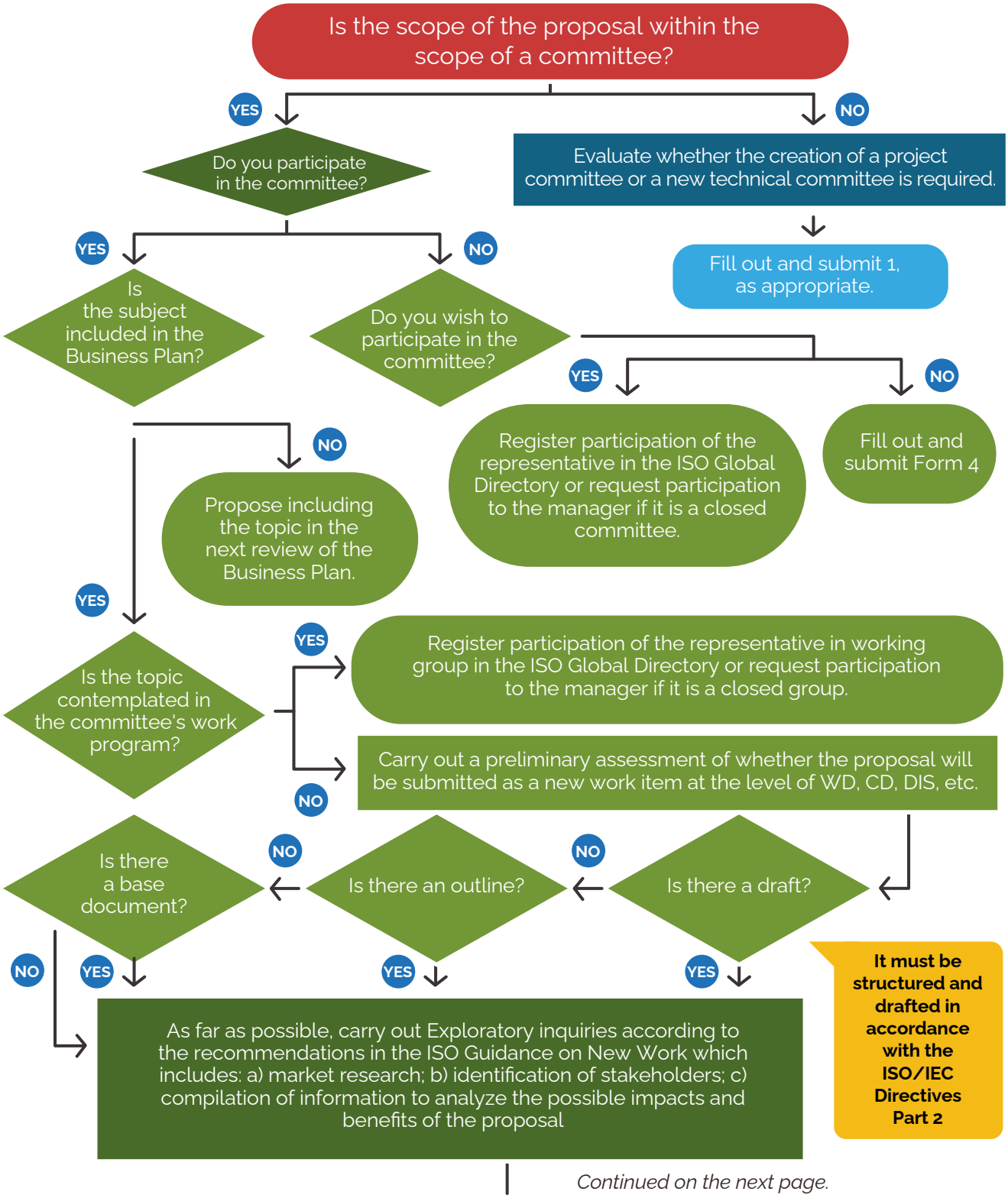
Annex(es) are included with this proposal

Details should be provided of any annexes included in the proposal, if applicable.

Additional information/questions

Option provided in case the proposing NSB wishes to include additional information or queries.

9.5. DO YOU WISH TO PRESENT A STANDARD ON NATIVE SPECIES AS A WORK ITEM TO ISO?



Continued on the next page.

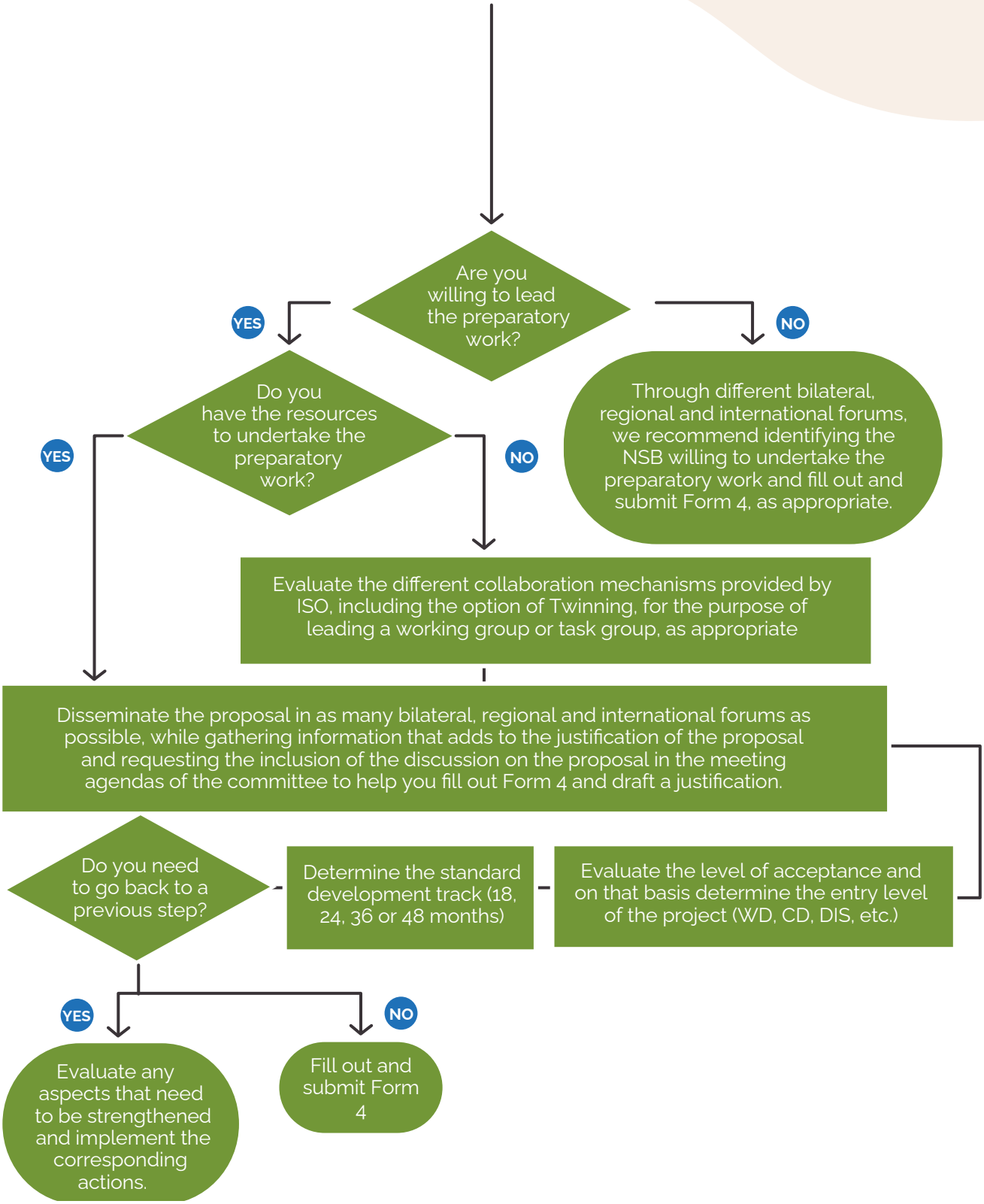


Figure 12. How to submit a standard on native species products as a work proposal to ISO?

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Further reading

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ANNEX 1

Links of interest

Enlaces Codex

General	
Portal web	http://www.fao.org/fao-who-codexalimentarius/en/
What is Codex?	http://www.fao.org/3/CA1176ES/ca1176es.pdf
A world full of standards	http://www.fao.org/3/ca0162es/CA0162ES.pdf
Trade and food standards	http://www.fao.org/3/i7407es/I7407ES.pdf
Information for new delegates	http://www.fao.org/fao-who-codexalimentarius/meetings/information-for-delegates/en/
Guidelines for co-hosting a meeting	http://www.fao.org/fao-who-codexalimentarius/en/

Work and management instruments	
Codex Alimentarius Commission Procedural Manual	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https://workspace.fao.org/sites/codex/Shared%20Documents/Publications/Procedural%20Manual/Manual_27/PM27_2019s.pdf
Online comment system	http://www.fao.org/fao-who-codexalimentarius/en/

Work tools	
Circular letters	http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
List of active committees	http://www.fao.org/fao-who-codexalimentarius/en/

Education	
Online learning course	http://www.fao.org/food/food-safety-quality/capacity-development/participation-codex/codex-course/en/

Information of interest	
General guidelines	http://www.fao.org/fao-who-codexalimentarius/en/
Codes of practice	http://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/
Databases	http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/en/
Information documents	http://www.fao.org/fao-who-codexalimentarius/en/

Events	
Meetings	http://www.fao.org/fao-who-codexalimentarius/meetings/en/
Calendar	http://www.fao.org/fao-who-codexalimentarius/en/

ISO links

General	
Web portal	https://www.iso.org/home.html
ISO 2030 Strategy	https://www.iso.org/publication/PUB100364.html
Members area	https://connect.iso.org/display/members/Member+Area
Toolkit for new members	https://isotc.iso.org/livelink/livelink/open/15507012

Management tools	
ISO Statutes	https://www.iso.org/publication/PUB100322.html
Code of conduct	https://www.iso.org/publication/PUB100397.html
Directives	https://www.iso.org/directives-and-policies.html

General guidelines on what delegates and experts should know about ISO's work	https://www.iso.org/publication/PUB100037.html
Member Handbook	https://www.iso.org/publication/PUB100399.html

Work tools

Guides	https://www.iso.org/iso-guides.html
Guidelines for new work	https://www.iso.org/publication/PUB100438.html
ISO formats	https://www.iso.org/iso-forms-model-agendas-standard-letters.html
Drafting ISO standards	https://www.iso.org/drafting-standards.html
International Harmonized Stage Codes	https://www.iso.org/stage-codes.html
ISO standards development tracks	https://www.iso.org/files/live/sites/isoorg/files/developing_standards/resources/docs/std%20dev%20target%20date%20planner.pdf
Strategic business plans	https://isotc.iso.org/livelink/livelink/fetch/2000/2122/687806/customview.html?func=ll&objId=687806&objAction=browse&sort=name

Electronic tools

Homepage	https://www.iso.org/it-tools-for-standards-development.html
Access to ISO electronic applications	https://login.iso.org/portal/
Comment templates and tool	https://isotc.iso.org/livelink/livelink?func=ll&objId=5156909&objAction=browse&sort=name
Video conferences via ZOOM	https://iso.zoom.us/
Online browsing platform	https://www.iso.org/obp/ui/

Events and calendar	
Events	https://www.iso.org/events.html
Calendar	https://www.iso.org/events_archive/x/

Capacity building	
ISO Capacity Building Unit	https://capacity.iso.org/home.html https://www.iso.org/capacity-building.html
Exports and standardization	https://www.iso.org/publication/PUB100261.html
Twinning – Capacity building partnerships	https://www.iso.org/publication/PUB100414.html
Twinning – Guidelines on twinning and activities to develop ISO standards	https://www.iso.org/publication/PUB100341.html

Standardization education	
Good practices for collaboration between national standards bodies and universities	https://www.iso.org/publication/PUB100354.html
Workshops on collaboration between National Standards Bodies and universities	https://isotc.iso.org/livelink/livelink/Open/17728776
Educational material on standardization for primary and secondary education	https://www.iso.org/sites/materials/teaching-materials/education_materials-higher-edu.html
Educational initiatives on standardization for primary and secondary education	https://www.iso.org/sites/materials/initiatives-in-education/education_initiatives-higher-edu.html

International Cooperation for Education about Standardization (ICES) Conference	https://www.iso.org/contents/event/2018/ices-2018.html
WSC Academic Day	https://www.iso.org/contents/event/2019/wsc-academic-day.html
Information about ICES and WSC	https://isotc.iso.org/livelink/livelink?func=ll&objId = 17729870&objAction = browse&sort = name

Developing countries

DEVCO home page	https://www.iso.org/devco.html
ISO Action Plan for Developing Countries 2016-2020	https://www.iso.org/publication/PUB100374.html

Stakeholders

Guidance for National Standards Bodies	https://www.iso.org/publication/PUB100269.html
Guidance for ISO Liaison Organizations	https://www.iso.org/publication/PUB100270.html
Additional Guidance on Stakeholder Involvement	https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100269.pdf

Consumers

Engaging consumers	https://www.iso.org/publication/PUB100277.html

Conformity assessment

ISO Conformity Assessment Resource Page	https://www.iso.org/resources-for-conformity-assessment.html
Presentations on conformity assessment standards	https://isotc.iso.org/livelink/livelink?func=ll&objId=17699314&objAction=browse&viewType=1
For regulators	https://casco.iso.org/home.html
Toolbox	https://www.iso.org/publication/PUB100230.html

Research

Benefits	https://www.iso.org/benefits-of-standards.html
Economic benefits of standards	https://www.iso.org/benefits-of-standards-the-iso-materials.html
Case studies	https://www.iso.org/sites/materials/benefits-of-standards/benefits_repository.html
Resources on innovation and standardization	https://www.iso.org/sites/materials/standards-and-innovation/education_innovation-list.html

Sustainable Development Goals and ISO

ISO page	https://www.iso.org/sdgs.html
Publication: Contributing to the United Nations Sustainable Development Goals with ISO standards	https://www.iso.org/publication/PUB100429.html

UNEP Links

Informea	
Access to information on multilateral environmental agreements	*https://www.informea.org/en*
CDB	
Convention on Biological Diversity	*https://www.cbd.int/intro/*
Nagoya Protocol (CBD)	
Protocol on access to genetic resources	*http://www.cbd.int/abs/*
Cartagena Protocol (CBD)	
Biosafety Protocol	*http://bch.cbd.int/protocol/background/*
CITES	
Convention on International Trade in Endangered Species of Wild Fauna and Flora	*https://cites.org/eng/disc/text.php*
Ramsar Convention	
Convention on Wetlands of International Importance	*http://www.ramsar.org/*
UNCCD	
United Nations Convention to Combat Desertification	*https://www.unccd.int/convention/about-convention*

UNFCCC	
United Nations Framework Convention on Climate Change	*https://unfccc.int/process-and-meetings/the-convention/what-is-the-united-nations-framework-convention-on-climate-change*

Kyoto Protocol (UNFCCC)	
Protocol that sets targets for the reduction in the greenhouse gas emissions	*https://unfccc.int/process-and-meetings/the-kyoto-protocol/what-is-the-kyoto-protocol/kyoto-protocol-'targets-for-the-first-commitment-period*

Paris Agreement (UNFCCC)	
Agreement outlining a new roadmap for mitigation and adaptation efforts to combat climate change	*https://unfccc.int/process-and-meetings/the-paris-agreement/the-paris-agreement*

ANNEX 2

Studies on Native Species of the Andean Region

Study on lulo de Castilla (*Solanum quitoense* Lam)

COLOMBIA

1. Importance of the project for the country

Colombia's geographical position has endowed it with a rich biodiversity. This is an important resource that both communities and State policies must protect in order to ensure that future generations can also use these natural resources appropriately and responsibly; not just because they are a source of income, but also because they will be recognized in other countries on account of their sustainable management and production.

Thanks to its unique characteristics, lulo de Castilla is one of a range of promising products from Colombia, but further promotion of this exotic fruit is required to boost sales and thus consumption. A standard that reaches beyond the country's borders will allow the fruit to become more well-known abroad, thereby increasing demand and at the same time enabling it to enter new markets.

2. Selection of the topic for consideration

In order to select the product in question, it was necessary to first conduct a review to find out which of the existing standards covered biodiversity products from the country or the Andean region in which Colombia is located. This exercise revealed that fruits constitute an important group of products, which have been characterized through research projects carried out by national institutions, and these have formed the basis for drawing up Colombian National Standards.

The next step was to identify which of these fruits had international trade projections to justify promoting its entry into different markets. The one chosen was lulo de Castilla (*Solanum quitoense* Lam), since it meets the established criteria: namely it is a fruit that is native to the Andean region, is covered by a National Standard and is an export product, in addition to the fact that there is a significant production volume, and there is information available about the areas where it is grown and the extent of the cultivated zone.

Furthermore, lulo de Castilla has been declared a promising fruit, given the exotic nature of its color and aroma, which has attracted the interest of European countries and the United States.

3. Definition of stakeholders

The product study and selection were carried out by the Technical Committee for Standardization of ICONTEC (Colombian Institute of Technical Standards and Certification) whose scope of work covers fresh fruits, vegetables and tubers. The participants of this committee included delegates representing lulo de Castilla producers and retailers, representatives of research centers such as the National Coffee Research Centre (Cenicafé), the Colombian Agricultural Research Corporation (Agrosavia), university teachers and researchers, government institutions such as the Ministry of Commerce, Industry and Tourism, the Ministry of Agriculture and Rural Development, the Colombian Agricultural Institute, the National Institute for Food and Drug Surveillance (Invima) and associations and laboratories, as well as the professional delegate from ICONTEC.

Each one of the committee members has made a significant contribution to the development of the lulo de Castilla standard: the research centers, the laboratories and academia provided the information for characterizing the fruit; producers and retailers provided information on market requirements and are familiar with the preferences of people that consume lulo de Castilla; while the ministries, for their part, provided information about fruit production policies, international agreements and regulatory provisions that impact their sale. The associations disseminated the standard under consideration among their members to obtain feedback that enriched the technical content of the regulatory document.

This work was coordinated by a professional delegate from the National Standards Body (ICONTEC), who was responsible for ensuring that the process was carried out in line with good standardization practices and

was responsible for completing the internal procedures for approving the document prepared by the committee.

4. Selection of the International Standards Body

Codex Alimentarius was selected as the International Standards Body to which the topic of lulo de Castilla would be presented, due to the fact that Colombia has prior experience of submitting issues related to fruits to this organization, and Codex also offers the possibility of developing an international or regional standard, depending on the criteria established by the body for consideration of the issue.

5. Structuring of the draft standard

Once the International Standards Body had been determined, a review was carried out of the structure required by Codex for standards on fruits and other products sold fresh. This involved identifying those aspects of the national standard that were of interest and fitted the standard template established by the *Codex Alimentarius*, including making any necessary adaptations required for drafting international standards.

Through this exercise, it was established that Codex standards require fruit to be classified by caliber based not only on equatorial diameter, as considered in the national standard, but also by taking the weight of the fruit as a criterion. For this reason, a process was implemented to characterize the weight of the fruits for inclusion in both in the national standard and in the proposed Codex standard. The study carried out to identify the lulo de Castilla caliber intervals based on weight was conducted by the Colombian Agricultural Research Corporation (Agrosavia), with the support of the German National Metrology Institute (PTB), which provided the resources to carry out the sampling, measurements and logistics needed to obtain this information.

6. Preparation of supporting documentation

The information to support the request for consideration of this new topic was put together based on the specifications detailed in the Codex Procedural Manual. This information was taken from different recognized

sources, both national and international, depending on the subject in question. Data on cultivated area and production areas can be obtained from entities such as the Ministry of Agriculture and Rural Development, which issues specialized publications, and from institutions attached to the Ministry, which manage this information. Data on export volumes and destinations can be obtained from Procolombia and the Ministry of Commerce, which also has statistical data on the topic, while institutions attached or linked to this ministry can provide related information. In addition, trade-related information is available from exporters associations and international organizations such as FAO, which also publish statistics on international food production and trade.

7. Submission of the proposal to the international organization

In order to submit the proposal, which is to say the draft standard and the supporting information, it was important to have the approval of the Technical Committee for Standardization, the National Standards Body (ICONTEC), as well as the National *Codex Alimentarius* Committee. The submission was made through the Codex Contact Point in the country, within the dates established by Codex for proposing new topics for consideration.

8. Possible strategies to consider

Taking into account the origin of the product, it is necessary to build alliances with other countries in the region to support the proposed work, since the standard will in fact not only benefit the proposing country but also any others that produce lulo de Castilla.

It is important to include a thorough description of the product and its characteristics (if necessary, include photographs), its nutritional composition, how the product is consumed, and so on. Another option is to prepare a presentation summarizing this information and the statistical data that accompany the request to consider the new topic, which can be very useful and can be shown to the International Codex Committee on fresh fruits and vegetables at the meeting where the topic is put forward.

Since lulo de Castilla is a fruit from the Andean region, if Codex considers it appropriate to develop the standard at the regional level through the Codex Committee for Latin America and the Caribbean (CCLAC), it will be important for Colombia to regard this as an initial step that can serve to publicize the product in other countries and then later request that it be considered as an international standard.

Study on Amaranth Grain (*Amaranthus caudatus L.*)

ECUADOR

1. Importance of the project for the country

Due to its outstanding nutritional properties (high protein content, essential amino acid composition, availability of polyunsaturated fatty acids, fiber, etc.) amaranth (*Amaranthus caudatus L.*), an agricultural biodiversity product, has been considered one of the most complete foods on the planet, which could be used as an alternative way to address problems of malnutrition (obesity or undernourishment) and contribute to food security. Although this native species is not currently grown in large areas, it has great potential as a commercial crop, either for the local market or for the export market.

2. Selection of the topic for consideration

Amaranth was chosen for its various agricultural advantages over traditional export crops such as wheat, soy, corn or beans. Known for its high tolerance to drought and its low irrigation water requirements, it rarely requires artificial irrigation. Amaranth can also tolerate hot and dry weather conditions, and it grows well at altitudes of between 2,000 meters and 3,000 meters above sea level, making it easy to sow in a wide range of climatic zones and thus facilitating crop rotation for farmers.

International markets have been sensitive to the comparative advantages of this so-called "pseudocereal", produced and consumed across five continents (in countries such as China, India, Nepal, parts of Africa, and it is starting to be eaten in North America and the European Union). The increase in exports that has been recorded worldwide in recent years shows a very encouraging compound growth, due to an increase in countries where amaranth is grown as well as those where it is consumed, thanks to three important sectors that make use of it in their products, namely food and beverages, pharmaceuticals and cosmetics.

3. Definition of stakeholders

The following stakeholders were involved in the process of analyzing and formulating a standard:

- Government: through the Ministry of Agriculture and Livestock (MAGAP), which is responsible for implementing agricultural development and food safety policies.
- Farmers, collective farms and agricultural production cooperatives interested in increasing amaranth production.
- Grain handlers, processors and agro-industrial associations involved in the amaranth business.
- Institutes or research centers such as the National Institute of Agricultural Research (INIAP), which have carried out several studies on amaranth.
- And others such as academia, laboratories, marketers, export promotion agencies and corporations and consumers.

All of these stakeholders put forward their proposals and shared their knowledge with the technical committees on standardization, which were guided by a technical secretary specialized in standardization.

4. Selection of the International Standards Body

For the purpose of participation in the international regulatory processes, within the scope of voluntary compliance, the body chosen was the International Organization for Standardization (ISO), which has been recognized internationally for facilitating access to markets, reducing technical barriers to trade and achieving global consensus, as represented by ISO International Standards.

As a full member, INEN can submit draft international standards of national interest, which is a process that is very similar to the one established in most National Standards Bodies (NSB). The first step is to analyses and draw up a draft standard. This proposal is then considered by the stakeholders

in the respective technical committee, at which stage observations can be submitted regarding the technical committee's conclusions. Once this process has been completed, the final standard is published. In addition, ISO has an extensive list of International Standards developed by ISO/TC Committee 34/SC 4 on cereals and pulses, making this international committee an appropriate forum for submitting a standard on the *Amaranthus caudatus* species of amaranth.

5. Structuring of the draft standard

Once the international body to which the draft standard will be submitted has been selected, a review will be conducted of the various elements that will be taken into consideration. The ISO has developed guides with examples on how to draft and structure international standards, such as the Model document of an International Standard "Rice model", available at: *https://www.iso.org/files/live/sites/isoorg/files/developing_standards/docs/en/model_document-rice_model.pdf*, which covers the following topics: purpose and scope of application, normative references, terms and definitions, specifications or requirements, sampling, test methods, packaging and labelling.

6. Preparation of supporting documentation

When preparing the documentation that will support the proposed draft standard, it is necessary to first consider the information that will be requested by ISO regarding the intended use of the product, market-related aspects and research studies.

Once the above components had been determined, the following methodology was established for compiling the supporting documentation for this amaranth proposal:

1. Amaranth bibliography detailing the origin, taxonomy, characteristics of the crop, the proximal chemical composition of amaranth, and its nutritional and agricultural advantages.

2. Market study and analysis describing the ways in which amaranth is

sold, global sales and its main destinations, exports from Ecuador and identification of the areas where the crop is produced.

3. Characterization of amaranth, the purpose of which was to establish its quality-related characteristics (moisture content, volumetric density, water activity, defective grains, foreign material and presence of insects), with background knowledge about growing, harvesting, post-harvesting, drying, packaging, cleaning, storage and transport carried out in Ecuador.

4. A research study comprising:

   - A list of laboratories where testing is carried out on the characteristics of amaranth, including basic physical properties, such as the loss of mass due to evaporation for the humidity test, electrical conductivity (through displacement of ions) for the water activity test, density to determine the mass per hectoliter, gravimetric mass with the physical selection to determine defective grains, infested grains and foreign matter, as well as the accreditation of the tests under ISO 17025.

   - A list of amaranth suppliers, for which an evaluation was made of production capacity, participation in agricultural production collectives, companies that prepare and process amaranth and its derivatives, as well as the people involved in the sale and export of amaranth grains.

   - Sampling, storage and transport procedure. The choice of the sample size, although it was limited to twenty (20) units, was made using tables of random numbers to select and divide up the sacks of amaranth from which the samples would be taken. The samples were immediately isolated and wrapped in an inert polymer bag, before being sealed to prevent the entry of moisture. Each bag was then coded and labelled with the main identification data, indicating the location and time. It is important

to highlight that good storage practices were in place at the amaranth warehouse where the samples were taken (cleanliness, orderliness, signage, and temperature and humidity control).

- Laboratory analysis. The samples were then delivered to the selected national laboratory in order to carry out tests on certain characteristics of the amaranth grains.

- Statistical study of the results. Specialized computer programs were used to analyses the laboratory data. These included graphs, equations and coefficients such as: histograms for continuous values in order to be able to observe the variability and dispersion of the results; box plot showing the interquartile range, the quartiles, the median, the mean and the minimum and maximum values, it also identifies outliers (Grubbs test); regression to graph the proximity of the values to a sloping line on which the equation and the Pearson coefficient are established; correlation analysis by establishing the relationship and proportionality between the statistical variables, from which a Pearson coefficient equation was obtained.

N.B. *Ideally it would beneficial to have a national and regional consensus on the proposed international standard, to facilitate its consideration and approval in the ISO subcommittees.*

7. Submission of the proposal to the international organization

It is important that when making the decision to propose and submit a draft voluntary standard to ISO, the following considerations are taken into account: identification of the corresponding ISO committee, prior participation or request to participate in the ISO Global Directory or as a manager; suggest including the issue in the next review of the chosen Committee's Business Plan; submit Form 4 for a new work item proposal (NP); identify the NSB willing to undertake the preparatory work; evaluate

the different collaboration mechanisms; institutional support and interest on the part of the Technical Committee for Standardization.

8. Possible strategies to consider

The difficulties encountered during the process of proposing an international standard that is based on a national standard included:

a. Not much information could be found on the amaranth trade and market in Ecuador, as although amaranth has great potential due its various characteristics that are highly valued in many countries, it is not yet a well-known product in Ecuador, nor is consumption high;

b. Due to economic constraints, the sampling was not representative at the national level, but it did make it possible to evaluate amaranth from the cultivated areas in the province of Imbabura, in the central-northern inter-Andean region of Ecuador. It should be noted that the establishment selected was a factory that produces amaranth-based beverages, whose quality requirements for the receipt of grains include good management of amaranth at the crop level and compliance with good storage and manufacturing practices;

c. The experimental study was also limited, due to the lack of accreditation of all the characteristics that needed be analyzed, with the humidity test being the only one that had the corresponding accreditation.

The lack of policies to promote and support the development of agro-industrial amaranth production projects has hindered the agricultural, productive and commercial development of this species at the national level. Development of this grain could be supported through tax and credit incentives that encourage the implementation of new agricultural initiatives, since there are climatic zones of Ecuador that are well-suited to growing and producing amaranth. There is also positive interest on the part of stakeholders in setting up businesses that make by-products from

amaranth and thus promoting the development of markets both nationally and internationally. It is important to remember that the country's research centers have carried out technical studies that have made it possible to characterize amaranth and supported the development of an official national standard in 2012, as well as a draft international standard to be submitted to ISO.

Study on Sacha Inchi Oil (*Plukenetia volubilis* L.) for cosmetic use

PERU

1. Importance of the project for the country

In this globalized world, international trade and business models like sustainable Biotrade are demanding products originating from native Peruvian biodiversity, which is why, as a country, Peru has prioritized 43 products, including sacha inchi. With this in mind, the development of economic activity is being promoted at the local level through strategic alliances designed to generate added value for biodiversity products that are competitive in the national and international market and are based around social equity and economic profitability. The cosmetics sector, whose emerging markets contribute over 50% of its global profits, is eager to innovate, and our products offer a new source that makes the sector more attractive in terms of quality and social responsibility, which after safety and efficacy is one of the main concerns of the cosmetics industry.

2. Selection of the topic for consideration

The product selected was Sacha inchi oil (Plukenetia volubilis L.). Derived from the country's native biodiversity, it has managed to access the European market as a "novel food" and has been shown to be very similar to flaxseed oil. It also been awarded GRAS (Generally Recognized as Safe) status by qualified experts trained in safety assessment and, therefore, does not require a pre-marketing study by the FDA (body responsible for regulating food and drug products in the USA) to ensure its safety. Since 2014, when authorization as a Novel Food and the GRAS status were achieved, the sacha inchi market has increased to 24 export destinations, and it is the first product to have implemented these two means of accessing the international market.

3. Definition of stakeholders

With the Sacha Inchi Regional Technical Board (a space for public-private institutional partnership whose mission is to facilitate, promote and connect the actors in the value chain, to create a supply of diverse, value added goods) participating since 2006, the sacha inchi value chain has the support of international cooperation agencies and government departments such as the Regional Government of San Martín, Ministry

of Agricultural Development and Irrigation (MIDAGRI), Ministry of the Environment (MINAM), Ministry of Economy and Finance (MEF) and Ministry of Production (PRODUCE), as well as the National Research Institute of the Peruvian Amazon (IIAP) and the National Institute for Agricultural Innovation (INIA), which worked together to improve the species and implement good field and research practices. Universities in the region and in the capital, both public and private, came together through research projects and used an open forum called the Biotrade Research Group, which was set up for seven (7) prioritized biodiversity products, including sacha inchi, with the involvement of the National Council of Science and Technology and the public and private analysis laboratories.

Throughout this process, the Peru Export and Tourism Promotion Board, PROMPERU, coordinated with International Cooperation and the business sector at different stages of the product quality improvement; as well as with the Peruvian Standards Body, currently managed by INACAL's Directorate of Standardization, on the promotion and approval of the Peruvian National Standards for this value chain. The standardizers (representatives from the production, consumption and technical sectors) met in a decentralized manner in Lima and San Martín at the Technical Committee for Standardization of Sacha inchi and its derivatives to develop the draft Peruvian standards covering the whole process from the seed stage for GAP, GMP, traceability, product requirements and so on.

4. Selection of the International Standards Body

Given the type of product, it was decided that the proposal for an international standard on cosmetic sacha inchi oil would be submitted to the International Organization for Standardization (ISO). After having analyzed the different market segments for sacha inchi oil and its close competitors in the cosmetics sector, a study was conducted of the European Parliament regulations for this sector and the family of ISO standards that best fit the country's vision and current market requirements with standardized processes based on competitive development criteria.

5. Structuring of the draft standard

The Technical Committee for Standardization of sacha inchi and its derivatives, together with the sectors involved, reviewed different standards for other products such as the UNE standards, ISO standards on raw materials for cosmetic use, which provided the framework for this proposal, and this was adjusted to incorporate the advances made for the Novel Food and GRAS applications. However, certain tests had to be updated in order to be submitted as an ISO standard. Although it is sold as a cosmetic ingredient in Europe and is part of formulations and patents, various tests were carried out to define certain requirements for the product characterization, along with the sensitization test in an ISO/IEC 17025 accredited laboratory as part of the supporting analysis. This was made possible thanks to the PTB's support for this Regional Subproject. The structure of the draft standard followed the ISO/IEC Directives on product standard.

6. Preparation of supporting documentation

The preparation of the documentation began with information on traditional use (ethnobotany and ethnopharmacology data), before moving on to collect scientific information on composition, as well as toxicological and allergenicity data from the main databases of peer-reviewed articles (Scopus, Medline, USDA, Patents, among others). The next step was to then draw up the product specifications and the composition to be declared based on tests carried out in accredited testing laboratories. This involved collecting historical data from recent years on product quality requirements, production process data (any compounds formed during the process that might alter the end product according to new regulations), toxicological data, absence of contaminants, and then complementing this information with the certifications of the producing companies.

7. Submitting the proposal to the international organization

The proposal was prepared based on the Peruvian National Standard, formulated in line with the ISO format by the Peruvian National Institute of Quality (INACAL), and support was then requested from the countries participating in the Subproject.

8. Possible strategies to consider

- Consider the support of International Cooperation due to the need to carry out new tests or repeat certain assays during the application proces.
- Take into account international market fluctuations and potential alliances to achieve sustainability through national programs.
- Discuss with government authorities and stakeholders the consequences of any events that might affect the workforce (e.g., a pandemic).
- Take advantage of the window of opportunity currently open for biodiversity products to be used in cosmetics, since there is a trend towards reducing chemicals that are applied directly to the skin and replacing them with beneficial natural products such as sacha inchi oil, which is used as a moisturizer and antioxidant for sensitive and mature skin, as well as for hair and nails.
- Submit the draft ISO International Standard through the mechanism developed by DEVCO in Working Group 1 entitled "Standardization areas of primary interest to developing countries". This ensures that the proposal will receive expert feedback and support from DEVCO countries, thus providing greater backing for the proposal when it is submitted to the ISO Technical Committee.

cooperación alemana
DEUTSCHE ZUSAMMENARBEIT

PTB
Physikalisch-Technische Bundesanstalt
Nationales Metrologieinstitut

INACAL
Instituto Nacional de Calidad

icontec

INEN
Servicio Ecuatoriano de Normalización