THE INTERNATIONAL FRAGRANCE ASSOCIATION

IOFI International Organization of the Flavor Industry

IFRA-IOFI Guidance Document for the Flavor and Fragrance Industry for dealing with the Nagoya Protocol and Access and Benefit Sharing (ABS) Regulations

IFRA-IOFI Nagoya Protocol TF

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1. Introduction and aim of the guidance document

This document aims to support fragrance and flavor industry members in identifying potential implications of the Nagoya Protocol, national legislations implementing that Protocol, as well as other Access and Benefit-Sharing ("ABS") Legislations on their business and operations and support the development of company internal policies and processes to properly ensure compliance with the obligations created by the Protocol and its implementing legislations with regard both to the countries:

i) where so-called "Genetic Materials" and/or "associated Traditional Knowledge" (also referred as aTK), or equivalent concepts, are sourced – i.e. Provider countries; and,

ii) those where utilization and commercialization take place – i.e. User countries.

The flavor and fragrance (F&F) industry fully support the objectives of the Nagoya protocol which aim at sharing benefits from the use of genetic resources or aTK with the respective holders and should be regarded as an element of sustainable and ethical sourcing of natural raw materials. On the other hand, non-compliance with the Nagoya Protocol or related ABS regulations can have significant negative impact on business – from a financial (e.g. fines) as well as reputational point of view.

Ensuring compliance requires traceability and therefore awareness and due diligence activities along the whole supply chain, which in the case of the F&F industry is complex (see Figure 1) and therefore requires excellent understanding by and communication between all stakeholders involved.

The overall architecture of regulations is complex, with the intertwining of international and national rules. In addition to that, it is commonly acknowledged that there is still a lack of clarity on specific concepts of the Nagoya Protocol, notably related to the definition of 'utilization' and the extent to which 'derivatives' fall in scope. This guidance document aims at describing a shared understanding of these concepts in the context of flavors and fragrances. It shall not replace national legislations or the interpretation that national authorities could make of those concepts.

Inside a fragrance or flavor house many departments may be engaged in dealing with implementation and compliance related elements of ABS regulations (see Figure 2), which is a significant effort depending on the complexity of the supply chain. This leads to the requirement for high traceability and excellent communication between the departments. Further it seems logical that one department takes the lead in ensuring the oversight on compliance with ABS regulations, but depending on structure and organization, companies might choose different departments (e.g. legal, R&D or regulatory) to take on this role.

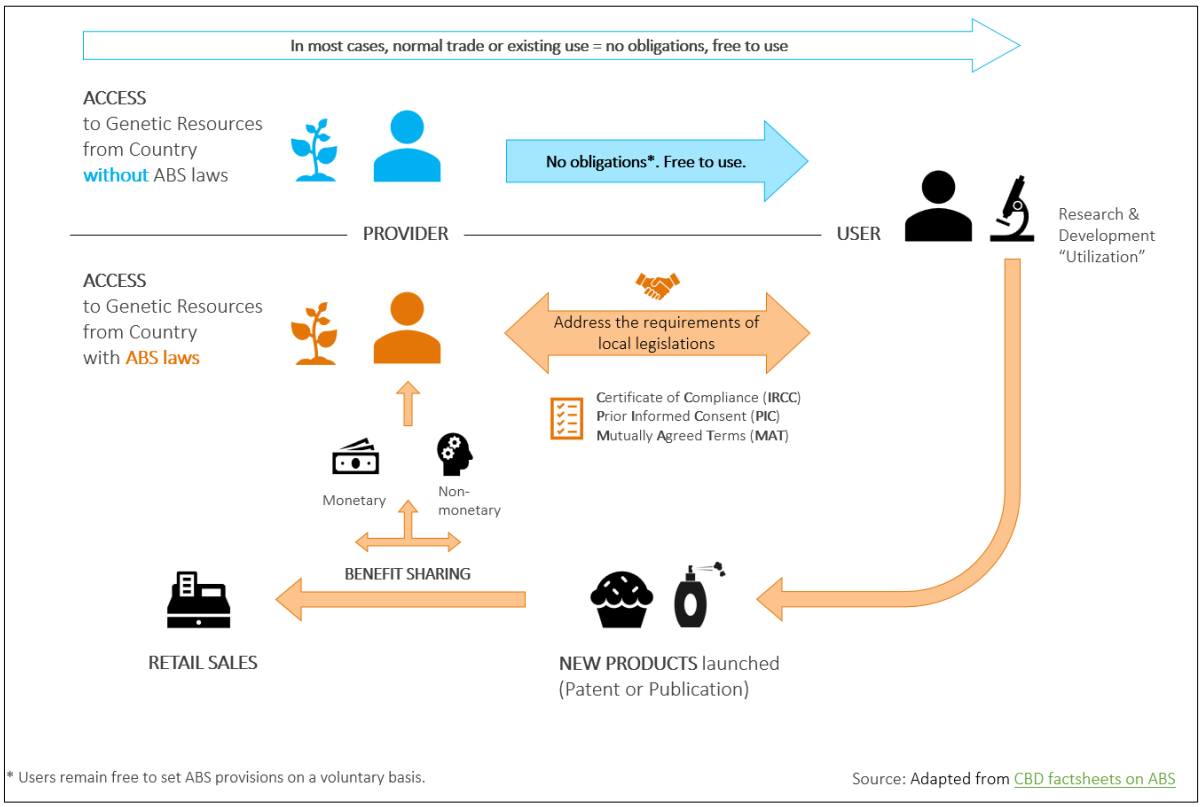

Figure 1: Principles of Access and Benefit Sharing (ABS)

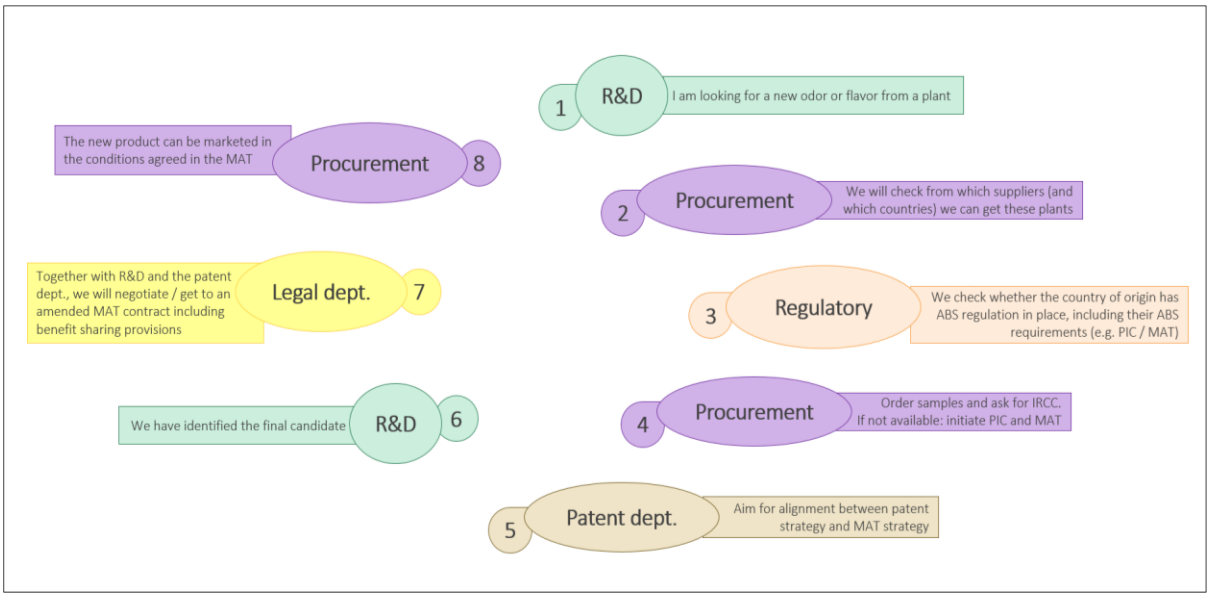

Figure 2: Company department interrelationship related to the implementation of ABS regulations (NB: the comment boxes are illustrative of the type of functions in such departments).

2. Basic elements of the Nagoya Protocol

The Nagoya Protocol implements the third element of the Convention on Biological Diversity (CBD), which is about regulating access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (ABS).

The Convention on Biological Diversity (CBD) was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit"). The CBD entered into force on December 29th, 1993, 90 days after the 30th ratification. According to the CBD, "*States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction*".

The CBD is the result of the growing recognition of the global asset and high value that the biological diversity represents for present and future generations. The CBD has 3 main objectives:

1 The conservation of biological diversity;
2 The sustainable use of the components of biological diversity; and
3 The fair and equitable sharing of the benefits arising out of the utilization of genetic resources (i.e. genetic material of actual or potential value).

The "*Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity (CBD)*"[1] (hereafter referred to as the "Nagoya Protocol") implements the 3rd pillar of the CBD. The Nagoya Protocol was adopted on October 29th, 2010 in Nagoya, Japan, and entered into force on October 12th, 2014. As of June 7th, 2017, 100 countries have ratified the Nagoya Protocol. A Party is a country that has signed the Nagoya Protocol and then taken the appropriate actions at a national level.

The Nagoya Protocol commits only its Parties, the list of which can be found on the website of the ABS Clearing House (https://absch.cbd.int/). By contrast, some Countries may not be Parties to the Nagoya Protocol but have ABS legislations in place (e.g. Brazil at the date of issuance of the present document).

The objective of the Nagoya Protocol is to ensure that any benefits resulting from the utilization of a Genetic Resource are shared fairly and equitably between user and provider[2]. This also contributes to the conservation and sustainable use of genetic resources by giving a value to biodiversity and recognizing its importance in ecosystems.

In order for the Nagoya Protocol to be effectively implemented, Parties need to transpose the rules and principles it sets out at the national level through their own legislations. The implementation of the Nagoya Protocol at national level ensures that Access and Benefit Sharing (ABS) rules are applied to access and/or utilize local genetic resources and/or their associated traditional knowledge. Through their national implementation, Parties have consequently created a wide variety of national legislations on ABS worldwide.

[1] https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf
[2] The third goal of the CBD: "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies". (https://www.cbd.int/gender/doc/fs_uicn-cbd_abs.pdf)

3. Activities of the fragrance and the flavor industry

People live through their (five) senses. Fragrances and flavors can play an important role in various aspects of triggering and stimulating senses. They can be uniquely designed to communicate cleanliness and freshness, or to make food and drinks much more enjoyable.

Not only does the fragrance and flavor industry provide products for many of our functional and emotional needs, but it also creates jobs and revenue. The industry constantly invests in research and development and the production of products, as well as in the retail of the products, which in turn supports the transport and logistics industries worldwide. All over the world we also sustainably source the raw materials we need to remain at the cutting-edge of creation. However, above everything, as a business-to-business (B2B) industry, we work together with regulators and industry stakeholders to diligently ensure the quality of products for our customers and final consumers.

Representing the sector interests, IFRA, the International Fragrance Association and IOFI, the International Organization of the Flavor Industry, deploy all their expertise to ensure consistent regulatory frameworks and to support product safety, issuing comprehensive standards for members to follow and sharing best practice recommendations.

In the fragrance and flavor industry new products can be developed through the development of new applications or formulating together new and/or already existing ingredients.
Depending on what research and development might be performed on bio-based materials in any of these steps, companies in the fragrance and flavor industry may be impacted by the Convention on Biological Diversity (CBD), the Nagoya Protocol, and/or National ABS legislations.

To develop new propositions to its customers, the industry works on different levels to deliver:

- new Formulation to match Client briefs using the existing ingredients of its Palette;
- new Application to potentially replicate an existing Formula in another sector (e.g. line extension from Fine Fragrance success to Body Care or Home Care, etc.);
- new innovative ingredients, new delivery systems or new production processes (e.g. through biotechnology as an alternative to synthetic chemistry).

The Formulation and/or Application work of the F&F industry is the mixing and blending of existing ingredients. This includes the adaptation of formulations for new applications, for example a fragrance that has been successful in the fine fragrance area is adopted for use in rinse off products like shower gels or bath gels.

While being part of the creative work of the Industry, the mere mixing and blending of existing ingredients could be considered not to qualify as utilization in the meaning of the Nagoya Protocol. However, national legislations may provide otherwise. As an example, the Brazilian Biodiversity Law encompasses the concept of technological development which may cover those activities. While Brazil not being a party to the Protocol, this evidences that each national specificity shall be considered.

By contrast, when the industry is developing a new innovative ingredient to be used in our Fragrance or Flavor compositions, this innovation would often have taken place through R&D activities. Such activity would likely be considered utilization of Genetic Resources under the scope of the Nagoya Protocol (provided that the other conditions of the Protocol are met).

3.1. Complexity of the fragrance and flavor supply chain

The F&F industry produces mixtures of fragrance and flavor ingredients, which are commonly called ‘compounds’, which are subsequently either sold to other creators of fragrance and flavor compounds as elements of compounds or are used in the formulation of finished consumer products (e.g. cosmetics, detergents, household care products, food and beverage products, etc.). Therefore, the fragrance and flavor industry is a business-to-business industry i.e. its products are not ending up in the hands of consumers. As a consequence, the F&F members can act both as suppliers and manufacturers, which can lead to a non-linear supply chain. As an example, an F&F company can source an ingredient, further process it and manufacture a different ingredient and then sell this ingredient to another F&F company, which will include it in the formulation of a fragrance or flavor compound.

The supply chain of the F&F industry with regard to natural raw materials can generally be described with the following steps:

- **Sourcing of natural raw materials**

  Natural raw materials can be sourced in-house, bought directly from the producer or from traders. Some natural raw materials can undergo chemical modification (transformation) before being used. This step can be implemented by the producer of the natural ingredient or by a third party or by the buyer of the natural ingredient. Chemically derived raw materials can be received directly from the producer but also from traders. F&F companies can be both producer and buyer of raw materials at the same time.

- **Production of fragrance or flavor compound.**

The main activity of a F&F company is the combination (blending) of ingredients to produce complex fragrance mixtures, called compounds. It is also possible that mixtures are produced (in the fragrance industry these are sometimes described as bases) that carry a special odor and are used by other companies as a component of a fragrance.

aims to describe the resulting complexity of the composition of a fragrance compound. Similar complexity exists in the flavor industry.

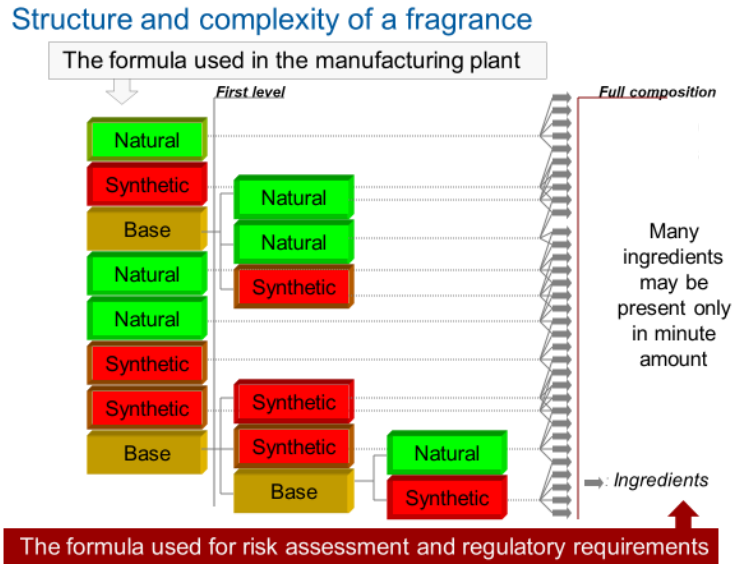

Figure 3: Structure and complexity of a fragrance.

- **Finished product manufacturing.**

  F&F companies sell the fragrance or flavor compound to manufacturers of finished consumer products for the production of e.g. cosmetics or personal care products, food and beverage products. The finished consumer products are then finding their way to the end user (consumers or professional users of consumer products, like hairdressers) via different distribution channels for consumer products (direct selling, retail, etc.). Consumers who purchase the finished consumer products represent the final element in the value chain.

3.2. Sourcing activities of the F&F industry

The odor or flavor of the finished consumer product is provided by the fragrance or flavor compound, which is a mixture of odorous and/or taste ingredients and functional components formulated to impart an odor or flavor. It is the particular mixture of these ingredients that will create the specific odor or flavor attributed to end-products (e.g. cosmetic and food products). In the F&F industry, based on information from regular volume of use surveys performed in the industry, approximately 6000 ingredients[3] of synthetic or natural origin are currently used. The F&F industry has a long-term history of using natural extracts, most of them being essential oils which are part of the palette of ingredients available to perfumers and flavorists. From these ingredients, about 1100 are of natural origin. Even though, the F&F industry is also impacted by the natural trend when it comes to R&D activities and looking for new ingredients or concepts, innovation can come from naturals as well as synthetic derived ingredients.

For many consumer product types, differentiation today often happens via natural ingredients. Those products can stay in the market for years, in some exceptional cases even for decades. The F&F industry therefore has a vital interest in ensuring a sustainable sourcing of these materials.

For many years, the F&F industry has developed and implemented programs to ensure that innovation goes hand in hand with responsible sourcing, the conservation and valorization of biodiversity as well as sustainable use of natural resources in the countries of origin. Such well-established activities can be seen as a form of voluntary non-monetary benefit sharing. For example, Patchouli oil, Vetiver oil and Vanilla are natural ingredients for which different initiatives and partnerships along the supply chain have been established, often in close collaboration with and for the benefit of local communities.

The majority of natural resources used in the F&F industry are grown on small to medium agricultural scale and extracted from fresh plant material at the origin or dried and extracted elsewhere to produce essential oils or other extracts such as powders, tinctures, resinoids, concretes and absolutes which are the materials traded and used in the F&F manufacturing industry.

On the largest scale, production is done on an agricultural scale of tens and hundreds of hectares of field or plantation crops such as Citrus, Mints, or Lavender with sometimes extraction facilities on the farms. On the medium scale production is typically done by specialist growers or in specialist plantations for example, Rose, Jasmin or Ylang Ylang, or by regional collection networks and local trade, for example spice oils from India or the Caribbean.

The small-scale production is often done by co-operatives or equivalent structures of small farmers or by local networks in a given area where the co-operative, or equivalent structures,

[3] www.rifm.org

operate a centralized extraction facility. Examples are patchouli in Indonesia or vanilla in Madagascar. On the smallest scale, the crops may be wild-crafted, i.e. collected from wild growing but maintained plantations, and sold to co-operatives or on the local market, as for example cistus from Spain, frankincense resins from Ethiopia, or Tonka beans from Venezuela. Finally, some materials, especially essential oils derived from tree species can be obtained from the by-products of the paper or timber industry, or from long standing forest plantations, such as pine oils or turpentine from papermaking, or eucalyptus, cedarwood and sandalwood from forestry plantations.

The materials traded internationally are mostly derivatives in the form of essential oils or extracts. The F&F industry also has many 'intermediate processors' all along the supply chain, these can be seen as 'value added' traders. They purchase raw materials, essential oils, extracts or dried spices and blend different qualities from various geographical origins to produce a standardized quality. They may also carry out further processing on these materials or derivatives to produce enriched or purified fractions or isolates such as "Eugenol ex clove oil", or they may carry out additional chemical processing to create a chemically modified natural with enhanced properties such as acetylated vetiver oil. These materials may still be considered 'natural' or 'of natural origin' but are no longer the primary extract from the original plant material. These 'value added traders' or the large multinational F&F manufacturers will use these traded extracts or derivatives for their formula creation. Their research and development programs could also use these traded extracts or derivatives and may occasionally also obtain the original plant material for research purposes.

The trade structure of natural ingredients for use in the F&F industry is very varied. It may involve a long supply chain from the growers, through collectors, processors, traders and retailers, or it may be very short with full back-integration with the end user owning the plantations and the processing facilities directly or through joint ventures. Some major large volume crops like Lavender, mint or citrus are produced and sold on contract in the more economically developed countries, but many of the essential oils and extracts are sold through the trade on spot purchases via traders, or with supply contracts between the processors and the F&F manufacturers. However, the F&F industry is also getting more involved in the growing and production to ensure traceability, price stability and quality of the essential oils and extracts. In this context, more and more sourcing is carried out directly through local processors, close to the cultivation areas.

In summary, the majority of the 1100[4] or so natural materials commonly used in the F&F industry are mainly derivatives, being extracted from their plant materials at source and are traded and further processed in the form of essential oils (e.g. Lavender oil), extracts (e.g. Rose absolute), or chemically modified materials (e.g. acetylated vetiver oil). With a few exceptions such as resins (e.g. Frankincense), dried spices (e.g. Pepper, Ginger) and some timber products, the original genetic resource for F&F materials usually do not enter trade for the purpose of fragrance and flavor use.

As a consequence of this structure in the supply chain, when obtaining materials for research and development, there is a clear distinction between buying the readily available essential oils, extracts or chemically modified materials from the trade, and accessing the original genetic material in the country of origin from which to make an extract. However, some of the genetic resources may also be available in the local markets of user countries as fruits, herbs, or spices from horticultural or culinary shops, either as imports or locally grown varieties.

[4] Based on internal information from IFRA and IOFI (to the best of our knowledge)

3.3. The R&D process in the F&F industry

As mentioned above (see item 3), one of the ways to develop new propositions to the customers is to develop new innovative ingredients, new delivery systems or new production processes (e.g. through biotechnology as an alternative to synthetic chemistry).

This may trigger "Research and Development" activities in the way it was defined in the context of the OECD[5] and notably referred to by the European Commission in its guidance related to compliance with the EU ABS Regulation[6], in the sense that systematic work to increase the knowledge on the capability of existing resources, etc. is undertaken.

We could summarize the main steps in the activities necessary to develop a new Ingredient in the following way:

1. Idea from literature, from nature or from other sources of inspiration.
2. Systematic work to find ways to extract, synthesize or produce the "molecule" identified in the idea.
3. Intellectual property phase for new ingredients, processes, and/or applications
4. Feasibility study on the different means of extraction or synthesis.
5. Screening of the first results for sensory application, costs, etc. Validation of the business potential: market & costs
6. Regulatory phase
7. Industrial phase

3.3.1. Potential sources of materials for R&D in F&F

- DNA/RNA or Enzymes: from living organism, or DSI

[See examples in Sections 7.7 (Bio-)Synthesis of a molecule/ingredient based on the use of published genetic information and 7.8 Synthesis of a molecule or preparation of an ingredient based on the use of published chemical information.]

- Whole living organisms or part of the animal, plant or micro-organisms, etc.

[See example in Section 7.1 Testing plant materials for the purpose of developing novel fragrance/flavor ingredients].

- Through extraction or isolation (including by Headspace[7] collection, i.e. technology called Solid Phase Micro-Extraction (SPME)).

[See example in Section 0 *Production of novel essential oils to find new flavor or fragrance* ingredients*].*

- Existing traded ingredients at disposal within the company e.g. extract without the original genetic resources like essential oils, which are commonly considered commodities.

[See examples in Sections 7.5 Testing of orange oil available on the market; 0 and 7.12

[5] Frascati Manual: Guidelines for Collecting and Reporting Data on Research and Experimental Development. https://www.oecd.org/sti/inno/frascati-manual.htm

[6] Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (C/2016/5337). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC

[7] Headspace analysis is the analysis of characteristic volatile compounds given off by the object without direct sampling. The analysis can be to evaluate and identify individual components for their odour or aroma characteristics.

Formulation using a derivative traded as a commodity].

3.3.2. Processing

As explained in section 3.2, the vast majority of the fragrance and flavor ingredients (as far as they are not derived from the synthetic chemistry) are directly bought in the market in the form of extracts. These extracts are usually produced in the country of origin and are then bought by and exported to the fragrance and the flavor industry. In a few cases, the biomass is directly processed by the F&F company and in this case the company directly imports the biomass.

In addition, "intermediate traders" or "value added traders" may buy the biomass (e.g. dried spices) or their derivatives (e.g. essential oils, extracts) from the crops and sell them to F&F companies as:

- Standardized qualities created by blending the essential oils or absolutes from different origins or qualities.
- Enriched fractions
- Purified fractions or isolates
- Chemically modified natural ingredient with enhanced properties (e.g. acetylation).

Figure 4 shows the different categories of natural materials and the types of processing that a genetic resource can follow.

[See example in Section 7.4 Formulation (mixing of ingredients) of a new flavor (or fragrance) composition].

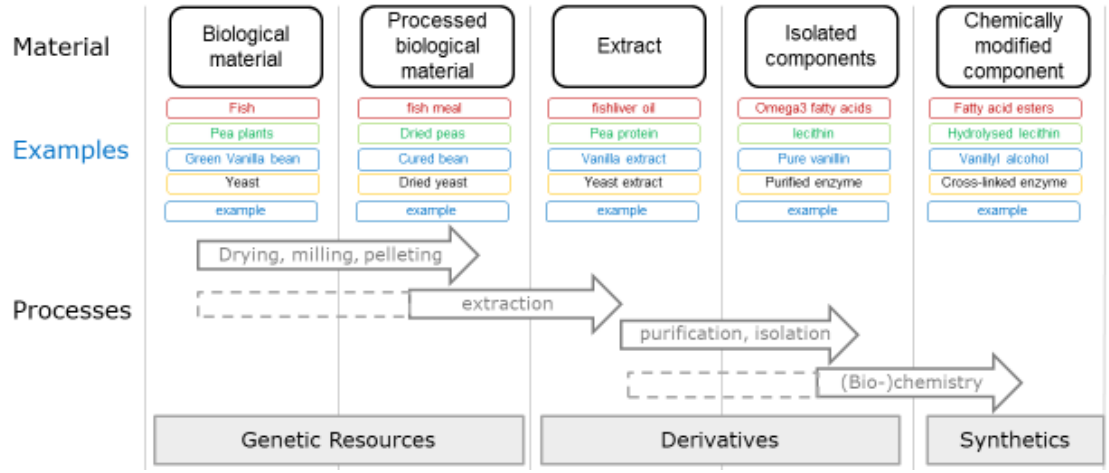

Figure 4: Typical development process for materials of biological origin by the F&F industry.

3.3.3. Synthesis

In some occasions, the (bio)chemical substance that is being investigated will have to be synthesized. The synthesis can be done through:

- biosynthesis, by the means of biotechnology leading to the creation of the compound through the use of enzymes or a (living) organism.
- chemical synthesis, by which the creation of the substance is the result of chemical reactions involving its precursors.
- a combination of biosynthesis and chemical synthesis.

In any case, the substance resulting from the chemical synthesis or the biosynthesis needs to be further studied for its adequate characterization, including its stability and its olfactory and functional properties.

4. Elements of the Nagoya Protocol and ABS regulations relevant to the F&F industry

Due to a lack of agreement between Parties on some important concepts used in the Protocol (see more details in Table 1), the Nagoya Protocol does not provide full legal clarity on its scope of application. Furthermore, as stated in previous sections, the Nagoya Protocol leaves a considerable margin of discretion for Parties to legislate on some its key requirements through their national implementing regulations. Due to the high number of Parties, this leads to a wide variety of national implementing legislations and makes it difficult for users to identify and understand the full extent of their legal obligations.

As examples of key issues on which the Nagoya Protocol lacks legal clarity, we note:

- The definition of "utilization". Although "utilization" could be commonly understood as research and development, there is still to date a lack of clarity and alignment between Parties on the exact activities that should be considered as R&D in the context of the Nagoya Protocol.
- The extent to which "derivatives" fall within the scope of the Nagoya Protocol, as such or in combination with the Genetic Resources.

Table 1: Summary of discussions during the preparation of the Nagoya Protocol.

Background discussions on the Nagoya Protocol
The negotiation of an international regime on ABS began at the third meeting of the Working Group on ABS (known as WG-ABS 3) in 2005. In the beginning, the key point of the discussion was whether or not to make a legally binding document, that is, a Protocol under the CBD. However, due to the wide gap between developing and developed countries, which included issues such as intellectual property rights, Parties could not reach consensus on building an international regime. From then, there had been a fierce confrontation between the two sides, extending beyond the period of discussion. The slow progress resulted in no substantive advancements being made on formulating an international regime on ABS until the Conference of Parties (COP)- 9 in Bonn, in 2008. In Bonn, Parties finally identified the elements of an international regime on ABS, including objective, scope, fair and equitable benefit-sharing, access to genetic resources, compliance, traditional knowledge associated with genetic resources, capacity, and nature of the document. Since then, the negotiations on the text of an international regime on ABS were a reiteration of progress and retrogress until the end of the deadlines, which was the end of COP-10 in Montreal, in October 2010. At that COP-10 meeting, a consensus was successfully reached on almost all draft texts. However, the text was approved although the negotiations reached no agreement by the deadline due to the sharply divided opinions on issues such as derivatives, scope (including retroactive application), and compliance (including disclosure of origin and checkpoints). As a consequence, the Nagoya Protocol may not provide full legal clarity on the application of its requirements and this creates difficulties for compliance by users. In addition, the fact that it is up to Parties to legislate and provide legal clarity leads to a variety of regulations worldwide.

4.1. Scope of the Nagoya Protocol

The Nagoya Protocol applies to the access and utilization of Genetic Resources and/or their associated Traditional Knowledge and to the benefits arising from their utilization.

The CBD defines some of the terms used by the Nagoya Protocol, i.e.:

- "Country of origin of genetic resources" means the country which possesses those genetic resources in *in-situ* conditions.
- "Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.
- "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.
- "Genetic resource" means the genetic material of actual or potential value.

The Nagoya Protocol provides a limited list of additional definitions of terms it uses as a basis for its scope of application:

- "*Utilization of genetic resources*" means "*to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the* [CBD] *Convention*".
- "*Biotechnology*" as defined in Article 2 of the CBD means "*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*".
- "*Derivative*" means a "*naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity*".

It should be noted that neither the Nagoya Protocol nor the CBD define the concept of "access" or that of "associated Traditional Knowledge" (aTK). Moreover, no guidance is provided in any of those international treaties on what is encompassed by "research and development on the genetic and/or biochemical composition of genetic resources". This is left open to interpretation and possibly to national legislations. As a principle, it is the role of Parties to the Nagoya Protocol to provide further legal clarity in their national legislation on these terms and on the scope of the legal requirements arising from the Nagoya Protocol. For that reason, those legislations remain the primary reference for interpretation. However, in absence of such clarity, users may need to derive an interpretation in order to identify their obligations. To that end, and for the purpose of interpreting the Nagoya Protocol itself, the user could rely on the ordinary meaning of the terms. It may often be for users to derive such interpretations in internal guidance documents.

Overall, a situation would fall in the scope of the Nagoya Protocol and the applicable national obligations (Provider Country and Country of Utilization) if the criteria of their geographical, temporal, material and personal scopes of application are fulfilled. The below section focuses on the scope of the Nagoya Protocol itself. The rules ultimately applying to a user are determined by the applicable national legislation, if any. The specificities of such rules should be verified by the user.

4.1.1. Geographical scope

The Nagoya Protocol will apply to the genetic resources and/or associated traditional knowledge that are accessed from a Party of the Nagoya Protocol if such Parties:

- Exercise sovereign rights on the specific genetic resource and/or associated traditional knowledge being accessed;
- Have established legal requirements on access.

It should be noted that Parties do not exercise sovereign rights in areas which fall beyond national jurisdiction (e.g. the high seas) and those covered by the Antarctic Treaty System.

The user is subject to the legal requirements of the provider country (in terms of access to the genetic resource and/or associated traditional knowledge) and of the country where utilization is performed (in terms of compliance measures). It is of upmost importance to note that, despite not yet being Parties to the Nagoya Protocol, some countries may still have ABS regulations in place regarding the use of their genetic resources and associated traditional knowledge (e.g. Brazil). While this, in principle, falls outside of the scope of the Nagoya Protocol, users who are accessing and/or utilizing those genetic resources and associated traditional knowledge should comply with any relevant national regulations on ABS from the provider country.

The Article 2 of the CBD defines the terms "*Country of origin of genetic resources"* and "*Country providing genetic resources*" as follows:

- "*Country of origin of genetic resources*" means "*the country which possesses those genetic resources in in-situ conditions*".
- "*Country providing genetic resources*" means "*the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country*".

In this context, the CBD defines "*ex-situ*" as "*components of biological diversity outside of their natural habitats*"(e.g. botanical gardens, gene banks, broker companies), while "*in-situ*" is when "*genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties*"[8].

This concept is important to those genetic resources that are accessed after – being imported to the provider country from another country and to those genetic resources that are accessed from public or private collections.

Article 6 (1) of the Nagoya Protocol states that "*in the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party*". Thus, Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) should be established with the countries in which the genetic resource and/or its associated knowledge is/are accessed, irrespective of whether the country in which the genetic resource and/or its associated knowledge is accessed is the country of origin or not.

Regarding collections, the CBD recognizes the research performed on *ex-situ* collections for the conservation of biodiversity. However, the research may also have a commercial value. As a matter of facts, such activities may trigger ABS obligations. If the provider country or country of origin where the collection is located has legal requirements for accessing its genetic resources and it is accessed from the collection after the Nagoya Protocol entered into force, then it would fall under the scope of the Nagoya Protocol.

Moreover, if the country where the collection is located has legal requirements for accessing its genetic resources and it is accessed from the collection after the Nagoya Protocol entered into force, then it could fall under the scope of the Nagoya Protocol. Moreover, national legislations may provide for additional rules. For example, they may extend the applicability of ABS obligations to the date at which the original genetic resources entered the ex-situ collection, it being after or also prior to the entry into force of the Nagoya Protocol and/or the national legislation at stake. This calls for a close monitoring of the applicable national rules.

[8] https://www.cbd.int/convention/articles/default.shtml?a=cbd-02

4.1.2. Temporal scope

According to its Article 33[9], the Nagoya Protocol entered into force on "*the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention*." This date was October 12th, 2014.

However, the Protocol does not provide for any specific date or time period from which the access to a genetic resource and/or associated traditional knowledge would fall in the scope of the Nagoya Protocol.

As a consequence, it is for the Parties to define the temporal scope of application of their ABS legislations. Although most of national implementing regulations may consider the date of entry into force of the Nagoya Protocol in their temporal scope (e.g. the European Union), there might be exceptions where a Party or a Third Country sets legal requirements for genetic resources and/or their associated traditional knowledge accessed prior to October 12th, 2014 (e.g. South Africa). Other legislations may apply independently from the Nagoya Protocol (e.g. Brazil).

4.1.3. Material scope (Sourcing)

The Nagoya Protocol applies to genetic resources and/or their associated traditional knowledge. The CBD provides a definition of Genetic material and Genetic resources (Article 2 of the CBD):

- "*Genetic material*" means "*any material of plant, animal, microbial or other origin containing functional units of heredity*".
- "*Genetic resources*" means "*genetic material of actual or potential value*".

Thus, the Nagoya Protocol concerns those genetic materials that have actual or potential value.

In addition, the Nagoya Protocol defines the term Derivative as "*a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity*". However, no further reference to this term is provided in the Nagoya Protocol (except in the definition of biotechnology[10]).

As a matter of fact, national legislations may sometimes refer to other terminologies, e.g. genetic heritage, biological resources. This is often true for legislations which preceded the entry into force of the Protocol. Those should be compared to the terms of the Protocol.

4.1.3.1. What is a Genetic resource and a material with associated traditional knowledge?

The definition of "*Genetic resource*" from the Article 2 of the CBD implies that any plant, animal, fungi, algae or microorganism must be considered genetic resources due to the fact that they contain functional units of heredity (e.g. DNA or RNA).

In the context of the Fragrance and Flavor Industry, Genetic resources can be used as such as an ingredient of the fragrance or flavor composition, or as a starting point to obtain specific ingredients of the fragrance or flavor composition.

[9] https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-33
[10] Article 2 of the Nagoya Protocol (https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-02)

Human genetic resources are not in the scope of the CBD nor the Nagoya Protocol[11].

Similarly, to date, Digital Sequence Information (DSI) (e.g. genetic sequences) can reasonably be considered not to fall under the scope of the Nagoya Protocol. However, national implementing legislations may consider otherwise, and subject activities conducted on DSI to access and benefit sharing obligations. Also, conditions related to activities conducted on DSI (including possible access and benefit sharing obligations) could be agreed upon in MATs covering a Genetic Resource.

[See example in Section 7.8 Synthesis of a molecule or preparation of an ingredient based on the use of published chemical information.*]*

The Nagoya Protocol does not apply to those genetic resources that are governed by specialized international instruments and other international agreements, if they are consistent with and do not run counter to the objectives of the CBD and Nagoya Protocol[12]. Examples of these specialized international instruments and other international agreements are:

- the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA),
- the WHO's Pandemic Influenza Preparedness (PIP) Framework,
- the Convention of the High Seas (UNCLOS) [13].

Please note that the ITPGRFA covers research on plant breeding towards the production of new varieties of plants. Research carried out on these species for other purposes may still attract obligations under ABS legislation from the country of origin.

However, if a country is not Party to any of the above-mentioned agreements, but is Party to the Nagoya Protocol, then the Nagoya Protocol would apply also for materials otherwise covered by the specialized international agreements. The Nagoya Protocol would also apply if the genetic resources are used for other purposes than those covered by the specialized international instrument (e.g. a food crop is used for pharmaceuticals).

While neither the CBD nor the Nagoya Protocol define "traditional knowledge associated with genetic resources", a definition may be provided in national implementing legislations. However, a common understanding of the term "traditional knowledge" is "the knowledge, innovations and practices that embody traditional lifestyles relevant for the conservation and sustainable use of biological diversity"[14]. Examples of traditional knowledge would include rituals, folklore and agricultural practices that have been gathered through experience over centuries and continuously adapted and developed. Alternative definitions and/or further specificities should be verified in the applicable national legislations.

4.1.3.2. What is a derivative and does it fall within scope of the Nagoya Protocol?

In its Article 2, the Nagoya Protocol defines derivatives as "*a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity*"[15].

Essential oils or resins from plants, organic compounds (e.g. flavonoids, polyphenols) as well as proteins, lipids, enzymes and DNA/RNA would likely qualify as derivatives under this definition.

[11]See CBD COP Decision II/11 and CBD COP Decision X/1
[12] Article 4 of the Nagoya Protocol (https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-04)
[13]At the time of drafting this guidance, discussions are taking place at the UN level to include a provision under the Nagoya Protocol that would include the High Seas under the scope of the Nagoya Protocol.
[14] https://www.cbd.int/traditional/what.shtml
[15] https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-02

However, no further reference is made to the concept of derivatives in the text of Nagoya Protocol and those are not explicitly covered by any of the obligations set up in the Protocol.

From that, the extent to and conditions upon which derivatives fall in scope of the Nagoya Protocol remains unclear and, as a matter of fact, left to the appreciation of the Parties. As a result, some national legislations may explicitly cover the situation of access to derivatives while others may remain silent, or possibly covering them to some extent.

To encompass Derivatives within their scope, some legislations have built upon the reference to the concept of derivative that is made in the Protocol through the definition of "biotechnology". The latter term is defined as "*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*"[16]. Because this concept is itself mentioned in the definition of Utilization, some legislations may link genetic resources and derivatives through the concept of Utilization.

This is for example the case for ABS obligations stemming in the EU from EU Regulation 511/2014.

[See example in Section 7.5 Testing of orange oil available on the market*].*

It is in such context that, for the purpose of compliance with EU ABS obligations, the industry has developed a reasoning method to identify situations where access and/or utilization of a Derivative may fall under the scope of EU ABS obligations, i.e. the so-called "continuity concept".

Because the Nagoya Protocol only explicitly foresees obligations for the access and utilization of Genetic resources, for a derivative to be subject to ABS obligations, there should be a link between that material and the access and utilization of a Genetic Resource, i.e. there must be an ascertainable level of continuity between the R&D activities conducted using a derivative and obtaining the derivative from the genetic resource from which it was generated.

First of all, following such reasoning method, a derivative would fall in scope of ABS obligations if generated from a Genetic resource which would itself be subject to ABS obligations.

Then, in this construct, if there is an ascertainable level of continuity between the utilization of a derivative and the access and utilization of the Genetic resource from which it was generated then it would fall in scope, sometimes described as accessing the derivative '...in combination with the Genetic Resource'. Such direct, continuous thread of activity or ownership from the genetic resource to the derivative could e.g. be expected to exist in the following situations:

- The R&D activities conducted using a Derivative form part of a research project, possibly involving several actors in different countries, covering the Genetic resource and include obtaining the Derivative from such Genetic resource.
- A user has obtained a Derivative or commissioned a third party to obtain the Derivative from a Genetic resource in a research collaboration or as a specific service (e.g. under a service agreement).
- The derivative is acquired from a third party and it is transferred with PIC and MAT conditions that cover the respective R&D activities using the Derivative.

If, however, there is no continuum between the derivative being handled and the genetic resource from which it came, then this would fall out of scope.

[16] Article 2d of the Nagoya Protocol (https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-02)

For instance, such continuity would not be expected to exist in case a derivative is acquired from a third party as a product available on the market (i.e. a commodity) and it is transferred without PIC and MAT conditions that cover R&D activities on the Derivative.

Also, a difficulty arises in the case when raw materials from different origins are bulked or blended, or when the same material can be purified or isolated from a variety of different biological species, but the origin or the potential specificities of the various species are irrelevant. In such cases, a claim could be made that a Derivative so generated would no longer directly be attributable to a specific Genetic Resource. This being said, such a claim would have to be tested before the relevant authorities. Some examples are given in Figure 3.

The continuum concept has also been endorsed by the International Chamber of Commerce as a position to advocate for[17] and is under discussion for being included in an updated version of the Guidance document of the European Commission for the purpose of EU ABS obligations.

4.1.4. Personal scope

The Nagoya Protocol applies to any actor who wishes to utilize genetic resources and/or their associated traditional knowledge which falls under the scope of the Nagoya Protocol. Therefore, the Nagoya Protocol obligations may apply to a public or private research institution, company of any size, museum or even individual persons. Similarly, the Protocol may apply to resources owned by museums, governments, retailers, indigenous local communities, farmers or even individual persons. The personal scope will generally be specified in the applicable national legislation of the Provider Country.

It shall be noted that ABS related obligations may not only apply to the actor accessing a Genetic Resource or associated Traditional Knowledge but also to actors who, despite not having accessed the said resource themselves, would perform utilization and/or commercialize products developed through the utilization of the said resources. In addition to that, several actors in the supply chain may be involved in access and/or utilization of Genetic Resources or associated Traditional Knowledge.

Finally, national legislation may also make a distinction between actors committed to obtain PIC and those who should share benefits.

This requires a precise understanding of the activities that the different actors of the supply chain perform on the genetic resource and on the potential utilization of traditional knowledge associated to that specific genetic resource.

4.1.5. Utilization and research and development

Despite being a key part of the third objective of the CBD and its Article 15(7) on benefit-sharing, the Convention does not define the phrase “utilization of genetic resources”. Late in the Protocol negotiations, the Parties inserted Subparagraph (c) in Article 2 of the Nagoya Protocol, defining the term “utilization of genetic resources” as “*to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology, as defined in Article of the Convention*”.

Although the definition of “utilization of genetic resources” in the Nagoya Protocol provides some clarification, the Protocol does not define the broad concept of “research and

[17] https://iccwbo.org/content/uploads/sites/3/2018/02/icc-position-on-derivatives-eu-regulation-final.pdf

development" (R&D), e.g. it does not provide any specific list of activities that would be considered (or not) as utilization. It seems the term R&D is more about research or development as opposed to the combined use of research and development – meaning that research alone (in absence of development) would already be in scope.

Given the lack of explicit provisions in the international treaties, it is left to Parties to further define those terms in their national legislations. Because of that, the understanding of those terms may differ widely between provider countries, and national legislations should remain the first source of reference for users.

This being said, in order to interpret those terms in the context of the Protocol only (i.e. regardless of national implementing legislations) the user could refer to the ordinary meaning of these terms. To that end the Oxford Dictionary's definition of research could constitute a useful source. It notably defines Research and Development as "*the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions*".

The definition of the "utilization of genetic resources", in the Nagoya Protocol includes both terms "research" and "development". National legislations may differ as to whether those terms are cumulative or alternative, with the latter interpretation being the most conservative. Both basic research (e.g. the investigation and study of the genetic and/or biochemical composition of genetic resources in order to establish facts and reach conclusions) or the applied research (e.g. the creation and development of innovations and practical applications) may be covered under the definition of "utilization of genetic resources". One could take the stance that utilization implies the creation of new insights on the genetic resource (or derivative) used. In such case, the mere blending or mixing of materials would likely not qualify as utilization. This being said, national legislations may provide otherwise (e.g. Brazil). It should be kept in mind that those national legislations ultimately determine the rules applicable to the user.

Also, given the lack of harmonized understanding of the terms, and even though they may not overrule national rules, literature sources may be taken as useful interpretative tools. An example is the Organization for Economic Co-operation and Development (OECD) Frascati Manual (2002). According to this manual, "*research and experimental development comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications*".

The manual further distinguishes three types of R&D:

- Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.
- Applied research is also the original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.
- Experimental development is systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

Additional insight can be taken from Morgera and Geelhoed[18] who interpret the term research and (experimental) development as "*two intimately related processes by which new products and new forms of old products are brought into being through technological innovation*".

[18] Morgera E, and Geelhoed M. 2016. Consultancy on the notion of "utilization" in the Nagoya Protocol and the EU ABS Regulation for the upstream actors. University of Edinburgh.

5. Ensuring compliance with the Nagoya Protocol and related ABS regulations in the F&F industry (Standard best practices)

5.1. Key highlights

Ensuring compliance with the Nagoya Protocol will require companies to ensure that any time they access and utilize Genetic Resources (and associated Traditional Knowledge) in the meaning of the Nagoya Protocol and more specifically in the meaning of the applicable implementing regulation, such access and utilization activities are conducted in compliance with those regulatory obligations. Users should comply with national ABS implementing legislations to ascertain that:

- genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and

- benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

The challenge is thus for companies to develop an internal process suiting their production chain, which ensures that all cases potentially falling in the scope of Access and Benefit-Sharing obligations are handled properly, while minimizing the administrative burden. This is particularly complex as several departments may be involved at different steps of the compliance to the Nagoya Protocol and its national ABS implementing legislations (Figure 5). Although the Nagoya Protocol focused on R&D activities, the regulatory, legal, procurement or sourcing, and patent or IP departments are also involved in the R&D process. Moreover, the involvement of the commercial, sales, and marketing departments is required to ensure that claims are compliant with the potential requirements of the national implementing legislations, if any.

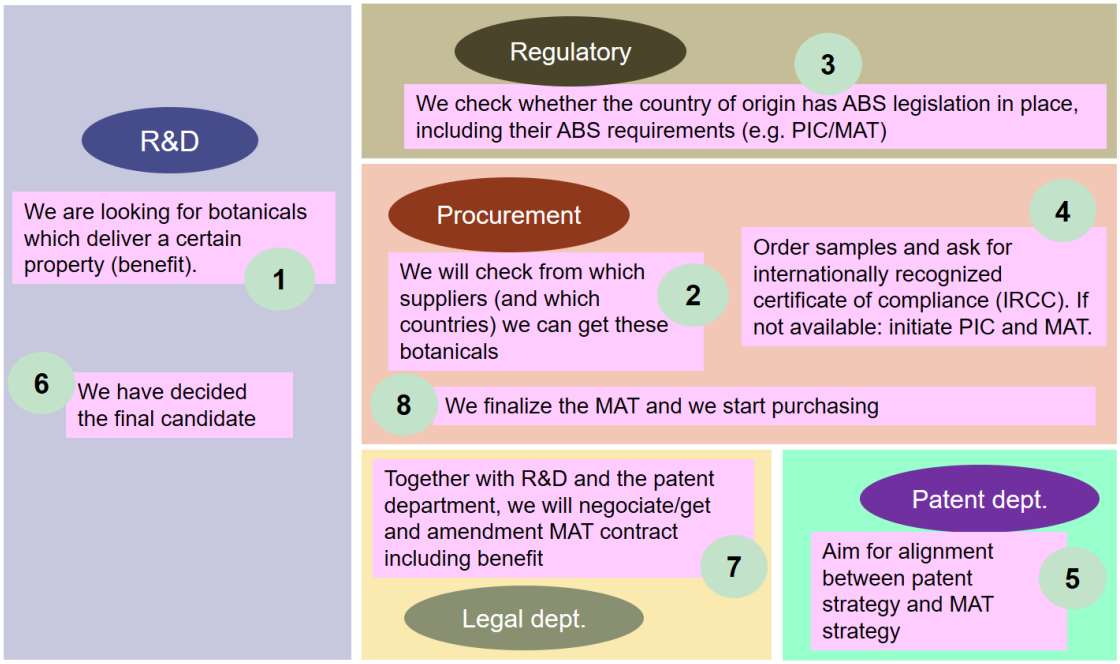

Figure 5: Example of company's departments involved in the procedure of access and benefit sharing arising from the obligations of the Nagoya Protocol.

Through sections 2, 3 and 4 of this Guidance, several issues have been raised due to the legal uncertainty associated with the Nagoya Protocol. The two main issues identified on the scope are:

- Definition of R&D activities that are considered as utilization under the scope of the Nagoya Protocol (See Chapter 3.3).
- Scope of the Nagoya Protocol regarding derivatives (See Chapter 4.1.3.2).

This is further illustrated by the examples included in Section 7.

[See examples in Section 7.3 Testing an essential oil resulting from access to the plant from which it is derived and 7.4 Formulation (mixing of ingredients) of a new flavor (or fragrance) composition].

5.2. Key elements to be considered for assessment and compliance

This section enumerates a series of key elements that should be considered by companies to assess and ensure compliance to the requirements of the Nagoya Protocol and associated national implementing regulations. These key elements are part of the due diligence process that all companies should implement to allow them to comply with the legal obligations arising from the Nagoya Protocol and consequent national ABS regulations. Independent from how companies are organized with regard to dealing with ABS related challenges, it is important that they:

- Collect all the available information on the acquisition of the material: date of acquisition, country of origin, type of material, contact details of the suppliers, etc.
- Collect information on the presence or absence of ABS regulation in the provider country and identify its legal requirements.
- Assess whether the material used for the R&D activity is considered as a genetic resource in the meaning of the national legislation.
- Assess whether the acquisition of the material may be considered as Access in the meaning of the national legislation.
- Identify which are the R&D activities that will be performed on the material and assess whether such R&D activities are considered as utilization in terms of the national legislation.
- Implement the obligations according to the national legislation as applicable. For this purpose, companies are invited to search for information (e.g. via National Focal Point).
- Keep a detailed record of all documentation proving the compliance of the company to the legal obligations from the national legislation.

[See example in Section 7.10 Application of due diligence in establishing the provider country in the context of EU ABS Regulation].

It is advisable for each company to assess on case-by-case basis whether their activity and/or the material and/or associated traditional knowledge they acquire and use fall under the scope of the Nagoya Protocol and the national ABS implementing legislation. As a rule of thumb, users should always ask themselves if what they are doing with what would qualify as a genetic resource or its derivative (see section 4.1.3.2) could generate new insight into the characteristics of that genetic resource or derivative, and thus be a potential source for innovation and product development. If this is the case, then it would likely fall under the Nagoya Protocol definition of "*utilization of genetic resources*" and would thus be within its scope.

Because the Parties retain the power to decide on regulatory requirements related to ABS, the adoption of the Nagoya Protocol has not prevented the development of a wide variety of

national implementing regulations worldwide. Because of the vagueness of some definitions and of the scope of application of the Nagoya Protocol, the national dimension of some of its important concepts (e.g. 'Access'), the peculiar situation of some important countries (e.g. Brazil or the US – see next sections), complying with the Nagoya Protocol will likely imply for companies to develop specific strategies. This will be true in particular for concepts such as 'access' (prospection, sourcing, purchase) or 'utilization' (R&D activities). They may also have to give a particular focus to identified key countries. As explained in the previous sections, the PIC and MAT are the key elements for compliance with national ABS legislations, which would identify obligations applying to a user company. Thus, it is of utmost importance for companies to ascertain whether PIC and MAT already exist for a material they access and/or for a material from which a derivative they access is derived. In such case, they should determine whether and to which extent the activities they intend to undertake on the material/its derivative are covered by the same intent of use in these documents, as well as other obligations possibly applying to subsequent users.

The Nagoya Protocol applies all along the supply chain and the obligations from the different actors may differ depending on the national implementation legislations. Companies will have to identify how and when their supply chain is impacted by obligations rising from the regulatory framework as well as how and when their own company is concerned. To that end, it is recommended to adopt a step by step approach, looking into the various steps of the production of a product in the context of the whole fragrance and flavor industry value-chain. Mapping the value chain will definitely constitute an advantage to ensure compliance.

5.3. Must Haves

To favor compliance with the obligations of the Nagoya Protocol, companies are strongly encouraged to:

- For traceability purposes, ensure adequate documentation and record keeping of:
  - the sourcing/purchasing activities of samples acquisition
  - the R&D activities
- Ensure that the actors involved in that sourcing/purchasing step are aware of the rules potentially applicable.
- Check the national implementing legislation on the legal requirements of the provider country[19].
- Ensure that the company itself complies with the compliance measures established by the user country.
- Transfer relevant information to other user across the supply chain when appropriate.
- Ensure due diligence obligations in the User country, when applicable.

[19] Information available at ABS Clearing House: https://absch.cbd.int/

6. Main requirements of the Nagoya Protocol for users

The Nagoya Protocol introduces, at the international level, the principle that 'Access to a genetic resource and/or associated traditional knowledge shall be subject to the 'Prior Informed Consent' ('PIC') of the Country providing the resource and that the 'Utilization' of such resource shall be on Mutually Agreed Terms ('MAT'), including benefit-sharing mechanisms. To that end, Parties to the Protocol shall empower dedicated authorities (i.e. National Focal Points and National Competent Authorities). When the PIC and the MAT are established for a specific user and utilization, an Internationally Recognized Compliance Certificate (IRCC), or its equivalent, may be issued and made available to the Access and Benefit-Sharing Clearing House (ABS-CH).

In the following sections, those various concepts are briefly explained.

6.1. Establishing prior informed consent and mutually agreed terms

Access to Genetic Resource is made subject to the Prior Informed Consent ("PIC") of the Party providing the Genetic Resource, unless otherwise determined by that Party (Article 15(5) CBD and Article 6 Nagoya Protocol). Where access is granted by that Party, it is conditional upon reaching Mutually Agreed Terms ("MAT") with the potential user (Article 15(4) CBD). On that basis, PIC and MAT are the primary tools for authorizing the access to genetic resources, control their subsequent use and establish the fair and equitable sharing of benefits stemming from the said use.

An actor accessing a Genetic Resource or an associated Traditional Knowledge shall obtain PIC from "*the Party providing such genetic resources and/or associated traditional knowledge (i.e. country of origin) or the Party that has acquired the genetic resources in accordance with the CBD, unless otherwise determined by that Party*[20]" (emphasis added). The terms "*unless otherwise determined by that Party"* confirm that the legal requirements pertaining to accessing a Genetic Resource remain a matter of national legislation.

The PIC is an administrative authorization issued by the Provider Country to the user granting access to a Genetic Resource. The objective of the PIC is to allow the affected actors in the Provider Country (e.g. indigenous populations, authorities) to be informed about the potential uses of their Genetic Resource and/or associated Traditional Knowledge in order to be able to make a fully informed decision on granting or denying access to their Genetic Resource to the potential user[21]. The specific information that an application should contain and the procedure leading to an approval or refusal of access are usually provided in the applicable national legislation.

If access to a Genetic Resource and/or its associated Traditional Knowledge is granted, its use is conditional upon reaching Mutually Agreed Terms (MAT) (Article 15 (4) CBD, Articles 5 and 7 Nagoya Protocol). MAT is a contractual agreement resulting from negotiations between the Party granting access to the Genetic Resource and the actor aiming to use that resource[22]. The MAT set out specific conditions for the fair and equitable sharing of monetary and/or non-monetary benefits arising from the utilization. They may also include further conditions for the subsequent application and commercialization[23].

[20] https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-06
[21] Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva, Frederic Perron-Welch in cooperation with Natasha Ali and China Williams (2012) An explanatory Guide to the Nagoya Protocol on Access and Benefit Sharing. IUCN, Gland, Switzerland. Xviii + 372 pp.
[22] Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva, Frederic Perron-Welch in cooperation with Natasha Ali and China Williams (2012) An explanatory Guide to the Nagoya Protocol on Access and Benefit Sharing. IUCN, Gland, Switzerland. Xviii + 372 pp.
[23] Overview of national and regional measures on Access and Benefit Sharing

Some examples of monetary and non-monetary benefits that may be included in the MAT are provided in the Annex of the Nagoya Protocol[24] and are listed in Table 1.

Table 2: Non-exhaustive list of monetary and non-monetary benefits as provided in the Annex of the Nagoya Protocol

Examples on monetary benefits	Examples of non-monetary benefits
• Access fees/fee per sample collected or otherwise acquired; • Up-front payments; • Milestone payments; • Payment of royalties; • Licence fees in cases of commercialization; • Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; • Salaries and preferential terms where mutually agreed; • Research funding; • Joint ventures; • Joint ownership of relevant intellectual property rights.	• Sharing of research and development results; • Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources; • Participation in product development; • Collaboration, cooperation and contribution in education and training; • Admittance to ex situ facilities of genetic resources and to databases; • Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity; • Strengthening capacities for technology transfer; • Institutional capacity-building; • Human and material resources to strengthen the capacities for the administration and enforcement of access regulations; • Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries; • Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies.

6.2. Compliance with applicable legislations of Providing Countries

Each Party of the Nagoya Protocol shall take appropriate, effective and proportionate national measures and legislations to ensure that a Genetic Resource and/or associated Traditional Knowledge utilized within its jurisdiction have been accessed upon obtaining PIC and that

[24] Annex to the Nagoya Protocol

MAT have been established, in accordance with the applicable national legislation of the Provider Country. Moreover, with respect to associated Traditional Knowledge, the said national measures should also ensure that access followed the approval and involvement of indigenous local communities.

This applies regardless of whether an individual Party decides not to require PIC to access genetic resources in its own jurisdiction.

To support compliance further, Article 17(1) of the Nagoya Protocol obliges all Parties to establish measures to monitor and enhance transparency about utilization of genetic resources and/or its associated traditional knowledge.

Among these measures, that Article lists the establishment of Checkpoints (see item 3.1.4) and the issuance of a permit or equivalent which may constitute an Internationally Recognized Certificates of Compliance ("IRCC").

6.3. The internationally recognized certificate of compliance (IRCC)

As part of their obligation to take the necessary measures and legislations to provide for legal certainty, Parties to the Protocol shall issue to users, at the time of Access, a permit or its equivalent, as an evidence of granting PIC and of the establishment of MAT.

The ABS Clearing-House should be informed accordingly. Upon its making available to the ABS Clearing-House, a permit or its equivalent should constitute an Internationally Recognized Certificate of Compliance ("IRCC").

Such IRCC constitutes a proof that the user has complied with the applicable requirements of the national legislation of the Provider Country, i.e. the genetic resource has been accessed upon obtention of a PIC, and MAT have been established between the user and the provider country. The IRCC can also be used as a source of information for users and provider countries, including their checkpoints established along the value chain (see item 3.1.4).

The IRCC are to be published in the ABS-CH website using the available template[25]. Some information may be covered by confidentiality.

6.4. The role of national focal points and competent national authorities.

To enable enforcement of the Nagoya Protocol and its national implementing legislations, Article 13 of the Protocol provides for the need for Parties to set up some specific institutional tools, and in particular to define i) a National Focal Points (NFP) and ii) a Competent National Authority (CNA).

NFPs and CNAs are to serve as the main contact points for users for them to obtain information on their obligations, on the conditions for being granted PIC and for finalizing MAT, as well as on issues of compliance. For that reason, the contact details of the NFPs and CNAs should be publicly available in the ABS-CH[26].

In more details:

[25] https://www.cbd.int/abs/en/commonformats/ABSCH-IRCC-en.doc
https://www.cbd.int/abs/en/commonformats/ABSCH-IRCC-en.doc
[26] https://absch.cbd.int/

National Focal Points (NFP) shall liaise with the CBD Secretariat and are also responsible for making available information to applicants seeking Access:

- on procedures for obtaining PIC and establishing MAT; and
- on Competent National Authorities, relevant indigenous and local communities and relevant stakeholders.

Competent National Authorities (CNA) are responsible for:

- granting access as such or, as applicable, issuing written evidence that access requirements have been met (e.g. through an IRCC); and
- advising on applicable procedures and requirements for obtaining PIC and entering into MAT.

6.5. The role of Checkpoints (CP) at the national level

As per Article 17(1) of the Nagoya Protocol, to monitor and enhance transparency about utilization of genetic resources and/or its associated traditional knowledge, Parties to the Protocol shall set up so-called "Checkpoints" to collect or receive relevant information on (notably)

- PIC;
- the source of a Genetic Resource;
- the establishment of MAT;
- the utilization of a Genetic Resource.

Parties remain free to decide on which information is to be submitted by users. In any case Checkpoints shall ensure that users of Genetic Resources provide the requested information, and Parties shall take measures to address possible situations of non-compliance.

The information obtained is to be shared with the relevant National Authorities of the Providing Country and the ABS Clearing-House. As a result, those Checkpoints ensure that provider countries, authorities and users are informed on the utilization of Genetic Resources and/or their associated Traditional Knowledge, as well as on relevant changes which might lead to an update or a new PIC/MAT. Parties shall set up sanctions to address possible situations of non-compliance.

6.6. Implementing the Nagoya Protocol through national legislations

Parties remain free in the measures adopted to ensure the implementation of the Nagoya Protocol. As a consequence, the obligations arising from the Nagoya Protocol for companies will highly depend on the national implementing legislations.

The need to obtain or not a PIC to access a genetic resource remains the sovereign choice of Parties to the Protocol, and the conditions for obtaining PIC will be specified in the national legislation of the Country of Access.

Such national measures should, among others, provide for legal certainty, clarity and transparency of their domestic Access and Benefit-Sharing legislation and/or regulatory requirements and for fair and non-arbitrary access rules. In addition, Parties should provide information on how to apply for Prior Informed Consent and establish clear rules and procedures for requiring and establishing Mutually Agreed Terms[27].

Even if a Party grants free access to its genetic resources to all users, it will nevertheless be obliged by the Nagoya Protocol to support the measures adopted by another Party, as per its

[27] https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-06

obligations under Articles 15 and 16 of the Protocol. Indeed, the national legislation of the Party where the resources are utilized shall provide for the compliance scheme described above.

All those measures should provide sanctions to be applied in case of non-compliance.

At the point of implementation, any company sourcing and/or conducting utilization on genetic resources in that jurisdiction may be obliged to comply with the legislation applicable in that jurisdiction.

6.7. The Access and Benefit Sharing Clearing House (ABS-CH)

The Nagoya Protocol establishes through its Article 14 the creation of an Access and Benefit Sharing Clearing House (ABS-CH) (https://absch.cbd.int/), which role is to facilitate the exchange of ABS relevant information, meaning:

- ABS measures and national and regional ABS regulations
- National Focal Points
- Competent National Authorities
- Permits or their equivalent, including IRCCs.

The ABS-CH also collects and publishes any other additional information related to ABS, if available and appropriate.

7. Examples

You will find below a list of examples of activities of the F&F industry that try to illustrate obligations arising from the requirements of the Nagoya Protocol implementing regulations. It has to be noted that in all cases, the requirements are specific to each country, and therefore users should always check the national implementing regulations of the provider and/or user country to ensure compliance on ABS requirements.

Note: *some countries do include Digital Sequence Information within the scope of their national implementing regulations. The Nagoya Protocol does not yet include DSI under its scope, but discussions are ongoing at the UN level to evaluate the possibility of establishing an access and benefit sharing framework for DSI.*

7.1 Testing plant materials for the purpose of developing novel fragrance/flavor ingredients

Title	**Testing plant materials for the purpose of developing novel fragrance/flavor ingredients**
Description	Whole plants, plant parts or their seeds are imported directly from a farmer or via a wholesaler from a country that has ratified the Nagoya Protocol or has ABS inspired regulation in place, by a fragrance/flavor company; for the first time, new essential oils are extracted in a search for certain new fragrance ingredients. Volatile compounds are identified for further use in product development.
Analysis	Whole plants, plant parts and their seeds constitute plant genetic resources in the meaning of the Nagoya Protocol or ABS inspired regulation. The extraction of essential oils and volatile compounds (which would qualify as derivatives under the Nagoya Protocol or ABS inspired regulation) and the study of their biochemical composition and properties could constitute utilization of the genetic resource in the meaning of the Nagoya Protocol or ABS inspired regulation.
Conclusion	In scope of the Nagoya Protocol principles.

7.2 Production of novel essential oils to find new flavor or fragrance ingredients

Title	**Production of novel essential oils to find new flavor or fragrance ingredients**
Description	Whole plants, plant parts or their seeds (cultivated or wild species) are imported by a fragrance company; new essential oils are produced for the first time to search for certain new fragrance ingredients. Volatile compounds are purified and identified.
Analysis	The extraction and purification of new essential oils and new volatile compounds, respectively, from a genetic resource, and the evaluation of their potential as new fragrance ingredients constitutes R&D on the biochemical composition of the plant genetic resource. Therefore, this activity would likely constitute utilization in the meaning of the Nagoya Protocol.
Conclusion	In scope of the Nagoya Protocol principle.

7.3 Testing an essential oil resulting from access to the plant from which it is derived

Title	**Testing an essential oil resulting from access to the plant from which it is derived**
Description	A plant is harvested by company A based in a country that is Party to the Nagoya Protocol, in order to obtain, through performing chemical analysis on a new essential oil, at the specific request of a fragrance company B in the EU. Company A produces the essential oil. This essential oil is purchased and imported by fragrance Company B, and further R&D activities are performed by Company B.
Analysis	The plant (a genetic resource) is accessed by company A to perform R&D (therefore utilization) to obtain a new essential oil which constitutes not a genetic resource but a derivative in the meaning of the Nagoya Protocol. Although the EU-based Company B does not access the genetic resource itself but a derivative thereof, some legislations may consider such situation to fall under their scope. For example, in the context of the EU Regulation, authorities could consider that there exists a continuum in the activities conducted by both companies, from the access to the genetic resource by Company A to the further R&D activities conducted by the fragrance company B. This continuum would be evidenced (in the present case) by the specific request made by Company B to Company A to produce the derivative. In such case, access to the derivative would be combined with access to the genetic resource from which it was obtained. The activities conducted by the fragrance Company B would constitute utilization of a plant genetic resource in the meaning of the EU ABS Regulation *[Note: to be confirmed with the adoption of the new version of EU Horizontal Guidance].*
Conclusion	In scope of the Nagoya Protocol principles.

7.4 Formulation (mixing of ingredients) of a new flavor (or fragrance) composition

Title	**Formulation (mixing of ingredients) of a new flavor (or fragrance) composition**
Description	The formulation of a new flavor composition for use as ingredient in food and beverage products is done by re-combining and physically processing ingredients with known sensory, taste and other functional properties. Such new flavor creation is carried out as iterative processes towards the desirable flavor characteristics and includes sensory and flavor application testing. Many of the used ingredients are of biological origin and, hence, sub-fractions or purified preparations of genetic resources, such as botanical extracts, oleoresins, fruit juices, gums, or sugar derivatives.
Analysis	This blending does not involve research and development on the genetic and/or biochemical composition of the genetic resources (or the products derived therefrom) involved. From that, it could be argued not to constitute utilization in the meaning of the Nagoya Protocol. If an ingredient being added to the formulation already carries ABS obligations defined by MAT (or similar agreement), those obligations might also be transferred to the final blended product according to the terms of the agreement.
Conclusion	The act of mixing or formulating is not considered a R&D activity, the obligations may arise from the ingredients mixed, but the activity of mixing may not qualify as utilization.

7.5 Testing of orange oil available on the market

Title	**Testing of orange oil available on the market**
Description	Orange oil is acquired by a European fragrance company on the market and is further used as the subject of a research programme in the EU.
Analysis	The fragrance company sources the orange oil from the market where it is traded as a commodity (i.e. from one or more origins). Moreover, the orange oil could be considered as a derivative, and the fragrance company does not source the essential oil in combination with access to the genetic resources from which it is derived. Indeed, there is no relationship between the production of the essential oil and its placing on the market on the one hand, and the research programme on the essential oil conducted in the EU on the other hand. Therefore, the research and development activities performed on the essential oil would likely not qualify as utilization in the meaning of the EU ABS Regulation. This being said national requirements may apply in the Country where the orange oil is acquired, and users should check with the national legislation law applicable.
Conclusion	In Europe, out of the scope of the EU ABS regulation.

7.6 Using a plant without using the available associated traditional knowledge

Title	**Using a plant without using the available associated traditional knowledge**
Description	According to an indigenous community a plant can be used as traditional anti-cancer medicine. The plant is imported by a company from another country. The company then extracts a new compound from the plant and uses the compound as a new F&F ingredient.
Analysis	The plant genetic resource has been accessed for R&D purposes and a new F&F ingredient has been identified. Identifying the new use of the extracted compounds (or synthetic versions either via organic chemistry, or biotechnology) would likely constitute utilization of the genetic resource in the meaning of the Nagoya Protocol as the compounds are directly derived from the metabolism of the plants. However, the associated traditional knowledge is not used by the company in the framework of its research and development. Consequently, no utilization of associated traditional knowledge has taken place in the meaning of the Nagoya Protocol, but there may be specific provisions in local regulations.
Conclusion	In scope of the Nagoya Protocol principles with regards to the genetic resource. Out of the scope with regards to its associated traditional knowledge.

7.7 (Bio-)Synthesis of a molecule/ingredient based on the use of published genetic information

Title	**(Bio-)Synthesis of a molecule/ingredient based on the use of published genetic information**
Description	A company synthesises compounds based on genetic information from a scientific journal wherein it is stated that the genetic sequence had been isolated from a plant.
Analysis	The use of digital sequencing data (DSI) stored in publicly available databases could, to date, be considered to be out of scope of the Nagoya Protocol. However, specific provisions of national legislations may apply in that regard, which should be verified. Moreover, the use or publication of such data may be covered by conditions set in the mutually agreed terms, which should be respected. In particular, those who accessed the genetic resources and obtained sequence data from them should respect the conditions of the agreement entered into.
Conclusion	Out of scope of the Nagoya Protocol principles.

7.8 Synthesis of a molecule or preparation of an ingredient based on the use of published chemical information.

Title	**Synthesis of a molecule or preparation of an ingredient based on the use of published chemical information.**
Description	A company synthesizes compounds based on structural information, or prepares a formulation, or an enriched fraction or isolate based on details from a scientific journal wherein it is stated that those compounds had been isolated from a specific plant.
Analysis	The use of published or public information about the chemical constituents of genetic resources can, to date, be considered out of scope of the Nagoya Protocol. However, specific provisions of national legislations may apply in that regard, which should be verified. Moreover, the use of the specified plant material may be covered by conditions set in mutually agreed terms established by those who initially accessed the plant and extracted the chemicals. Such Mutually Agreed Terms (MATs) should be mentioned in the publication and should be respected by subsequent users to whom they may also apply.
Conclusion	Out of the scope of the Nagoya Protocol principles.

7.9 Accessing and testing plants in a country with compliance legislation (e.g. EU country)

Title	**Accessing and testing plants in a country with compliance legislation (e.g. EU country)**
Description	A company collects Yuzu plants from two nurseries in Belgium and the Netherlands to perform R&D in the EU towards new citrus flavors. The acquired plants had been accessed and imported from an East Asian country into the European Union before October 12, 2014. They have been kept and propagated in nurseries since.
Analysis	Utilization from all these nurseries would be outside the scope of the EU regulation since the genetic resource was accessed from the provider country before October 12, 2014. This being said, despite the date of access, national law obligations may apply and should be verified.
Conclusion	In Europe, out of the scope of the EU ABS regulation.

7.10 Application of due diligence in establishing the provider country in the context of EU ABS Regulation

Title	**Application of due diligence in establishing the provider country in the context of EU ABS Regulation**
Description	A Yuzu plant was delivered by a supplier from an East Asian country into the European Union on December 1, 2015. The EU-based company purchased the plant from the supplier, kept it and replicated it in nurseries in Belgium and the Netherlands. On January 1, 2016, the company collects the Yuzu plants from all three nurseries, to perform R&D towards new citrus flavors. The non-EU supplier refuses to disclose the origin of the Yuzu plant. The research by the company's scientific, regulatory, and legal staff shows that the plant likely originated in Japan. The company documents its assessment.
Analysis	Utilization from all these nurseries is inside the scope of the EU ABS Regulation, since the genetic resource was accessed from a provider country after October 12, 2014 (date of entry into force of EU ABS Regulation). The company made an effort to fulfil its due diligence obligations in seeking to locate the country of origin of the plant. If the country of origin was a Party to the Nagoya Protocol at the time of access, the access is subject to obligations under the EU ABS Regulation. The company is obliged to clarify if PIC and MAT from the provider country (Japan) is required.
Conclusion	In Europe, in the scope of the EU ABS Regulation

7.11 Formulation using a derivative traded as a commodity

Title	**Formulation using a derivative traded as a commodity**
Description	Company X, based in the EU, acquires a batch of an essential oil A (e.g. Citrus) from a large Company Y based in China, but with production around the globe, which offers its orange essential oil on markets around the globe. The essential oil is composed of a blend from different producers and/or different varieties from different countries (Country 1,2,3,4). The material is used by Company X as Flavor and Fragrance compound. No R&D on the genetic or biochemical composition has been conducted neither by Company X, nor by Company Y. Both companies use Essential Oil A since many decades.
Analysis	Because no utilization (R&D activities) takes place, the EU ABS regulation does not apply. However, it is recommended that Company X and Company Y ensure traceability of the various origins of Essential Oil A (mixed by Company Y) in order to check the possible existence of an applicable ABS legislation at the national level. Indeed, in addition to the Nagoya Protocol, national ABS rules have already been observed as going beyond the rules provided in the Nagoya Protocol, sometimes applying regardless of R&D activities being conducted on the materials as in the present case. Enhanced traceability will enable companies to identify if the standard quality of Essential Oil A (at least partially) originates from countries providing such specific ABS rules (e.g. material scope including derivatives; activity scope including biotrade and commercial use without R&D). Compliance activities may be triggered by the said national rules. PLEASE NOTE: Some countries, such as India or Brazil, may exclude under certain conditions some agricultural commodities from their scope.
Conclusion	In Europe, out of the scope of the EU ABS regulation.

7.12 R&D on a derivative traded as a commodity

Title	**R&D on a derivative traded as a commodity**
Description	Company X, in its EU-based research centre, analyses the composition of the essential oil A purchased from Company Y, since Company X wishes to identify known and new chemical structures and to determine their organoleptic (odour, flavor, texture) properties. The essential oil is composed of a blend from different producers and/or different varieties from different countries. These are not known to Company X, and considered as a commercial secret by the Chinese Company Y. The analytical data obtained by Company X guides further R&D towards the creation of a new food flavor or may be used for the design of a chemical or biotechnological process for the production of a new substance identified in the essential oil, for applications in food.
Analysis	No continuum in accessing the genetic resource and accessing its derivatives can be demonstrated or assumed in the present case. The investigation and chemical analysis described in this case falls outside the activity scope of the EU ABS Regulation because: Company X has not accessed them in combination with the genetic resource. The same recommendations as in Example 12 on enhanced traceability apply.
Conclusion	In Europe, out of the scope of the EU ABS regulation (upon confirmation of the content of EC Guidelines).

7.13 Development of process flavors

Title	**Development of process flavors**
Description	Process flavors are typically manufactured by heating a reducing sugar (such as glucose or xylose) with amino acids (or sources thereof such as yeast extracts, protein hydrolysates etc.) together with further raw materials such as fats (e.g. chicken fat), table salt and water. The sensorial profile is optimised according to the intended application in an iterative process by variation of the reaction parameters (within typical ranges, e.g. for temperature, duration, concentration of individual raw materials and moment of addition) and subsequent sensorial evaluation.
Analysis	The description above constitutes “processing”. The properties of the biochemical compound contained in the genetic resources are already known. No research and development is carried out on the Genetic Resources involved and therefore this activity would likely not constitute utilization in the meaning of the Nagoya Protocol.
Conclusion	Out of scope of the Nagoya Protocol principles

7.14 Quality Control of a natural flavor (or fragrance) material

Title	**Quality Control of a natural flavoring (or fragrance) material**
Description	Many natural and fragrance ingredients are sources from different countries as raw or processed botanicals. It is normal practice to obtain a 'pre-shipment' sample for quality control purposes. The pre-shipment sample is usually analyzed and evaluated against a defined set of criteria or specifications and the result is usually expressed as a pass or a fail. A pre-shipment sample of powdered chili is obtained from a new supplier in a country that is a Party to the Nagoya Protocol. The sample is analysed for its capsaicin content, which is found to be above the minimum specification required. A microbiological test is also performed to ensure it meets regulatory requirements. It is reported as a 'pass' and an order is placed for the bulk material.
Analysis	The work described above is based on routine analysis applied to a product already on the market. The new chili powder is a genetic resource, but there is no 'utilization' since it is being developed in its conventional use as a flavor ingredient. This being said, the acquisition of the pre-shipment sample could be subject to national obligations.
Conclusion	Out of the scope of the principles of the Nagoya Protocol.

7.15 Quality Control related analyses of a flavoring (or fragrance) formulation

Title	**Quality Control related analyses of a flavoring (or fragrance) formulation**
Description	F&F formulations are composed of many different ingredients often highly complex in biochemical composition. Hundreds of different molecules may be detectable in a given flavor. A stability issue occurs in a flavor formulation containing natural ingredients which are used in a commercial product. This results in a customer complaint, a test sample fails QC and is referred for detailed analysis. To investigate the problem, a series of analytical methods is employed to understand the nature of the off-note (unpalatable flavor). In-depth compositional analysis is carried out, not only on the flavor but also on some of the natural raw materials which were used for preparing the flavor. Thanks to the analytical efforts, the cause of the off-note is identified. Identification of the issue is used to redefine the compositional specification of the raw material to avoid similar problems in future.
Analysis	The work described above is based on routine analyses applied to a product already on the market (post-R&D), for the sole purpose of avoiding inadvertently occurring off-notes. Some of the natural raw materials may be GRs, but it could be argued that these activities do not constitute utilization in the meaning of the Nagoya Protocol. Note: In the event that an 'accidental discovery' in the course of the analytical work leads on to further research towards a novel ingredient or new product, that additional work could be considered 'utilization' and may fall in scope of ABS obligations.
Conclusion	Quality control activities are generally out of the scope of the Nagoya Protocol principles.

7.16 Use of a genetic resource as a host

Title	**Use of a genetic resource as a host**
Description	Lipases are useful enzymes for the hydrolysis of esters but also their production. Genes coding for lipases can be isolated from many different organisms including plants, animals, or microorganisms. A person clones a lipase gene isolated from the yeast *Yarrowia lipolytica* in *E. coli* as one step in a gradual assembly of a gene expression construct to develop a microbial production platform for producing the lipase. During that work, biochemical and genetic analyses are carried out on the recombinant *E. coli* strain to understand its performance during the fermentative production of the lipase.
Analysis	The use of the lipase gene to develop a genetic construct qualifies as utilization of the yeast *Yarrowia lipolytica* strain used in the meaning of the EU ABS Regulation. The *E. coli* cloning host is only used as a vehicle, and it could be argued that such use of the cloning host would not qualify as utilization of the *E. coli* strain in the meaning of the Nagoya Protocol.
Conclusion	The donor organism of the isolated gene (yeast Yarrowia lipolytica) would be in scope of the Nagoya Protocol principles. To the extent that the function of E.coli as receiver organism of genes is commonly practice it would be considered as out of scope of the principles of the Nagoya protocol.

7.17 Use of a genetic resource from a public strain collection

Title	**Use of a genetic resource from a public strain collection**
Description	The user obtains a microbial strain from a public strain collection in 2016, in the EU. The strain was originally isolated from compost from a country that later became a Party to the Nagoya Protocol and deposited to the collection in 1963. The collection is located outside the country where the strain was isolated from. A gene is isolated from the strain and its sequence determined as part of a research project in the EU.
Analysis	The activity concerns utilization of a genetic resource. Because the strain was accessed and deposited to the public strain collection prior to the date the Nagoya Protocol entered into force, the deposit of the resource in the collection is out of the temporal scope of the Protocol and of the EU Regulation 511/2014. This being said, despite the date of early access prior to deposition, national law obligations may apply to the research activities and should be verified (country of origin and country where the collection is located).
Conclusion	Out of scope of the Nagoya Protocol principles.

7.18 New flavor or fragrance ingredients via headspace analysis

Title	**New flavor or fragrance ingredients via headspace analysis**
Description	An odorous tropical flower was discovered by a botanist who described his finding in a scientific publication. Inspired by that publication researchers travel to the same forest of a country that is Party to the Nagoya Protocol. Headspace analysis is carried out in that forest to capture the odorous molecules emanating from that flower. The odorous molecules are captured and analyzed without physically accessing the flower. From those captured molecules, new odorous chemical structures are discovered and synthesized by organic chemistry for performance tests in perfume and flavor formulations.
Analysis	Even though at a molecular scale, the odorous molecules are derivatives, they are captured and analyzed although without physically acquiring the genetic resource from which they originate. The capture and analysis of odorous molecules from the air surrounding the flower would constitute utilization of the genetic resource, i.e. it implies R&D on the biochemical composition of the plant genetic resource. However, the genetic resource was not necessarily physically acquired.
Conclusion	Following the spirit of the Nagoya Protocol, such situation would fall in the scope of the Protocol. This being said, the criteria and conditions of access remain a matter of national law. The subsequent development work for synthetizing novel odorous molecules or formulating a fragrance compound to mimic the flower scent would no longer constitute R&D on the genetic resource. However, compliance obligations may remain for such subsequent work, as a possible example of utilization of a derivative in continuity with the utilization of the genetic resource from which it is derived.

8. Access and benefit sharing requirements in key countries for the F&F industry

The IFRA-IOFI Nagoya Protocol TF has identified a list of key countries for the F&F industry and is providing in the Annexes of this Guidance document a short summary of the ABS legislative measures and requirements for each of them. This list is not exclusive and may be updated when new developments are made available. Such countries are:

- Brazil
- European Union
- South Africa
- Switzerland
- India

9. Conclusions

The concepts provided in the Nagoya Protocol and in the subsequent ABS laws and regulations being implemented by countries/regions around the world have an impact on the F&F industry. Individual companies and members are expected to recognize their obligations and put in place their own procedures to enable due diligence and compliance.

Some aspects of the Nagoya Protocol and ABS are complex, and others lack clarity. In these latter situations, a consensus across the F&F industry and a constructive approach up and down the supply chain can be beneficial for all involved. Biodiversity is a key element in the continued success of the F&F industry, and it is in everyone's interest to protect it and use it wisely.

10. List of abbreviations

ABS	Access and Benefit-Sharing
ABS-CH	Access and Benefit-Sharing Clearing House
aTK	Associated Traditional Knowledge
B2B	Business-to-business
CP	Checkpoint at National level
CAN	Competent National Authority
CBD	Convention on Biological Diversity
COP	Conference of Parties
DSI	Digital Sequence Information
GR	Genetic Resource
IK	Indigenous Knowledge
IPTGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IRCC	Internationally Recognized Compliance Certificate
MAT	Mutually Agreed Terms
NFP	National Focal Point
OECD	Organisation for Economic Co-operation and Development
PIC	Prior Informed Consent
PIP	Pandemic Influenza Preparedness
R&D	Research and Development
TK	Traditional Knowledge
UEBT	Union for Ethical BioTrade
UNCLOS	Convention of the High Seas

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