BOTANICALS AND NOVEL FOODS: CHALLENGES FROM A REGULATORY PERSPECTIVE

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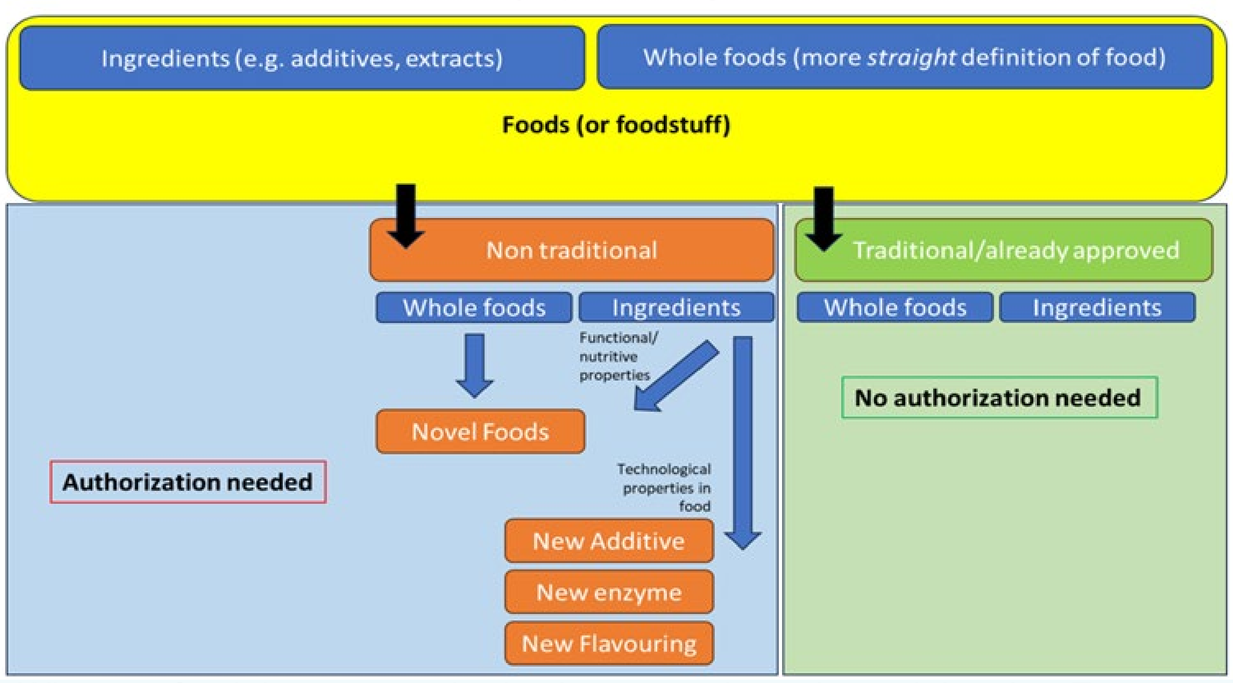
What is a Novel Food?

By definition, "Novel food" means any food that was not used for human **consumption to a significant degree** within the European Union before **15 May 1997**, irrespective of the dates of accession of Member States to the Union, and that falls under, at least, one of the ten categories listed in the Regulation 2015/2283.

Traditional foods vs Novel Foods

With the entry into force of the first of the Novel Food Regulation No 258/97 (updated in 2105 by the Reg. No 2283/2015), the European Union started to differentiate "novel" foods from "traditional“ (o conventional) ones. This definition extends to whole foods and ingredients (e.g., additives, flavoring). However, new food ingredients with technological functions follow a different framework and are addressed by specific regulations.



When a food is new, authorization must be released by the European Commission after a scientific opinion released by the European Food Safety Authority (EFSA). In this context, the Guidance released by the EFSA asks applicants to deeply characterize the proposed novel food from analytical and toxicological perspectives to ensure a safe and nutritionally advantaged food product for consumers.

What is a botanicals?

Botanicals are all extracts or preparations derived from plants with medicinal value or health benefits. In this context, botanicals are intended to be used as food supplement ingredients. Some plants and their ingredients have been known and used for centuries, while other botanicals have only recently come into use.

Botanicals may be *novel*

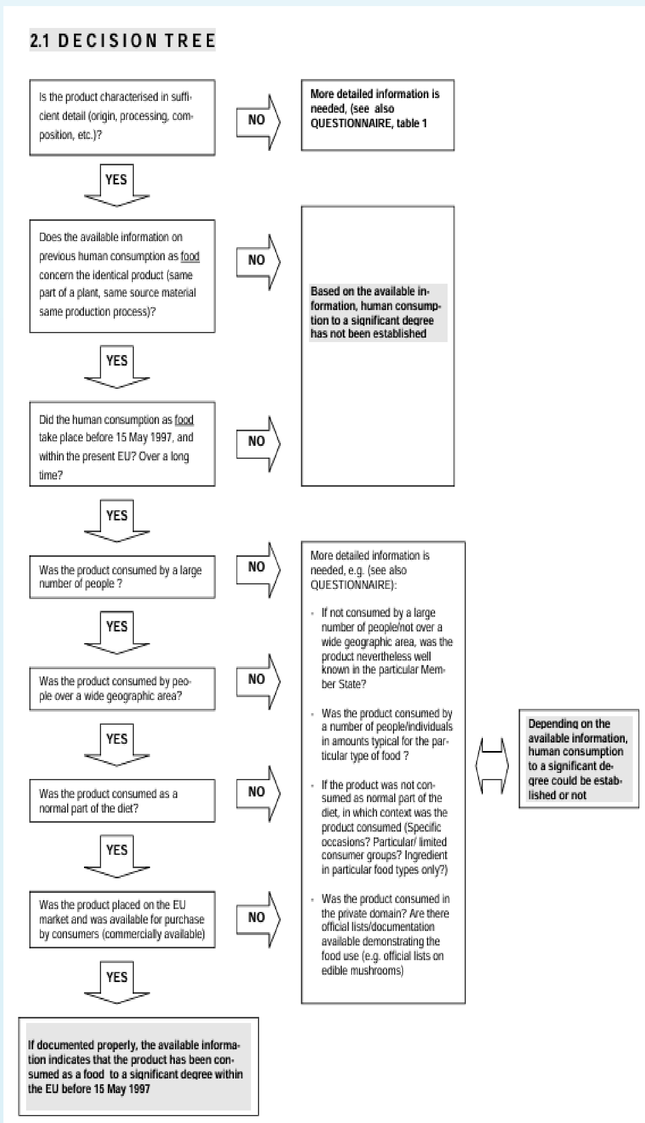
The Food Business Operator (FBO) that wishes to place their botanical-based supplement on the EU market should first establish whether their product falls under the definition of “novel”, according to the novel Food Regulation.

As said, the **cut-off criteria** for the Novel Food status is the significant food consumption before 15 May 1997.

“Human Consumption” before 1997

In 2016, soon after the update of the NF Reg., the European Commission shared the ***«Human Consumption to a Significant Degree»*** Guidance Document, which has the goal of helping FBOs collect evidence to support the traditional use of their foods.

In case of doubt, the procedure foresees that the FBO may ask to the National Competent Authority for a **Consultation process** on the Novel Food status. In that scenario, the selected Member State has to release an opinion on the NF status.



Consumption data is the central part of a consultation process to succeed (i.e., obtaining a non-novel food status). However, the essential part of collecting evidence, which is also the most difficult one, is knowing ***what*** is under assessment (i.e., the identity of the extract) and ***how*** it is produced (i.e., the production process).

The ultimate goal is that FBOs must prove, with evidence, that the same extract, well characterized and produced in the same way before and now, has already been consumed by consumers in the Union.

Challenges

Challenges of the FBOs can be related to the following three questions:

- **Is the plant allowed to be used?**
- **Is the identity of the botanical preparation known?**
- **Is the production process a “traditional ” food process?**

The first stumbling block in establishing the Novel Food status is that no **harmonized list of botanicals** (or plants) traditionally used in the European Union is available. In Italy, for example, Annex I from the Decree of the Ministry of Health, 10 August 2018, provides a list of plants and plant parts admitted for food supplements and some labelling information. Belgium, France, and Italy tried to combine their expertise by releasing the BELFRIT list, a common list of admitted plants in food supplement preparation, to simplify the movements of these goods among nations. FBOs have to rely on Member state knowledge.

The second big challenge is that botanical preparations have not always been described as titrated mixtures. There is no comprehensive description of what is inside an extract (quali-quantitatively). Different extracts can be obtained from the same plant and extraction process but purified in different contents. Proving a history of consumption without evidence of their identity may be a failing strategy.

Last but not least, according to the Novel Food Reg., the production process affects the conclusion, meaning that a new production process can easily lead to the novel food status. The Reg. 1334/2008 on flavouring, Annex II, is the only regulation that lists the traditional process allowed in the food sector and can be used in support, but it is not specific.

Tools

Some databases can be used to assess the State of the Art of on botanicals:

- **the EU Novel Food Catalogue** (EC website https://food.ec.europa.eu/safety/novel-food/novel-food-status-catalogue_en)
- **the List of Consultation process on novel food status** (EC website https://food.ec.europa.eu/safety/novel-food/consultation-process-novel-food-status_en)
- **the Union list of Novel Food** (i.e., novel food already authorized, Reg. 2017/2470. EC website https://food.ec.europa.eu/safety/novel-food/authorisations/union-list-novel-foods_en)
- **OpenEFSA**, the EFSA tool of the ongoing EFSA project (EFSA website https://open.efsa.europa.eu/).

The EFSA also provides the Compendium of Botanicals, which helps with the safety assessment of botanicals and botanical preparations intended for use in food, including supplements. Its role is to facilitate hazard identification rather than assess novel food status (EFSA website https://www.efsa.europa.eu/en/data-report/compendium-botanicals).

Conclusion

The novel food status of botanicals is not an easy topic for FBOs. For those who want to prove a history of use of their botanicals, the path may be intricate.

Characterization and production processes of botanicals are usually information challenging to find, close to impossible if we want them dated before 1997. These difficulties prevent FBOs from submitting and proving the non-novel status of their botanicals, leaving them confused about how to proceed with compliance.

In addition, Member States may operate differently in their consultation process, which would translate into a different conclusion on the novel food status based on the Member State approach.

References

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- Morán J., Kilasoniya A. (2024) *Application of the “Novel Foods” Regulation to Botanicals in the European Union*. Laws 13:10
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