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BOTANICAL FOOD SUPPLEMENTS: UNDERSTANDING THE WAY TO INFORM AND PROTECT CONSUMERS

Introduction:

One of the primary goals set out in the EU's Farm to Fork Strategy is the creation of favourable food environments which allow consumers to make healthy and informed dietary choices thanks to the delivery of clear food information. Nutritional composition, health claims, and front-of-pack labelling are therefore at the cornerstone of the Strategy, trying to tackle those shortcomings within the current regulatory framework proven to hamper consumer comprehension and consumption habits.

Worldwide, sustainability concerns are becoming increasingly more predominant among European consumers, pushing lower consumption per capita of meats, calling for the realisation of a production system with more sustainable products available on the market. Significantly, the number of vegetarians and vegans increased all over Europe and the world, where the EU meat consumption per capita is projected to decline by 1.1 kg, reaching 67.6kg by 2030[1].

Alongside with the increasing number of people shifting to different diets, the botanical market is expanding, with 18.8% Europeans estimated to be using at least one botanical food supplement a day[2], notably coinciding with a renewed interest in other holistic approaches to health care, such us nutritional therapy and complementary and alternative medicine therapies[3].

As many of SAFE's members are vegetarian and vegan associations widely using these kinds of products, we believe the topic of botanical food supplements and its related health claims constitutes a key issue which, if not addressed, could prevent the achievement of the Farm to Fork objectives.

Based on the analysis provided by this report, SAFE has identified the main considerations to be addressed in order to maintain high standards of consumers information:

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[1] https://ec.europa.eu/info/news/eu-agricultural-outlook-2020-30-sustainability-objectives-impact-meat-and-dairy-along-supply-chain-2020-dec-16_en

[2] Garcia-Alvarez, A. Et al. (2014), "Usages of Plant Food Supplements across Six European Countries: Findings from the PlantLIBRA Consumer Survey", *PLOS One,* vol 9, no 3.

[3] Ritchie, M.R. (2007), "Use of herbal supplements and nutritional supplements in the UK: what do we know about their pattern of usage?", *Proceedings of the nutrition society*, vol 66, no 4, pp 479-482.

- The EU should ensure a harmonised system providing equal and substantial information to all consumers around Europe
- To ensure a high level of safety, the EU should reconsider the current assessment applied to botanical food supplements, permitting consumers increased access to information through labelling.

1. Botanical food supplements[4] – State of play

Botanicals are "all materials (e.g. whole, fragmented or cut plants, plant parts, algae, fungi and lichens) including preparations obtained from botanicals by various processes[5] obtained by various processes (e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation)"[6]. They can be used to create **botanical food supplements**, i.e. foodstuffs with nutritional or physiological benefits destined to supplement a normal diet and usually found in doses (e.g. capsules, pastilles, tablets, or pills, or liquids or powders with recommended intake amounts)[7].

According to the European Food Safety Authority, these products are usually labelled as natural foods, with a variety of claims being made about their potential health benefits[8].

Recent studies show that 18.8% Europeans use at least one plant food supplement a day[9], probably increased by the increasing interests in alternative (vegetarian, vegan) diets and attention to environmental concerns[10]. It is proven that consumers have recourse to botanical food supplements in order to improve and/or maintain their health as well as engage in a healthy lifestyle[11].

Overall, the growing consumption of food supplements attests to a mindset shift, with consumers now favouring a holistic approach to health where they no longer solely focus on the absence of illness, but also on prevention of risk factors associated with illness and improvement of their wellbeing[12].

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[4] In this report, food supplements are meant as concentrated sources of nutrients or other substances with a nutritional or physiological effect, and not intended to treat or prevent diseases in humans or to modify physiological functions. (taken from definition present in Directive 2002/46/EC).
[5] EFSA Journal 2009; 7(9):1249 https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1249
[6] Definition taken from EFSA Journal 2009; 7(9):1249 https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1249
[7] Silano, V. Et al. (2011), "Regulations applicable to plant food supplements and related products in the European Union", *Food and Function, vol 2, pp 710-719.*
[8] https://www.efsa.europa.eu/en/topics/topic/botanicals.
[9] Garcia-Alvarez, A. Et al. (2014), "Usages of Plant Food Supplements across Six European Countries: Findings from the PlantLIBRA Consumer Survey", *PLOS One,* vol 9, no 3.
[10] Ritchie, M.R. (2007), "Use of herbal supplements and nutritional supplements in the UK: what do we know about their pattern of usage?", *Proceedings of the nutrition society*, vol 66, no 4, pp 479-482.
[11] Schuster T.L., Et al. (2004), "Wellness lifestyles I: a theoretical framework linking wellness, health lifestyles, and complementary and alternative medicine", *Complement Med.,* vol 10, pp 349–56.
[12] Egan, B. Et al. (2017), "Consumers' Understanding of Plant Food Supplements: Benefits, risks, and Sources of Influence", *Food Supplements Containing Botanicals: Benefits, Safe Effects and Regulatory Aspects,* pp 437-458.

2. The current Regulatory framework on food supplements

2.1. European and national provisions regulating botanicals

In the EU, food supplements are considered as foodstuffs[13], meaning that their use is largely regulated by Directive 2002/46/EC on food supplements[14], in conjunction with additional horizontal EU food laws and specific national dispositions. In the case of botanical food supplements, they are considered a food supplement subcategory, following the same regulatory framework.

Botanicals can be regulated according to their medical or food uses, following different legislations. The **medical use** of botanicals is harmonised through the 2004 Traditional Herbal Medicinal Product Directive[15], aiming at providing a simplified regulatory approval process for traditional herbal medicines in the European Union (EU).

Food use is ruled by several EU legislations[16], the most important ones being the General Food Law Regulation (GFLR)[17] and the Food Supplements Directive of 2002[18]. They aim at harmonising rules to protect consumers from potential health risks and to ensure that they are not provided with misleading information. This directive specifically states that supplements **must not be labelled, presented or advertised as capable of preventing or curing a disease.** Advice on storing the product out of reach of young children as well as recommended daily intakes must also be featured.

According to the Regulation on food supplements, Member States are first and foremost responsible for classifying which product is to be considered as food or medicine. To this day, 19 Member States have adopted national laws on plants authorised in foods - often used to simultaneously incorporate the principles established at community level[19].

This duality means that, while botanicals are vastly accessible across the EU food market, the current lack of a harmonised definition of botanicals in food **leads some products to be considered as "food" in one Member State, while being classified as "medicine" or both in another**.

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[13] As specified in the General Food Law Regulation (GFLR) 178/2002.
[14] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
[15] Directive 2004/24/EC amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.
[16] https://www.raps.org/news-and-articles/news-articles/2018/7/food-supplements-in-the-european-union-the-diffic.
[17] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[18] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
[19] Commission Staff Working Document SWD(2020) 96 final https://ec.europa.eu/food/system/files/2020-05/labelling_nutrition-claims_swd_2020-96_sum_en.pdf .

Due to the lack of a harmonised system, some Member States have come to specific agreements for the identification of plants that can be used in food supplements. Since 2014, there has been a common list for France, Belgium and Italy, known as the "BelFrIt". Although it has no legal value, it was established with the assistance of the DGCCRF (*Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes*)[20]The list became a reference also for other Member States authorities.

This non-exhaustive list of plants that can be used in food supplements, provided that certain restrictions are respected to guarantee consumer safety, was developed to provide the control authorities with a framework to rely on[21].

2.3. The Nutrition & Health Claims Regulation (EC/1924 2006) (NHCR)

In addition, Regulation (EC) No 1924/2006 regulates nutrition and health claims made on foods. According to it, the Commission should have established a set of **nutrient profiles by 2009**, which is still currently under revision. The **regulation also advances that health claims should not be misleading or** suggest that a balanced diet cannot provide the necessary nutrient intake[22]. This means that the use of nutrition and health claims will only be allowed if the presence, absence or reduced content in a food of a substance has been shown to have a beneficial effect, **based on the provision of evidence-based and scientifically backed data[23].**

Lastly, the regulation states that, in order to be accepted by the European Food Safety Agency following a scientific assessment, claims must systematically feature information regarding:

- the target population
- the importance of a varied and balanced diet
- the intake needed to reach the claimed beneficial effect
- disclaimers on population groups who should avoid consuming the supplement (e.g. pregnant women)
- products likely to present a health risk if consumed to excess.
- In the case where a reduced risk of disease is claimed, a statement that “the disease has multiple risk factors and altering one of these may or may not have a beneficial effect” must be affixed.

It is important to notice that Regulation 1924/2006 provides for the prior approval of all claims referring to both the nutritional and physiological effects of a food on health, as well as to the reduction of risk factors associated with disease. However, this legislation has extended the concept of 'beneficial physiological effect' to such an extent that the overlap with indications

[20] General Directorate for Competition, Consumer Affairs and Fraud Control
[21] http://www.senat.fr/rap/r20-346/r20-3469.html#fn22
[22] As laid down by article 3 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
[23] As laid down by article 4 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

for medicines has increased, making the assessment of food supplements and the related information to consumers more difficult to manage, due to their intrinsic difference.

2.2. Assessment procedure for botanicals health claims and the "on-hold" list

The all-important details of the authorisation process are not given in the NHCR. They were established later by the implementing regulations (EC/353/2008) and by EFSA guidelines, including its *General Scientific Guidance for Stakeholders on Health Claim Applications.*

The NHCR stipulates that health claims made on foods including botanicals should only be authorised after a scientific assessment of the highest possible standard by the European Food Safety Authority (EFSA) in which human intervention studies are an essential element[24]. Following EFSA assessment, the final decision relies on European Commission and Member States, who will decide on the receivability of the claims.

In 2009, none of the health claims on botanicals received a favourable assessment by EFSA, mainly due to the absence of human intervention studies, which led to a suspension of the authorisation procedure in 2010.

In 2012, the Commission established an 'on-hold' list of 2,078 health claims for botanicals, **which may still be used on the EU market under the responsibility of the business operators** provided that they comply with the general principles and conditions of the Claims Regulation and the relevant national provisions, pending a final decision.

In 2016, the European Commission started assessing the Claims Regulation in order to evaluate whether it was fit for purpose or needed to be reviewed. The Staff Working Document (SWD), published in May 2020, evaluates the state of play of both nutrient profiles and health claims on plants. The Commission concludes that the specific objective pursued by nutrient profiles (i.e. to prevent a positive health message on foods high in fats, sugars and/or salt content) is still relevant today but that the overall objectives of the Regulation have not been reached.

A key problematic identified by the SWD is that "the evaluation findings show that in the current situation consumers continue to be exposed to unsubstantiated health claims from the on-hold list and may believe that the beneficial effects communicated with the on-hold claims have been scientifically assessed and risk managed, whilst this is not the case".

2.4. The grey zone for consumers: regulatory inconsistencies leading to less information.

[24] As laid down by recital 22 and article 13.1 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

There are several regulatory issues that lead the Commission to decide to create the "on-hold" list for many botanicals, creating a system misleading for consumers. In fact, the requirements for scientific substantiation for health claims on plants are difficult to meet, having now only 267 health claims authorised, most of which relate to essential nutrients, such as vitamins and minerals.

The reason is that, according to the Traditional Herbal Medicinal Product Directive[25], traditional herbal medicines do not require to be scientifically substantiated. It is sufficient to demonstrate that a product has been used for 30 years (of which 15 in the EU) and that the efficacy is plausible due to this long-term use and experience. On the contrary, **food supplements must be approved based on high-quality scientific evidence, such as through clinical trials in humans**. It should be noticed that this assessment is not required under national legislation.

Therefore, the Commission created the 'on hold' list after noticing that most of the health claims on botanicals food supplements were being rejected, resulting from the decision of applying clinical trials in humans for the purpose of health claims justification. Due to this inconsistency, consumers are currently being deprived of proper information on the use of food supplements and are experiencing a reduction of options.

3.1. Policy recommendations

Given described uncertainties, SAFE believes that the European Commission should act to avoid further confusion caused by the legal grey zones embedded in the current regulatory framework.

For this reason, SAFE would like to urge to:

- Create a tailored risk assessment based on appropriate methodologies to ensure health claims are respecting consumers' expectations on botanical food supplements in order to allow them to access more information from the labelling while buying these products.
- Establish a harmonised system equal in all Member States where botanical food supplement can be identified with same criteria by all national authorities.

In order to ensure the Farm to Fork and Green Deal objectives, these regulatory inconsistencies need to be tackled, and a new system for assessing health claims for botanicals needs to be found in order to allow consumers to be aware of their choices.

[25] Directive 2004/24/EC amending, as regards traditional herbal medicinal products, HYPERLINK "https://en.wikipedia.org/wiki/Directive_2001/83/EC" \o "Directive 2001/83/EC" on the Community code relating to medicinal products for human use