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Exploitation of the traditional evidence for botanical health claims on foodstuffs in Europe

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ABSTRACT

In the European Union, health claims on foods are considered as voluntary food labelling information. While health claims for nutrients and specific bioactive ingredients were subject to strict scientific evaluation, the health claims for botanicals have regulatory status 'pending evaluation'. They are commonly used on the market, although there is no consensus on the strength of the evidence needed for their support. In the EU the evidence regarding traditional use is sufficient for traditional herbal medicines. Consequently, we investigated the approach of using such evidence to support botanical health claims. The study was conducted on ten commonly used botanicals in Europe. Using data on previously identified relevant health effects and the wording used for authorised health claims, the possible wordings for botanical health claims were constructed. The study results support further discussions and policy options about the use of botanical health claims.

1. Introduction

1.1. Borderline between food and herbal medicinal products

In the European Union (EU), botanicals are typically referred to as products from plants, algae, fungi, or lichens (EFSA, 2009a). The use of botanicals for various purposes has been experienced for a long time. The rise in use of functional food products, especially food supplements, based on botanical ingredients is depicted as part of a trend empowering consumers to manage their day-to-day health needs (Peacock et al., 2019). Data in the literature indicates that approximately 19% of adults in the Europe use plant-based food supplements (Garcia-Alvarez et al., 2014). Overall, products are most often taken "periodically" (37%) with respondents also reporting using plant food supplements when experiencing a "flare up or worsening of a condition" (22%). A survey conducted within the European Union-funded project PlantLIBRA identified ginkgo, evening primrose, artichoke, ginseng, aloe, fennel, valerian, soybean, lemon balm, and echinacea as the most frequently used botanicals in six European countries (with prevalence between 4% and 8%), with notable differences found between age groups and countries (Garcia-Alvarez et al., 2014).

In the European Union, the use of botanicals in foods, food supplements or medicinal products is regulated in frameworks that are mutually exclusive (Schieber, 2020): whereas herbal medicinal products are considered pharmaceuticals and are subject to the pharmaceutical law, plant food supplements are classified as foods (Gulati, Ottaway, Jennings, Coppens, & Gulati, 2019). However, foods with botanicals have to comply with the EU General Food Law, that is, Regulation (EC) 178/2002 (EC, 2002b) and Directive 2002/46/EC (EC, 2002a) on the approximation of the laws of the member states relating to food supplements. To assure food safety, regulation (EU) 2015/2283 (EC, 2015b) is also applicable, where novel foods or novel food ingredients are used. Besides, the use of the commercial botanical products as traditional medicinal products or food products in specific EU member state, depends largely on national regulations and procedures of the competent national authorities and on the interpretation of existing regulations by the manufacturers, rather than on the intrinsic properties of the botanical products and their constituents (Anton, Mathioudakis, Pramono, Sezik, & Sharma, 2019; Restani, 2019; Silano, Coppens, Larrañaga-Guetaria, Minghetti, & Roth-Ehrang, 2011).

Abbreviations: EC, European Commission; EFSA, European Food Safety Authority; EMA, European medicines agency; ESCOP, European Scientific Cooperative on Phytotherapy; EU, European Union; HMPC, Committee on Herbal Medicinal Products'; ICF Body functions, WHO International Classification of Functioning, Disability and Health; NDA Panel, The Panel on Nutrition, Novel Foods and Food Allergens; NHC regulation, Regulation (EC) 1924/2006 on nutrition and health claims; OpE, OpenEFSA portal; REFIT, EC's Regulatory Fitness and Performance program; THMP, traditional herbal medicinal products.

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Communication of health-related effects of such products is important for both manufacturers and consumers (Anton et al., 2012b; Schwitters, 2012). On one hand, such claims enable manufacturers to successfully market their products, while on the other hand, consumers are informed about the properties of the product. Communication on health-related topics on products must be in accordance with the legislation, which is relevant for each group of products. In line with the EU regulations, medicinal product can refer pharmacological effects, while foods can only have (nutritional) physiological effects (Quintus & Schweim, 2012). Depending on the composition and presentation, the botanical product can be either a medicine or food (supplement), because of the ambivalent character of its constituents (Silano et al., 2011). However, while communication of health properties of botanicals is very well defined for traditional herbal medicinal products (THMP) (EC, 2004), this is not the case for foods and food supplements (Anton et al., 2012b; Coppens, 2012; Lapenna et al., 2015; Schwitters, 2012).

1.2. Current use of health claims for botanicals on foods

The use of health claims on food products was harmonised in the EU by Regulation (EC) 1924/2006 on nutrition and health claims (NHC regulation) (EC, 2006a). It should be noted, that in contrast to authorisation of medicinal products, the authorisation of health claims for foods does not include assessment of the safety. Safety assessment of novel foods (or novel food ingredients) is defined in Regulation (EU) 2015/2283 (EC, 2015b), but with a separated authorisation procedure, which cannot be joined with authorisation of a new health claim. The NHC regulation requires that health claims are preauthorised by the European Commission (EC) through the Comitology procedure, following a scientific assessment and verification of a claim by the European Food Safety Authority (EFSA) (Martini, Del Bo', & Cavaliere, 2019; Pravst, 2015; EFSA, 2021a) (Fig. 1). These rules ensure the free circulation of foods bearing claims, as any food company may use the same claims on products anywhere in the EU. However, in comparison to many nutrients, for which health claims were evaluated and included to the list of authorised claims (EC, 2012b), the situation turned out to be much more complex for many other ingredients, including botanicals (Verhagen & van Loveren, 2016). When the NHC regulation was accepted in 2006, it was not foreseen that many food constituents (i.e. probiotics, lutein, coenzyme Q10, and practically all botanicals) will not meet the standard of substation of health claims on foods (EC, 2021a). For example, over 2,000 health claims for botanicals were sent to scientific evaluation, but after EFSA stared publishing negative scientific opinions, the EC decided to put all health claims for botanicals 'on hold' (EC, 2020), pending further consideration on how to proceed with them (EC, 2011; Lenssen et al., 2020; Lenssen et al., 2019; Pravst & Kusar, 2014). Currently, the requirements for use of such 'on hold' health claims on food (supplements) are different among EU Member states; in many cases, their usage is possible without any notification procedure.

The EC's decision to put the botanical health claims assessments 'on hold' was the result of a long-lasting debate on whether or not to allow the use of traditional evidence to substantiate claims on foods, similar to the evidence requirements for traditional herbal medicinal products (Lenssen et al., 2019). Since health claims for botanicals become a challenging part of the NHC regulation, it was included in the EC's Regulatory Fitness and Performance program (REFIT) (EC, 2015a, 2015c, 2017). The results of the REFIT evaluation (EC, 2020), published in May 2020, showed that in the current situation, consumers are exposed to unsubstantiated botanical health claims from the 'on hold' list and may believe that the beneficial effects communicated with those claims have been scientifically assessed and risk managed, whilst this is not the case. Since the NHC regulation is currently not meeting its objectives of protecting consumers from false and misleading claims and harmonising EU legislation, future possible regulatory changes were highlighted (EC, 2020; Kušar et al., 2021). Until a final decision is adopted at the EU level, health claims on botanicals included in the 'on hold' list can be used across the EU, under the responsibility of food business operators, provided that they comply with the general principles and conditions of the NHC regulation and with existing national provisions (EC, 2020). However, the main challenge when botanical health claims from the 'on hold' list are used is how to provide sufficient evidence of a cause-and-effect relationship for each claim used.

1.3. Evidence on traditional use of botanicals

Although the international approach toward evidence on traditional use for substantiating efficacy of botanicals is very variable, many jurisdictions allow the use of such evidence on herbal medicines (Lenssen et al., 2019). This is also the case in the EU; if herbal medicinal products are used to treat a specific disease for more than one generation, Directive 2004/24 allows for the use of evidence on traditional use for both safety and efficacy substantiation (EC, 2004). According to this Directive, traditional use is established when product has been used for the treatment of a specific disease for 30 years, of which at least 15 years within the EU. Products can be then authorized as traditional herbal medicinal products (THMPs). Folk knowledge of the use of botanicals has been passed on from generation to generation and later been systematically recorded (Anton et al., 2019). Today an extensive body of monographs covering the traditional use of botanicals exists. Over time, this knowledge may have been further confirmed by scientific data, identifying the compounds responsible for the beneficial effects and researching these effects in a more structured way. For evaluating safety and efficiency of botanicals, Community Herbal Monographs are

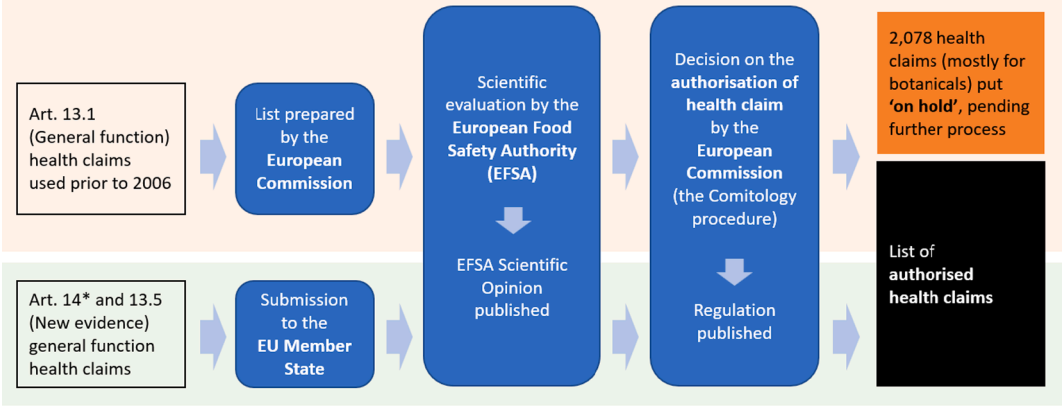

Fig. 1. Key steps in the process of authorization on health claims made of foods in the EU.

officially accepted documents during a THMP registration procedure. They are based on the Committee on Herbal Medicinal Products' (HMPC) scientific opinions on safety and efficacy data for herbal substances and their preparations. The HMPC evaluates all available information, including non-clinical and clinical data, and also documents long-standing use and experience in the EU (EMA, 2020a).

Contrary, the evidence on traditional use of botanicals in medicines has not been sufficient to substantiate health claims on foodstuffs. Although several stakeholders are generally in favour of using such evidence, Lenssen et al. (2020) highlighted key challenges in their arguments. Their study indicated not only high complexity of the problem, but also that stakeholders can have very different interpretation of various underlying concepts, including consumer misleading. It should be also noted, that in contrast to medicines (where claims can communicate therapeutic effects), health claims for botanicals on foods should refer to the maintenance of physiological functions (Anton et al., 2012b, 2013; Lenssen et al., 2019; Pravst, 2015). However, health effects listed in many herbal monographs are often not related only to therapeutic indications, but also to the maintenance of physiological functions such as 'reduction of tiredness and fatigue', 'resistance to mental stress', etc. (Anton et al., 2012b, 2013). Beside HPMC monographs, the European Scientific Cooperative on Phytotherapy (ESCOP) monographs also represent a long-standing relevant source of information on plants' traditional use (ESCOP, 2003, 2009, 2020).

1.4. Objective

As the decision on how to proceed with botanical health claims on foods in the EU is still pending, there is a need to explore the traditional use of botanicals as supportive evidence for the substantiation of health claims, to support not only researchers and manufacturers, but also policy makers. The main objective of the present paper was to investigate, if 'on-hold' health claims for most commonly used botanicals on the EU market can be supported with evidence on traditional use, and to discuss possible future regulatory approaches. We also constructed examples of possible wordings of such botanical health claims, supported only with traditional use.

2. Design of the study

2.1. Selected botanicals for the study

The assessment of health claims in the present study was conducted for ten commonly used botanicals in Europe: ginko (*Ginko biloba*), artichoke (*Cynara scolymus*), ginseng (*Panax ginseng*), aloe (*Aloe barbadensis*; syn. *Aloe vera*), fennel (*Foeniculum vulgare*), valeriana (*Valeriana officinalis*), lemon balm (*Melissa officinalis*), purple coneflower (*Echinacea purpurea*), soybean (*Glycine max*), and evening primrose (*Oenothera biennis*) (Garcia-Alvarez et al., 2014).

2.2. Regulatory framework

The design of the present study was prepared with consideration of the existing regulatory situation in EU (EC, 2006a, 2012b), which enables the use of health claims for botanicals from the 'on hold' list pursuant to the transitional periods foreseen in Article 28(5) of the NHC regulation, which requires a causal link between the consumption of such foods and the claimed effect, which should be beneficial for human health and supported by evidences. In addition, EFSA's published scientific and technical guidance documents (EFSA, 2017b, 2021a) were also considered.

2.3. Methodological concept

A four-step approach (Fig. 2) was used:

1. *Characterisation of selected botanicals and evaluation of data in their health claim applications*

All selected botanicals were defined by latin name and plant part used. The characterisation was based on data from THMP (EMA, 2020a) and ESCOP monographs (ESCOP, 2003, 2009). Further on, the data in the health claim records in the Open EFSA (OpE) portal (EFSA, 2021b) was collected, and cross checked with the established 'on hold' list of the EC (EC, 2012a). Search in the OpE portal was conducted using latin names of the plant. Identified application ID and wordings of proposed health claims were extracted and included into Excel dataset for further evaluation. Each identified application ID was then searched within the EC 'on hold' list (EC, 2012a), and only health claims with ID number, present on EC 'on hold' list, were included to list of further evaluated health claims.

2. *Evaluation oftraditional use*

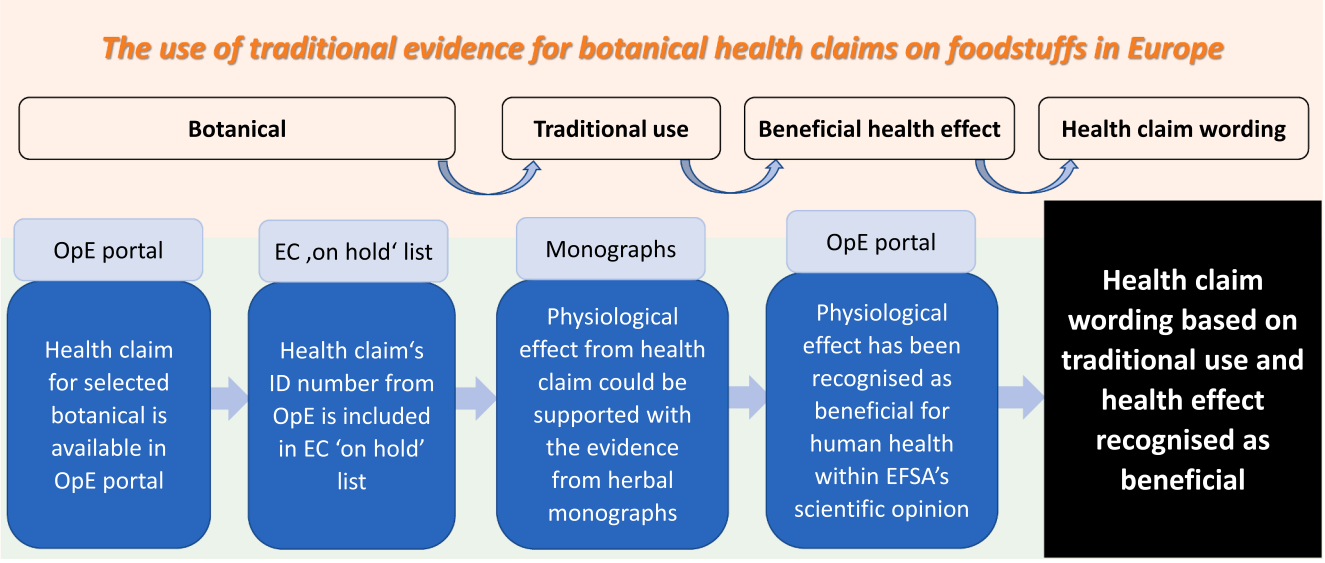

Fig. 2. Methodological approach of the study.

Table 1
Presentation of the methodological concept for establishing health claims for botanicals based on traditional use - case study with valerian (*Valeriana officinalis)*.

Health claim wording in OpE portal	Traditional use in HMPC and ESCOP monographs	Related health effects recognised as beneficial for human health from EFSA's scientific opinions in the OpE portal	Examples of health claim wording based on traditional use and health effects recognised as beneficial
***Valeriana officinalis*; Common Name: Valerian) - Mental health** (EFSA, 2021b) Helps to maintain a natural sleep; Helps maintain normal quality of sleep; Helps you cope calmly with the stress of a busy lifestyle; Support of mental wellbeing in cases of tension and stress; Contributes to optimal relaxation; Helps to support the relaxation and mental and physical wellbeing; To help sleep onset; Clinically/ scientifically proven to help normalise/promote sleep (onset); Valerian helps to maintain a natural sleep; To support calmness and in case of irritability; Helps you cope calmly with the stress of a busy lifestyle; Support of mental well-being in cases of tension and stress; Contributes to optimal relaxation; Helps to support the relaxation and mental and physical well-being.	The relief of mild symptoms of mental stress and to aid sleep (EMA, 2020b). The relief of mild nervous tension and sleep disorders, including difficulty in falling asleep (ESCOP, 2003).	The improvement of sleep quality - maintenance of normal sleep (EFSA, 2011a). The maintenance of normal physical and cognitive functions (EFSA, 2011b). The contribution to normal functioning of the nervous system (EFSA, 2009b). The reduction of tiredness and fatigue (EFSA, 2010).	**Valerian root** has been traditionally used to contribute to the maintenance of normal sleep and sleep quality. **Valerian root** has been traditionally used to contribute to the maintenance of normal physical and cognitive functions. **Valerian root** has been traditionally used to contribute to the normal functioning of the nervous system. **Valerian root** has been traditionally used to contribute to the reduction of tiredness and fatigue.

Notes: OpE portal - Open EFSA portal; EMA - European medicines agency; HPMC - Committee on Herbal Medicinal Products': ESCOP - European Scientific Cooperative on Phytotherapy; EFSA - European Food Safety Authority.

The HPMC (EMA, 2020a) and ESCOP (ESCOP, 2003, 2009) monographs represent a credible source of data about the traditional use of botanicals. Therefore, selected botanicals were searched in these monographs and the information on the traditional use were included in the dataset. Within monographs data on traditional use of botanicals are included in paragraph IV, entitled '*Therapeutic indications'* within HPMC monographs and in paragraph 'Clinical particulars, *Therapeutic indications'* in ESCOP monographs.

3. *Beneficial physiological effects*

According to Regulation (EC) No. 1924/2006 (EC, 2006a), the use of health claims is permitted only if the food (constituent), for which the claim is made, has been shown to have a beneficial physiological effect. In the evaluation of health claims, the EFSA's The Panel on Nutrition, Novel Foods and Food Allergens (NDA Panel) makes a scientific judgement, whether the claimed effect can be considered as a beneficial physiological effect. Therefore, the available (previous) decisions of the NDA Pannel regarding beneficial physiological effects identified in previous step were searched using OpE portal (EFSA, 2021b). This topic is included in the published scientific opinions for the substantiation of a health claims related to nutrients and other substances, which are publicly available in the EFSA journal. Numerous physiological effects have been recognised as beneficial. Each physiological effect was identified in at least one relevant scientific opinion, which was used for data extraction.

4. *The formulation of possible wordings of health claims*.

This study also aimed to explore possible wordings of health claims for botanicals with consideration of traditional use. Wordings of the physiological effects were constructed with consideration of the existing wordings of authorised health claims in EU register (EC, 2012b) and information from established dataset. The information on the strength of the evidence, i.e., traditional use, was also included to ensure non-misleading and informed food choices: "X (botanical) have been traditionally used to contribute to Y (physiological function)". Claimed health effects were classified in accordance with the WHO International Classification of Functioning, Disability and Health (ICF Body functions) (WHO, 2020) to provide an overview of body functions of selected botanicals.

3. Results

The approach used in the present study builds on suggestions presented in some previously published research papers (Anton et al., 2012a, 2012b, 2013; Coppens et al., 2006), with additional improvements, which enabled more systematic and rapid usage in practice. In accordance with existing EU legislation, one of key conditions for a botanical health claim to be used for labelling and marketing purposes is its inclusion in the 'on hold' list (EC, 2012a). The presented methodological approach builds on the collection of botanical health claims in the OpE portal (EFSA, 2021b) by their Latin and/or English names, followed by an assessment of the compliance of the identified claim (on the 'on hold' list) with the provision of supportive evidences about the traditional use. Such an approach enabled us to address primary objective of the study – to investigate if claims for commonly used botanicals can be supported with evidence on traditional use.

Table 1 provides a detailed insight into results of the assessment for valerian (*Valeriana officinalis*), which was chosen as a case study, while data for all other selected botanicals are presented in Supplementary Table S1.

Altogether, seven different health claim applications were identified in the OpE portal (EFSA, 2021b) for valerian; one of these was chosen for presentation of the tested methodology. The dossier refers to the beneficial health effect 'maintenance of a natural sleep', expressed by different variations in the health claim's wording, as presented in Table 1. In relation to this health claim dossier, the scientifically evaluated traditional use of valerian in herbal monographs was checked and resulted in following effects: 'the relief of mild symptoms of mental stress and to aid sleep' (EMA, 2020b) and 'the relief of mild nervous tension and sleep disorders, including difficulty in falling asleep' (ESCOP, 2003). These health coherent effects were then searched in the OpE portal (EFSA, 2021b) to check if similar claimed effect has been

Table 2
List of suggested wordings of botanical health claims with supportive evidence on traditional use for most commonly used botanicals in EU.

Plant species	Plant part	Possible wording of traditional health claim wording, based on traditional use and beneficial health effects*	Health relation (ICF body functions)
Ginko *Ginko biloba*	**Ginko leaf** Ginkgo folium	**Ginko leaves** have been traditionally used to contribute to normal brain function in elderly people.	**Mental functions** (b1)
		Ginko leaves have been traditionally used to contribute to the maintenance of normal cognitive functions in elderly people.	
Artichoke *Cynara scolymus*	**Artichoke leaf** Cynarae folium	**Artichoke leaves** have been traditionally used to contribute to normal liver function.	**Digestive system functions** (b510-b539)
		Artichoke leaves have been traditionally used to contribute the reduction of gastrointestinal discomfort.	
		Artichoke leaves have been traditionally used to contribute to normal lipid metabolism.	**Haematological system functions** (b430)
Ginseng *Panax ginseng*	**Ginseng root** Ginseng radix	**Ginseng root** has been traditionally used to contribute to the maintenance of normal physical and cognitive functions.	**Mental functions** (b1)
		Ginseng root has been traditionally used to contribute to normal brain function.	
		Ginseng root has been traditionally used to contribute to the reduction of tiredness and fatigue.	
Aloe *Aloe barbadensis syn. Aloe vera*	**Aloes dried juice of leaves** Aloe bardadensis	**Aloe dried juice of leaves** has been traditionally used to contribute to the reduction in intestinal transit time. *	**Digestive system functions** (b510-b539)
		Aloe dried juice of leaves has been traditionally used to contribute to the maintenance of normal bowel function. *	
Fennel *Foeniculum vulgare*	**Fennel fruit** Foeniculi fructus	**Fennel fruit** has been traditionally used to contribute to the normal function of the upper respiratory tract.	**Respiratory system** (b440-b449)
		Fennel fruit has been traditionally used to contribute to the reduction of menstrual discomfort.	**Genitourinary and reproductive functions** (b6)
		Fennel fruit have been traditionally used to contribute to the reduction of gastro-intestinal discomfort.	**Digestive system functions** (b510-b539)
Valerian *Valeriana officinalis*	**Valerian root** Valerianae radix	**Valerian root** has been traditionally used to contribute to the maintenance of normal physical and cognitive functions.	**Mental functions** (b1)
		Valerian root has been traditionally used to contribute to the improvement of sleep quality and maintenance of normal sleep.	
		Valerian root has been traditionally used to contribute to the normal functioning of the nervous system.	
		Valerian root has been traditionally used to contribute to the reduction of tiredness and fatigue.	
Lemon balm *Melissa officinalis*	**Melissa leaf** Melissae folium	**Melissa leaves** have been traditionally used to contribute to the improvement of sleep quality and the maintenance of normal sleep.	**Mental functions** (b1)
		Melissa leaves have been traditionally used to contribute to the reduction of tiredness and fatigue.	
		Melissa leaves have been traditionally used to contribute to the maintenance of normal physical and cognitive functions.	
		Melissa leaves have been traditionally used to contribute to the reduction of gastro-intestinal discomfort.	**Digestive system functions** (b510-b539)
Purple coneflower *Echinacea purpurea*	**Purple coneflower herb** Echinaceae purpureae herba	**Purple coneflower herb** has been traditionally used to contribute to the normal function of the upper respiratory tract.	**Respiratory system** (b440-b449)
		Purple coneflower herb has been traditionally used to contribute to the maintenance of the normal function of the immune system.	**Immunological system functions** (b435)

* The use of Aloe containing hydroxy-anthracene derivative is currently limited in the EU by Commission Regulation (EU) 2021/468 (EC, 2021b).

previously recognised as beneficial for human health by the NDA Panel. Four related beneficial health effects were found as relevant: 'the improvement of sleep quality – maintenance of normal sleep' (EFSA, 2011a), 'the maintenance of normal physical and cognitive functions' (EFSA, 2011b), 'the contribution to normal functioning of the nervous system' (EFSA, 2009b), and 'the reduction of tiredness and fatigue' (EFSA, 2010). Altogether, the search for the selected botanicals in the OpE portal (EFSA, 2021b) resulted in identification of 77 health claims, of which 63 (83%) are included in the EC 'on hold' list. Cross-checking these claims in EMA/HMPC and ESCOP monographs showed that 56% (N = 35) of these claims could be supported by evidence on traditional use. Cumulatively, 23 different health claims for eight botanicals are listed in the Table 2, where the list of possible wordings of such botanical health claims is presented. For two of the selected botanicals, namely, soybean (*Glycine* max) and evening primrose (*Oenothera biennis*), such an approach did not result in any health claim. There are two health claims dossiers for soybean (*Glycine* max) in the OpE portal; but none of them are included in the EC 'on hold' list. Consequently, under the current regulatory situation, the use of Art. 13(1) general function health claims (EC, 2012b) would not be possible, even if evidence on traditional use would exist. Contrarily, in the case of evening primrose (*Oenothera biennis*), there was one health claim dossier in the 'on hold' list, but in the scope of the methodology used in present study, supportive data on traditional use in EMA/HMPC and ESCOP monographs do not exist. Across the rest of the selected botanicals, the lowest percentage of 'on hold' health claims supported by evidence on traditional use was found for aloe (*Aloe barbadensis*) with 18%, while for other botanicals the percentage was much higher; 50% for artichoke (*Cynara scolymus*) and ginseng (*Panax ginseng*), followed by fennel (*Foeniculum vulgare*) and lemon balm (*Melissa officinalis*) with 67%, and valeriana (*Valeriana officinalis*) with 71%. For purple coneflower (*Echinacea purpurea*) and ginko (*Ginko biloba*), all 'on hold' health claims could be supported by scientifically observed traditional use evidenced EMA/HMPC and ESCOP herbal monographs.

Additional step was to build on available evidence to form possible wordings of such health claims, with consideration of existing regulatory framework. The wordings of the health claims for botanicals in the OpE portal (EFSA, 2021b) were constructed with reference to traditional use and previously established beneficial physiological effect. As suggested by Anton et al. (2012b), a statement regarding traditional use: "X (botanical) have been traditionally used to contribute to Y (physiological function)" , was added to the wording to assure that claim in not misleading. As shown in a case study with dossier EFSA-Q-2008-4932 (EFSA, 2021b) in Table 1, four different health claims were constructed for valerian. These claims are all referring to mental functions, more specifically to normal sleep and sleep quality, physical and

cognitive functions, functioning of the nervous system and reduction of tiredness and fatigue. To establish clear and non-misleading wordings, which would fit into existing regulatory context, claims were construction based on the wordings of already authorised health claims. For example, authorised health claim "Biotin contributes to normal functioning of the nervous system" was used to inform construction of possible health claim for valerian ("Valerian root has been traditionally used to contribute to the normal functioning of the nervous system"). Same approach was used for other selected botanicals, for which possible health claims wordings are presented in Table 2, together with classification in accordance with the WHO International Classification of Functioning, Disability and Health (ICF Body functions) (WHO, 2020). The most frequent referred health relationships were 'mental functions', observed for ginko, ginseng, valerian and lemon balm and 'digestive system functions' for artichoke, aloe, fennel and lemon balm. On the other hand, 'immunological system functions', 'genitourinary and reproductive functions' and 'haematological system' functions were presented only for a single botanical, purple coneflower, fennel and artichoke, respectively. It should be mentioned that the construction of possible wordings of health claims we needed to avoid claiming therapeutic effects, which are not allowed on foods. For example, in case of *Ginkgo biloba* L. folium (ginkgo leaf) the ESCOP monograph (ESCOP, 2003, 2009, 2020) specify a therapeutic statement "Symptomatic treatment of mild to moderate dementia syndromes including primary degenerative dementia, vascular dementia and mixed forms. Enhancement of cognitive performance…", we transformed this into "Contribute to the maintenance of normal cognitive functions" without mentioning 'dementia' (Supplementary Table 1).

4. Discussion

In the European Union, health claims on foods are carefully regulated to ensure the functioning of the internal market whilst providing a high level of consumer protection. According to the NHC regulation, foods can only carry authorised health claims that are published in the EU Register of Nutrition and Health Claims (EC, 2021a). However, an exception are those health claims that were used on the EU market before acceptance of NHC regulation in 2006 (EC, 2006a) and are still pending scientific evaluation. Most of botanical health claims were put on the 'on hold' list by the European Commission (EC, 2012a). These claims may continue to be used if they comply with the NHC regulation. The EC's decision to put the assessment of health claims for botanicals 'on hold' was the result of a longer debate on the possibility of the use of traditional evidence to substantiate efficacy claims on foods, similarly with the requirements in traditional herbal medicinal products (Lenssen et al., 2019). Besides, those applications which were evaluated by the NDA Panel (prior to the decision of the EC to put these evaluations 'on-hold') using currently applicable standards (EFSA, 2017b, 2021a; Lenssen et al., 2019), in all cases resulted in negative opinions (Geurts, 2018). The REFIT assessment report on the regulatory situation (EC, 2017, 2020) highlighted that currently "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." The report also notes inconsistency between medicinal and food regulations regarding the possibility of using "traditional use" data for substantiation of claims. Such data are currently not considered relevant for the substantiation of health claims on foods, while contrary is the case with traditional herbal medicinal products. The evaluation also showed safety-related issues, reflected in different lists of approved/banned plant substances in different EU member states. The report conclude that EU harmonization of the use of botanicals in foods (including safety aspects) would support smoother functioning of the internal market, and that "it could be appropriate to explore the notion of 'traditional use' in the efficacy, quality and safety assessment of health claims on plants used in foods" (EC, 2020).

This topic has been also broadly discussed in the scientific literature, without a specific consensus (Anton et al., 2012a, 2012b, 2013; Coppens et al., 2006; Coppens, 2018; EC, 2012b; Kraft, 2016; Lapenna et al., 2015; Schwitters, 2012). Arguments provided by the stakeholders show that a wide array of topics need to be considered in addressing the needs and wishes related to traditional use evidence; a recent review on this topic concluded that there are various options possible, and therefore a political decision is required to resolve this issue (Lenssen et al., 2020). The multiple European Court of Justice cases and the observed similarities between food products and traditional herbal medicines indicate that the definition and classification of botanicals as foods or medicinal products remain difficult (Lenssen et al., 2019). Firstly, we need a clarification whether a specific botanical could be marketed as food or medicine. To resolve this, a major reform of the legal framework for food and/or medicines should be considered. A possible option is an introduction of new regulation for such border-line constituents, which would specifically address both safety issues and health claims.

Manufacturers have been also working on proposal, that would address the requirement for scientific stringency, would be practical for the industry, and would also provide consumers with relevant information about the products (EHPM, 2021). They support the approach that health claims are substantiated with pertinent scientific evidence, as provided in the NHC regulation, and that health claim applications are systematically evaluated by the EFSA, but they proposed that wording of health claims reflect the strength of the available scientific evidence. Three types of graded health claim are suggested: (A) scientifically established health claims, similar to those already authorized, (B) scientifically well supported health claims based on significant developments in modern science and experience, and (C) scientifically plausible health claism for traditionaly used constituents that have been used for at least one generation. A goal is noted, that over time health claims could be supported with additional evidence, to move them from grade C towards grade A. Somewhat similar approach is already used in the United States (US); based on the First Amendment freedom of speech grounds they introduced Qualified health claims (QHC), which can be used where there is some credible scientific evidence for a food constituent/disease relationship, but the strength of the evidence falls below the significant scientific agreement standard (US FDA, 2017a). Such claims in the US need to be accompanied by a disclaimer and qualified, typically with the level and quality of the scientific evidence used to support such claim (US FDA, 2017b). An example of such QHC is: *"Consuming 500 mg each day of cranberry dietary supplement may help reduce the risk of recurrent urinary tract infection (UTI) in healthy women. FDA has concluded that there is limited scientific evidence supporting this claim.*" (FDA, 2020). As wordings of such claims are complex, their usefulness for the food business and consumers has been questioned (Hasler, 2008). However, it should be mentioned that QHC in the US are typically not substantiated with traditional use, but with lower grade studies, which might include animal and *in vitro* experiments.

As mentioned above, the use of botanicals in foods (and food supplements) in the EU is also challenged in safety issues, which are addressed differently in different EU member states (Geurts, 2018; Gulati et al., 2019). Some countries have established positive lists of permitted ingredients, while other use negative or prohibited lists. In addition, classification of products as foods/medicines can differentiate considerably; classification si commonly done on a case-by-case basis, depending on composition and presentation of the product. However, we need to note an effort of Belgium, France and Italy to align their national lists of botanicals (Martini et al., 2019). They introduced a harmonised BELFRIT list of botanicals allowed in the category of food supplements (Cousyn et al., 2013; Restani, 2019). However, further harmonisation on this is very challenging because of very different positions among countries. From regulatory perspective, the simplest way for harmonisation of this area would be the use of existing Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (EC, 2006b), in which Annex III

provide substances whose use in foods is prohibited/restricted. Currently this list is very limited, but it already contains some botanical constituents. For example, Part A (Prohibited substances) also includes Ephedra herb and its preparations originating from *Ephedra* species, preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives, and Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe*). In future this list could be further extended. Another possible approach is of course to introduce above mentioned new regulation, which would cover both safety and health claims for botanicals.

Particularly in case of botanicals it is very important, that health claims for food (supplements) are only allowed under conditions, which assure their safe long-term usage. It should be mentioned that in absence of specific precautionary statements, users of such foods commonly perceive supplements as safe and efficacious, when compared with medicinal products (Peacock et al., 2019). There is also a dangerous misperception by many consumers that 'plant-derived' means 'natural' and 'safe' (Schieber, 2020). Product safety need to be assured with sufficient quality control of the raw materials, production chain, and final products (Gulati et al., 2019; Restani, 2019). Supplements containing plants are still considered foods and therefore must comply with food legislation in terms of production and control. Raw material represents the first stage of the chain and plays a crucial role in quality; the plants that will be used (as such or as derivatives) must be strictly controlled for biological contaminants (bacteria, viruses, molds and their toxins) and chemicals (pesticides, heavy metals, etc.). A guideline for the identification of possible risks for consumers coming from botanicals is collected in the 'Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health' published by EFSA in 2009, and revised in 2012 (EFSA, 2012). Compendium also lists the botanicals known to contain toxic, addictive, psychotropic or other substances of concern, and therefore present a useful resource in the evaluation of safety of usage of specific plants in foods(EFSA, 2017a).

5. Conclusions and policy implications

Currently non-authorised health claims for botanicals are used on foodstuffs in the EU without information on the strengths of the scientific evidence behind such claims, even in cases, where claims are only refereeing to traditional use. This could be misleading for consumers, because other (authorised) claims are based on stronger scientific evidence. Considering that evidence on traditional use is acceptable for substantiation of the claims on medicinal products (THMP), similar approach might be also used in foods, but this is related with challenges. Among key challenges are assuring that health claims for botanicals on foods are non-misleading for consumers, and that such products are safe.

It should be mentioned that traditional knowledge and experience regarding many botanicals can also be part of a consumer's common knowledge; many plants have a long history in Europe and their use is based on experience and long-term practice. With this in mind, such information could be also useful for consumers, if non-misleadingly communicated on food labels, with clear distinction to health claims, which have been substantiated using higher grade scientific evidence. Our study showed that many currently used health claims for botanicals could be supported with established evidence on traditional use. We constructed examples of possible health claims' wordings, referring to physiological functions (non-medicinal) and traditional use. Such an approach supports mitigation of risks for misleading consumers within the currently poorly regulated area, whilst informing future policy improvements. However, regulatory changes in this area would also need to carefully address specific safety issues of botanicals, which are currently not sufficiently resolved on the EU level. In contrast to medicines, foods are consumed on long-term, more frequently, and without medical supervision. Botanical health claims on food (supplements) are therefore only acceptable in the absence of safety risks. It would be therefore necessary to conduct safety assessments on the use of botanicals in foods (and/or food supplements) together with the evaluation of the botanical health claims. A regulatory reform would be needed, to address this.

CRediT authorship contribution statement

Anita Kušar: Conceptualization, Data curation, Investigation, Writing – original draft. **Igor Pravst:** Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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