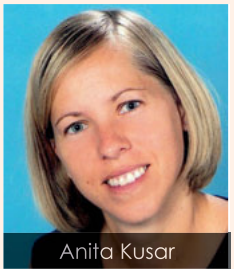

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Quality and safety of botanical food products and their labelling

KEYWORDS: botanicals, plants, quality, safety, labelling, health claims, food

Abstract Plants or botanicals are commonly used in both foods and medicines because they contain many different biologically active substances with very different physiological activities. However, the borderline between these uses is often unclear and depends on several factors, including the content of botanicals and their constituents (and their physiological/pharmacological effects), the labelling of a finished product (i.e. the use of health or medicinal claims) and the territory in which a product is being sold. In the European Union, legislation covering the food use of botanicals is not yet harmonised and there are significant differences between countries although, in general, the quality, safety and labelling of those products should comply with all provisions of food law.

INTRODUCTION

The health promoting and therapeutic properties of botanicals have compliance their use for decades. The use of plant ingredients in food products is well established, for example as vegetables and fruits, herbs and spices, herbal teas and infusions, beverages, plant food supplements etc., and has steadily increased in the last decade (1, 2). The perception of consumers that such products are not only natural and safe but also beneficial to human health plays an important role in their growing use.

In the Council of Europe's guidelines on plant-based food supplements (3) the reasons for the increased consumption are defined by socioeconomic factors such as longer life spans, higher education, active consumers etc. and behavioural factors whereby it has become a preference to use, where possible, only 'natural' products in order to maintain a certain level of physical and intellectual health. The consumer expects that such products are safe, perfectly defined, of properly controlled quality, possess a positive physiological effect in a healthy person on the basis of convincing traditional uses and/or strict scientific data, and provide non-misleading and honest product information.

The quality, safety and labelling of food products is the full responsibility of the producer, but can be controlled by national authorities. In practice, such controls mainly focus on assuring adequate safety by controlling contaminants and additives, while nutritional composition is usually not considered as a critical health risk and is therefore less controlled (4-6). However, botanicals are known to have varying levels of quality with significant differences not only in the content of the active ingredients but also in toxicity principles, and the fact is that several cases of replacement with a toxic alternative or pharmaceutical agents have already occurred (2, 7). Beside this, the presentation of their potentially beneficial health effects on food products in practice is often misleading. In some cases, medicinal claims occur even though such claims on foods are prohibited. The present paper proposes several factors that need to be considered when assessing the quality and safety of botanical food products and the transparency of the information on such products to maximise consumer health protection.

DEFINITIONS

Botanicals or herbal substances may be whole or fragmented whole plants, parts of plants (roots, bark, flower heads, leaves, flowers, fruit, seeds etc.), algae, fungi, lichen in an unprocessed, usually dried form, sometimes fresh (3, 8). Certain juices removed by pressure or incision of the living plant (oleoresins, gums, latex etc.) which have not undergone any specific treatment are also considered to be herbal substances. Botanicals or herbal substances should be precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

Botanically based foods are composed of plant substances or plant-based preparations and/or other nutrients, or of mixtures of several plant substances or plant-based preparations either combined with other ingredients or not (1-3, 8). Preparations may be obtained by treating plant substances with traditional methods like extraction, distillation, expression, fractionation, purification, concentration or fermentation. They include crushed or powdered plant material, tinctures, extracts, essential oils, juices obtained by pressure and processed exudates.

It is well known that botanicals and botanical preparations contain many different biologically-active substances with very different physiological activities and health promoting properties (amino acids, alkaloids, mono-, di-, tri- and sesqui-terpens, phenolic compounds, plant sterols, vitamins, minerals and many other substances) (1, 3, 8). This situation explains the wide use of herbal substances or botanicals in different food product categories, including botanical or plant food supplements, traditional herbal medicinal products and herbal medicinal products.

Botanicals have a long tradition of use in both food and medicine. As medicinal products, botanicals can, apart from herbal medicinal products, be registered using a simplified traditional use registration and sold as a Traditional Herbal Medicinal Product (THMP) (9). There is no requirement that such products be subjected to clinical trials on their effectiveness, although products must have sufficient safety data and their production must comply with Good Manufacturing Practices (GMP) (10). On the contrary, when botanicals are used in food products the final product should be safe for use and labelled in line with the legislation pertaining to food, including the regulation on health claims. The use of botanicals in foods is not yet harmonised in the EU and member states are taking different approaches as to which botanicals can be used in foods, and under which conditions (11). However, some botanical food products, especially food supplements, can at first look very similar to medicinal products even though their intended use is different (1, 3, 12). While medicinal products are intended to prevent or treat a disease or modify the way in which the body functions, food products are intended to complement the diet with substances possessing health maintenance or promoting properties. In some cases, the distinction between medicinal and non-medicinal health effects can present a problem. A classification distinction could be based on the concentration of active principles or their posology. The dividing line can usually be defined on a case-by-case basis for each product with regard to its pharmacological properties and safety assessment. Maximum levels for active substances included in food products have to be reduced to levels below the recognised proven therapeutic active level based on clinical evidence or evident traditional use (ESCOP monographs, EMA monographs, WHO monographs etc.) and this provides a cut-off point for those substances. By determining the cut-off point, the physiologically active level should be set at a sufficiently significant level to still satisfy the expected health promotional benefits. In most cases, this is easier said than done and the distinction between a food and a medicinal product is therefore often made on the basis of the effects which are communicated to the consumer. A product labelled with medicinal claims is therefore classified as a medicinal product regardless of its composition.

QUALITY AND SAFETY ASSESSMENT OF BOTANICAL FOOD PRODUCTS

However, with regard to botanical food products quality and safety concerns must be highlighted since the use of plants may pose a potential risk to human health. In terms of quality, the use of plants involves several unique problems due to the nature of herbal ingredients which are complex mixtures of constituents and their concentrations can vary considerably depending on environmental and genetic factors. On the other hand, in terms of safety the consumer may be exposed to potentially toxic substances from the herbal ingredients of food products. An important tool for manufacturers when assessing the safe use of botanicals in food products is the EFSA's "Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health" (15). In this compendium the EFSA has compiled the information available on a large number of botanicals reported to contain substances that may be a health concern when specific parts are used and/or inadequate processing procedures are employed to make botanical extracts and/or botanical products.
The quality and safety assurance of botanical products must be performed by manufacturers by controlling the herbal ingredients and adhering to good manufacturing practice standards (1, 2). Food products as such are not subject to pre-marketing procedures like in the case of medicinal products, but must conform to the established food law framework. This legal framework consists of authorisation procedures for additives, novel foods and genetically modified organisms etc.; maximum limits for residues and contaminants; the general requirement for hygiene and manufacturer responsibility; permitted extraction solvents; general food labelling legalisation; the addition of nutrients and other substances to foods; and a pre-marketing authorisation system for the use of nutrition and health claims.
In order to ensure the quality and safety of botanical food products, parameters like botanical identification, cultivation data, the chemical profile of the plant, the manufacturing process, determination of the conditions of use and the identification of warnings should be monitored, evaluated and registered during the production and manufacturing process. When it comes to the use of plants, plant parts and extracts in food products, the most crucial factors are (1-3, 12-14):

- **botanical identification of the plant material**: scientific botanical name (botanical family, genus, species, variety), genotype, chemotype, determination of the plant part used, geographical origin, plant state (wild or cultivated), monographs available, potential risks of adulteration by a toxic neighbouring species;
- **cultivation data:** origin, cultivation technology, harvesting period, plant health treatments, drying process, storage. Plants intended for use in foods should be cultivated or harvested using good agricultural practices (GAP) and good collection practices (GCP) published in guidelines by the WHO programme on traditional medicines. Those guidelines provide a well-defined framework for the reproducible quality of a plant material. Plants without an assurance of GAP or GCP should be examined more carefully;
- **chemical profile:** determination of the content of constituents responsible for beneficial health effects or possible markers, constituents responsible for undesirable

effects (investigation of foreign toxic substances like alkaloids etc.), analysis of purity (foreign elements, pesticides, herbicides, heavy metals, bacteria, mycotoxins, pharmaceutical agents, radioactivity, sand, soil), misidentified initial plant species, adulteration with other plants, addition of illegal substances etc.;

- **manufacturing process**: the extraction process of plant material with all details of the extraction procedures (specifications of the plant material used, conditions of extraction, solvents, reagents, method of extraction, plant material/solvent ratio); defining the food matrix; standardisation of the intermediate product and the final product; purity examination (microbiology, heavy metals, residual solvents, other contaminants), variability and stability studies, storage conditions, packing and labelling;
- **conditions of use**: concerning the safe use of botanicals, they can be generally considered to be safe in normal conditions of use in food and food supplements, but there are some exemptions for which special observations should be made before placing them on the market. Those exemptions are botanicals whose use in foods could be unsafe due to their toxic or pharmacological effects, presence in nonconventional food or conventional food or food supplement use in higher concentrations than usual;
- **identification of critical issues**: some botanical ingredients might carry the risk of different adverse effects like an allergic reaction, carcinogenic properties, neurotoxicity, teratogenicity and mutagenicity and might influence models of action, interactions with prescribed drugs etc. In order to assure the safe use of food products with identified warnings, warning statements about safe use should be provided on food labels. In addition, special recommendations about conditions of use should be addressed to vulnerable population groups such as pregnant women, breast-feeding women, babies and children.

Appropriate and well-documented management of the specification, processing, quality testing (particularly in relation to the identification and purity) and standardisation are paramount in the production of safe botanical food products (1). Such management provides a well-defined framework for quality testing and can guarantee the reproducible quality of botanical products.

LABELLING OF BOTANICAL FOOD PRODUCTS WITH A FOCUS ON HEALTH CLAIMS

In order to give consumers a high level of health protection and guarantee their right to information, it should be ensured that they are appropriately informed about the food they consume. In accordance with food legislation, the labelling in general should be understandable by the average consumer and not mislead them (16). It must provide information on the identity and composition, properties or other characteristics of the food, durability, storage and safe use, must not encourage over-consumption of the product, should provide information on nutritional characteristics so as to enable consumers to make an informed choice, must include information about target groups or potentially vulnerable population groups and must provide information about how

to use the product (3). Several regulatory approaches in Europe impact on food labelling. In general, the labelling of foodstuffs is covered by Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs and by new Regulation (EU) No 1169/2011 on the provision of food information to consumers. In addition, some other legislative documents are important for labelling, such as Regulation (EC) No 1333/2008 on food additives, Regulation No 1924/2006 on nutrition and health claims, EU Directive 2002/46/EC on food supplements etc.
The health-related properties of botanical food products are an important reason that many plants or plant ingredients are used in food products because consumers tend to perceive botanical food products as healthier (1, 17). Claims on products seek to respond to consumers' interest in health by conveying messages about product-specific benefits that potentially add value to products. Labelling with health claims based on the relationship between the botanical ingredient and health is voluntary, but needs to be done in accordance with the EU's Nutrition and Health Claims Regulation (NHCR) (18). The NHCR requires all health claims made on foods to be scientifically justified and states they are only acceptable for use when specifically approved following an assessment by EFSA (12). This requires claims to be supported by controlled intervention trials that demonstrate cause-and-effect relationships between the intake of a compound and a health benefit. For botanicals, it has never been required that the acquired knowledge be confirmed with studies; however, traditional use is currently not accepted as sufficient evidence in the approval process for health claims on food products (11). The consequence is that the requirements to demonstrate the health effects of botanicals (health claims) on food products are more demanding than those required to claim medicinal effects (medicinal claims) on Traditional Herbal Medicinal Products.

In the scientific assessments, a number of health claim applications for botanicals have therefore received negative opinions. Consequently, there has been a wide debate within the EU about the difference between the food and medicinal legislation in dealing with evidence of traditional use of botanicals. The European Commission noted that the same botanicals are commonly used in both foods and medicines and consumers may sometimes struggle to perceive the difference between certain claims or indications of their physiological effect. The Commission therefore decided to launch a reflection on whether this difference should continue to be maintained (19). Accordingly, in 2010 the assessment of health claims for botanicals, together with several already assessed botanicals, was put on hold. Two options for resolving this problem have been suggested by the European Commission. The first is to continue with the scientific evaluations by applying the same criteria and standards as for other food ingredients, with the likely result of negative opinions emerging for the vast majority of claims made for botanicals. The other proposal is to introduce a special regulation and establish different rules that recognise the traditional use of botanicals. No further decision has been made on this issue and whilst ever health claims for botanicals remain *on hold* they may continue to be used at the full responsibility of the operators. It should be noted that such claims also need to be in line with the general requirements of the NHCR and should not mislead consumers (20).
With regard to the quality and safety of botanical foods and labelling of foods with health claims, a few EU-funded (FP7) projects are currently in progress. The PlantLIBRA project (21) aims to foster the safe use of food supplements containing plants or botanical preparations, including risk and benefit assessments and quality monitoring. The ambition of the CLYMBOL project (22) is to better understand the effects of health claims and symbols on food labels, and how this influences purchase and consumption behaviour. In addition, the REDICLAIM project seeks to understand the way in which the European regulation on nutrition and health claims made on foods and associated legislation has had and continues to have an impact on the substantiation and use of 'reduction of disease risk' claims on food and drinks.

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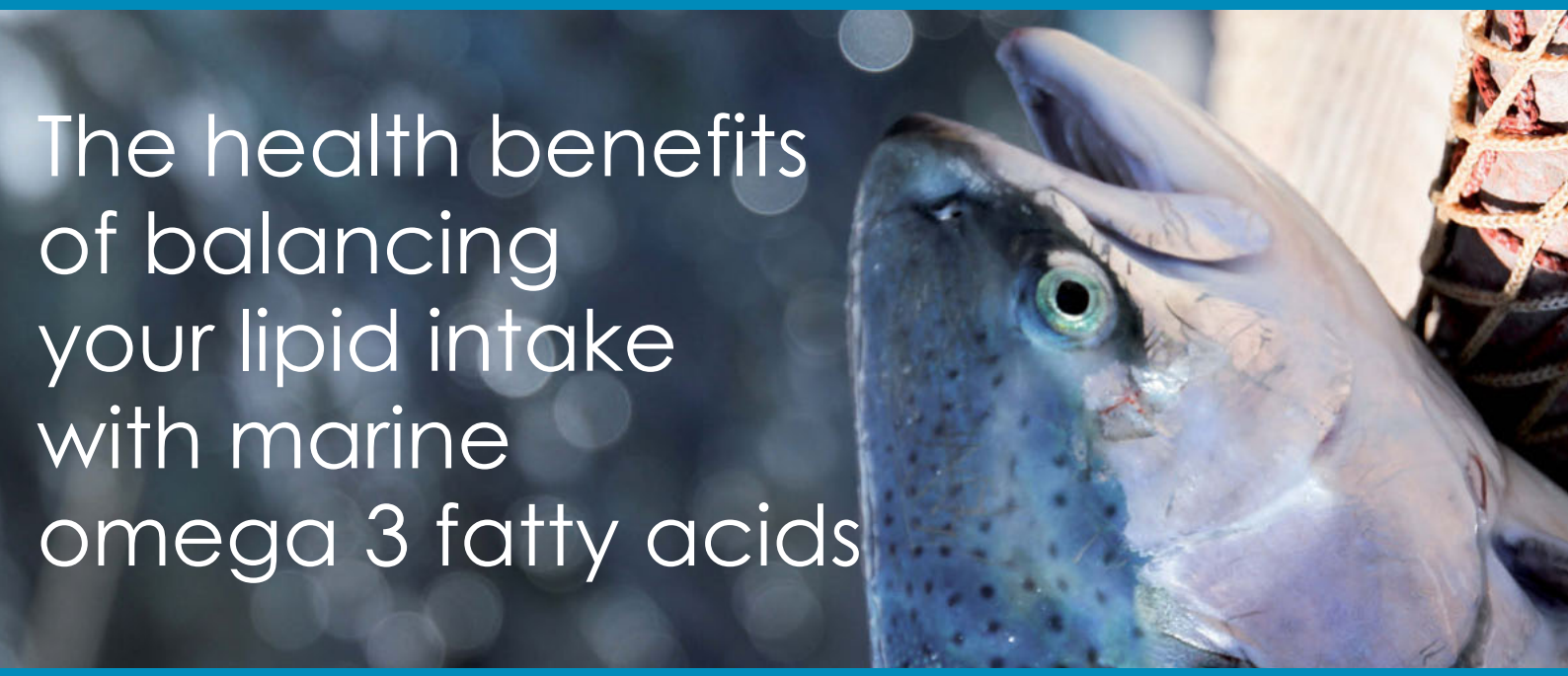
The health benefits of balancing your lipid intake with marine omega 3 fatty acids



Whilst the fats portion of our diet has been demonized in recent years, it is, in fact, an essential part of our nutrition. The challenge is facilitating a healthy, balanced intake of fatty acids. Changes in lifestyle, agricultural practices and dietary preference over recent decades have made achieving a healthy balanced lipid intake virtually impossible for large sections of the population, necessitating dietary supplementation of several "vital" lipids either by fortified foods or supplements.

Anthropologists believe that the development of the human brain was because successful species obtained a significant portion of their diet from aquatic sources. Many fish and shellfish are useful sources of the omega 3 fatty acid, docosahexaenoic acid (DHA), which is an essential structural part of the brain and facilitates communication between neurons. In addition, early man possessed fatty acid desaturase (FADS) enzymes that were able to convert the widely found terrestrial omega 3 fatty acid alpha linolenic acid (ALA) to DHA. Recent work by Mathias et al., which studied the genetic nature of human evolution, has shown that as humans spread across the world from their original home in central Africa, the FADS1 and FADS2 genes have become less effective, which means that most non-African races have very limited ability to convert ALA to DHA (often as low as 0.5%).

To make matters worse, the massive increase in the use of vegetable oils derived from maize (corn), soya, sunflower and rapeseed (canola), has flooded our dietary lipid intake with omega 6 PUFA's. This is a problem as they use the same fatty acid conversion enzymes as the omega 3's, ensuring that any residual ability to convert ALA to EPA and DHA is suppressed to levels that have no dietary significance.

To make matters worse, as we age our ability to make use of our tissue levels of EPA and DHA decline (Castellano et al.), which means we have to consume higher levels to achieve a healthy homeostasis. This effect is particularly pronounced in those over 50 years of age.

Current EFSA Health Claims in the EU state that 250mg per day intake of EPA and DHA is required for maintenance of heart health whilst 250mg of DHA alone per day is required for maintenance of brain and visual health. For most individuals, except those who consume high levels of fish or are lucky enough to have a gene set derived from central Africa, some form of supplementation of marine PUFA's is required this. This is best achieved by consumption of fish or algal oils. These oils can be concentrated to ensure that the advised daily intake of EPA and DHA can be achieved. In addition, modern oil refining techniques mean high purity oils can be made that are light in colour, of high organoleptic quality and ensure contaminant levels are kept to an absolute minimum. Vegetarians, and people who just don't like to consume fish, can get their EPA and DHA from algal oils.

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