

## Accompanying note on conditions of use for botanicals

Botanicals (fruits, vegetables, herbs, spices, mushrooms, etc) have many different applications in foodstuffs. They are used as such as fruits and vegetables, or processed as ingredients in foodstuffs. They are used in dried form or as herbal tea's and infusions. Extracts and isolates of botanicals are used as ingredients in foods and food supplements. Many botanicals possess health effects which are communicated to the consumer. Many botanicals have a long history of traditional use because of such attributed effects on the body. All these effects are considered health claims under Regulation 1924/2006 and are therefore included in the list provided for by article 13 of this new legislation.

**In many cases, the described health effect is only relevant for one or more specific parts of the botanical. The use of such parts constitutes a valid prerequisite of use and is therefore indicated as a conditions of use.**

In many cases the use of botanicals in foods does not entail any standardisation. This is the case when botanicals are consumed as fruits and vegetables, as infusions and herbal teas or as ingredient of foodstuffs. This consumption is part of the diet and communication on the role or health effects of the botanical helps the consumer understand the purpose of the product. Consumption of the foods is not intended to provide a standardised dose of active substances that will provoke a specific effect in the body, as is the case with medicinal products. Ingestion will contribute to the ascribed health effect.

**For these reasons it is not possible for such products to give a quantitative indication of the amount of botanicals or constituents as a condition of use for the use of a health claim. In such cases the way in which these products have been traditionally used for decades should continue to apply. Such use is indicated in the list by the sentence: "Usual consumption as traditional foodstuff in a normal diet".**

In the case of food supplements, the aim of such products is to supplement the normal diet with concentrated sources of nutrients or other substances with a nutritional or physiological effect, including botanicals. These products are covered by Directive 2002/46 which requires manufacturers to declare the amount of the nutrients or substances with a nutritional or physiological effect present in the product on the labelling of the product. Such products are specifically formulated and may contain botanicals as such in dried and comminuted form or botanical extracts or isolates. As these products are standardised, it is possible to indicate a quantitative condition of use. Because each product has its own characterisation, depending on its concentration, extraction process and standardisation method, conditions of use will vary for each individual product.

**The condition of use included in the list is therefore expressed as an equivalent of the plant part or one of its components. It falls under the responsibility of the manufacturer to ensure that each individual product would be in conformity with this requirement and contains a quantity of the plant or one of its constituents that is equivalent to the amount given in the table. In this way the conditions of article 5 of the Regulation would be met.**