

**NO SPECIAL
TREATMENT FOR
BOTANICAL
CLAIMS!**



BOTANICALS

"Botanicals" are plant preparations which have become widely available on the EU market in the form of food supplements.

Such products are regulated under EU food law and examples include ginkgo, garlic, St. John's Wort and ginseng.

They are typically marketed in dose forms such as capsules, pastilles, tablets, pills, sachets of powder, ampoules of liquids, etc. and can be bought over the counter in pharmacies, supermarkets, specialist shops and via the Internet.

What are botanicals?



Tighter controls needed

Just like any other foods (and provided this is supported by scientific evidence), botanical supplements can make all kinds of health claims about supporting, maintaining or optimising normal physiological functions but they must not, in their labelling or advertising, refer to the prevention, treatment or cure of diseases.

This is not always properly enforced - especially on products for sale over the internet - and products can still be found that indirectly suggest they may help against severe diseases such as cancer or Alzheimer's.



Ginkgo biloba's leaf extract supplement that can be purchased online from a Portuguese website that implies it might help slow down Alzheimer's evolution and improve patients' quality of life.

Source: www.serdanatureza.com/artigos-alzheimer.php (see Ginkgo biloba)

Aloe vera-based multibotanical combination that can be purchased online from a Greek website that implies it might help against cancer and heart disease.

Source: www.pharmshop.gr/en/ProductView_en.aspx?Prod_Id=2250&cat=76

Cat's claw supplement that can be purchased from a German online shop that indirectly suggests it can help against cancer.

Source: www.vitabon.de/produkt14.php

Grandma's remedies or proven health effects?

The vast majority of botanical supplements "only" promise healthy nail, hair, joints, etc. but it is vital to guarantee that consumers can trust claims they see on these products and that they do not spend their money on products bearing false promises.

Therefore, botanical claims - just like any other claims made on "normal" foods - should undergo a rigorous scientific assessment of the highest possible standard.

Over 1500 botanical claims are still on hold pending evaluation by EFSA. This follows the publication, back in 2010, of a series of EFSA opinions assessing the evidence on 44 botanical claims, which were all negative (i.e. EFSA concluded the claims were not proven).

Some have argued that EFSA's evaluation was too strict and have called for a special treatment allowing substantiating botanical claims by referring to the "tradition of use" (instead of submitting more robust data from clinical studies).

BEUC sees no justification for a different treatment of botanical claims and we strongly warn against moving away from the rigorous scientific assessment that has been the rule to date.

"Tradition of use" does not equate efficacy as shown by EFSA's negative verdict on a first series of botanical claims which, although they are wide-spread across the EU, turned out not to be backed by science.

It is high time that these claims are taken off the market: this does not mean that the botanicals bearing these claims will disappear but simply that they will no longer be able to carry misleading, unsubstantiated health messages.

GREEN TEA

Green tea (*Camellia sinensis* (L.) Kuntze)

promoted for its slimming properties although according to EFSA, cause-effect relationship has not been established between the consumption of green tea and contribution to the maintenance or achievement of a normal body weight.

Examples of the following botanicals/claims which are currently sold on the EU market have been collected by BEUC and our members.



HORSETAIL

Horsetail (*Equisetum arvense*)

promoted for healthy hair and bones although according to EFSA, cause-effect relationship has not been established between the consumption of *Equisetum arvense* and maintenance of normal hair or bone.

PINE SHOOT SYRUP

Pine shoot syrup (*Picea abies*) promoted for relief in case of tickle in the throat and coughing although according to EFSA, cause-effect relationship has not been established between the consumption of *Picea abies* (L.) Karsten and relief in case of irritation in the upper respiratory tract.



JERUSALEM ARTICHOKE

Jerusalem artichoke (*Helianthus tuberosus*) promoted for maintaining normal body weight although according to EFSA, cause-effect relationship has not been established between the consumption of *Helianthus tuberosus* and maintenance or achievement of a normal bodyweight.

CARROT JUICE

Carrot juice (*Daucus carota* L.) promoted for eye health although according to EFSA, a cause-effect relationship has not been established between the consumption of *Daucus carota* L. and maintenance of normal vision.



COLTSFOOT JUICE

Coltsfoot juice (*Tussilago farfara* L.) promoted for helping eliminate irritation and inflammation of the respiratory system and helping relieve dry persistent coughs although according to EFSA, cause-effect relationship has not been established between the consumption of *Tussilago farfara* L. and normal function of the upper respiratory tract.

FRAXINUS

Fraxinus (*Fraxinus excelsior* L.) promoted for healthy joints although according to EFSA, cause-effect relationship has not been established between the consumption of *Fraxinus excelsior* L. and maintenance of normal joints.



GUAR GUM

Guar gum (*Cyamopsis tetragonoloba* (L.) Taubert) promoted for increasing satiety feeling, regulating intestinal transit and reducing fat absorption although according to EFSA, a cause-effect relationship has not been established between the consumption of *Cyamopsis tetragonoloba* (L.) Taubert and maintenance or achievement of a normal body weight.



DRIED COCOA BEAN EXTRACT

Dried cocoa bean extract (*Theobroma cacao* L.) said to help restore a slim figure although according to EFSA, a cause-effect relationship has not been established between *Theobroma cacao* L. and maintenance or achievement of a normal bodyweight.



BISHOP'S WEED / AJWAIN

Bishop's Weed / Ajwain (*Aegopodium podagraria* L.) said to be useful in relieving flatulence and discomfort in the stomach due to indigestion although according to EFSA, a cause-effect relationship has not been established between the consumption of *Aegopodium podagraria* L. and "digestive health".



HORSERADISH

Horseradish (*Armoracia rusticana* P. Gaertn.) promoted for nourishing and supporting the urinary tract although according to EFSA, a cause-effect relationship has not been established between the consumption of *Armoracia rusticana* P. Gaertn. and improvement of diuretic function.



AMLA FRUIT

Amla Fruit (*Emblica officinalis* Gaertn.) said to protect the heart by reducing cholesterol although according to EFSA, a cause-effect relationship has not been established between the consumption of the raw fruit of *Emblica officinalis* Gaertn. and maintenance of normal blood LDL-cholesterol concentrations ("cardiovascular health").



Why there should be no special treatment for botanical claims

Granting a special treatment to botanicals would mean giving up on ensuring meaningful consumer protection against exaggerated and unsubstantiated claims.

It would also mean running the risk that all claims made on "normal" foods that were already assessed and rejected by EFSA as being unproven would be re-submitted for re-evaluation according to the new weaker standards.

Natural does not mean it is safe!

Consumers tend to believe that because they are natural, botanicals are safe.

This perception is reinforced by the fact that these products are freely available at health shops and supermarkets.

However, interactions between herbal substances and conventional drugs have been reported: for instance, people on anticoagulants should not take *Angelica sinensis* (Dong Quai) supplements and women taking oral contraception should avoid *Hypericum perforatum* (St. John's wort).



DONG QUAI ROOT EXTRACT

Dong Quai Root Extract (*Angelica sinensis*) is marketed as a food supplement said to "help maintain hormonal balance during difficult times of women's monthly cycle". Interactions between *Angelica sinensis* and certain drugs have been reported: for instance, people on anticoagulants should not take *Angelica sinensis* and it may also be contraindicated for diabetics. *Angelica sinensis* is also known to increase the risk of photosensitivity and sunburn.

St JOHN'S WORT

St. John's wort (*Hypericum perforatum*) is marketed as a food supplement said to "exert a balancing effect on mood swings". Interactions between St John's wort and certain drugs have been reported: for instance, St. John's wort has been associated with breakthrough and irregular menstrual bleeding in women taking oral contraceptives.

Food or medicine?

Plant materials are also used in herbal medicines regulated under EU medicinal law. The classification as food supplement or herbal medicine normally depends on the presentation/intended use (is it to cure or prevent a disease or just to maintain normal health?) and the effect in/on the human body (therapeutic effect or physiological/nutritional effect?).

However, the distinction between botanicals and herbal medicines is not always straightforward. Additionally, due to incomplete harmonisation of EU legislation on herbal products, Member States may have different national rules in place which affect the classification of these products (and where both statuses are authorised to co-exist, the decision to market a given plant material under either one of them is largely left to the manufacturer).

This creates a lot of confusion for consumers: a same product can be considered as a botanical food supplement in an EU country and as an herbal medicine in another country, and a same substance can sometime be marketed as both a food supplement and an herbal medicine within a same country.

Unlike "well-established" herbal medicines which have a recognised efficacy and are eligible to full market authorisation, so-called "traditional" herbal medicines benefit from a simplified registration procedure that allows them to refer to "long-standing use and experience" to demonstrate (plausible) efficacy.

It is questionable whether this is strong enough evidence to prove efficacy but at least, when it comes to quality and safety, traditional herbal medicines provide higher guarantees to consumers as compared to food supplements (e.g. standardisation, pharmacovigilance). Moreover, unlike botanicals, herbal medicines must bear all necessary warnings against possible contraindications, interactions and undesirable effects on their label or the information leaflet.



St John's wort (*Hypericum perforatum*). In Spain, the product is marketed as an herbal medicine "for the symptomatic and transitory treatment of mental exhaustion accompanied with loss of interest, fatigue and sleep disturbance". In Belgium, the same product is marketed as a food supplement said to "exert a balancing effect on mood swings". Whilst the Spanish product warns against a series of interactions and refers to possible adverse effects, this information is missing from the Belgian one.

Harmonisation of the EU market for herbal products is needed to better protect for consumers

As it is less costly and burdensome, some manufacturers tend to favour the food supplement status over the herbal medicine one (provided national legislation allows them to do so).

In that case, it is only legitimate to require from these operators that they abide by EU *food law*, which requires that health claims made on food be backed by convincing scientific evidence.

Looking forward, we call on the Commission to put an end to today's most confusing situation by harmonising the EU market for herbal products.

Harmonisation should be upwards and keep the most positive elements from the food/medicine legal frameworks: consumers need to have access to high-quality, safe herbal products that bear reliable information and that deliver the health promises they show.

References

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