



The State of Play in Botanical Ingredient Regulation in Food Supplements

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The State of Play in Botanical Ingredient Regulation in Food Supplements

A lack of clarity on the difference between a herbal medicine and a food supplement containing botanical ingredients has left a grey area in regulation. With health claim assessments officially on hold and no clear guidelines on safe consumption levels, Luke Murphy discusses how FBOs must take it on themselves to ensure the safety and regulatory compliance of their products.

A healthy, balanced diet is one that contains a large proportion of edible plant material.

However, partly due to convenience, consumers in the EU are increasingly turning to plant extracts in the form of food supplements to complement their diet, in the belief that these have similar health benefits to the original plants, vegetables or fruits. This raises a number of key questions, such as:

- What are the health benefits of botanical food supplements?
- Which health claims can be used for marketing purposes?
- What are safe consumption levels?

Whether or not health benefits exist from consuming botanical food supplements (and consequently the validity of health claims) is one of the issues EU regulators have tried, and failed, to clarify in recent years. This confusion has created more than a few headaches for national regulators, toxicologists, manufacturers and risk managers alike.

When is it a medicine and when is it a food supplement?

There is sometimes a lack of regulatory clarity on the use of botanical ingredients in food supplements. This stems from the borderline (and ultimately overlap) between traditional herbal medicines and food supplements. In some cases these contain similar, or even identical ingredients, the only difference being how they are marketed or labelled.

Enforcement decisions are currently based on interpretation of regulations at a national level, rather than using a harmonised, EU approach. What is allowed in one European country is not necessarily permitted in another.

Even a seemingly simple product such as garlic capsules can be treated differently in different European countries. In Germany, for example, the authorities classified garlic capsules as a medicine. However, in this case (C-319/05¹), the European Commission did eventually overthrow the German decision, judging it disproportionate.

¹ C-319/05 - Commission v Germany <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-319/05>

'Hold' on the health claims

This confusion between what constitutes a traditional herbal medicine and what constitutes a food supplement containing botanical ingredients was recognised during the health claims assessment process; botanical health claim assessments were put 'on hold' by the European Commission pending further 'reflection'.

This resulted in a position paper², published in summer 2012 which discussed two options for resolving the halt on claims. The first option was to resume health claims assessment for botanicals with no change to the approach, i.e. each individual health claim would have to be proven to a very high standard to the satisfaction of the European Food Safety Authority (EFSA). This would probably result in most (if not all) botanical health claims being rejected. The second option discussed was to address the issue with a review and amendment of the legislation itself, i.e. creating a special procedure for botanicals, taking into account 'traditional use'. This may mean botanicals used in food supplements could be assessed in a similar way to 'traditional herbal medicines', where safety is the main consideration, and substantiation of the claim itself is less important.

We are now well into 2016 and no decision has been made on this, the only activity of note being a further mention in the European Commission 'Better Regulation' agenda as

part of a wider review of the health claims Regulation (EC) 1924/2006³. In this document, the Commission acknowledges that 1500 health claim submissions for botanicals remain incomplete, and therefore these health claims sit in transition, or in other words a semi-regulated grey area, covered by member state national law. As this review is not intended to conclude until July 2017, further delays are almost guaranteed.

A definition may provide greater clarity

From a regulatory perspective, one of the key challenges is no historical harmonised EU definition of 'botanical substance'. At least now there is some movement on this, albeit in a different regulatory framework entirely. A draft EU amendment on food contaminants⁴ proposed the following detailed definition in July 2015:

"Botanical preparations are preparations obtained from botanicals (e.g. whole, plant parts, fragmented or cut plants) by various processes (e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation). This definition includes comminuted or powdered plants, plant parts, algae, fungi, lichen, tinctures, extracts, essential oils (other vegetable oils), expressed juices and processed exudates."

This definition will hopefully be the first step in providing clarity in this area.

² Discussion paper on health claims on botanicals used in foods <http://izbamleka.pl/wp-content/uploads/2012/09/instrukcja.pdf>

³ Evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_595_evaluation_health_claims_en.pdf

⁴ draft ANNEX to the COMMISSION REGULATION (EU) .../... amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in cocoa fibre, banana chips, food supplements, dried herbs and dried spices http://www.parlament.gv.at/PAKT/EU/XXV/EU/07/27/EU_72769/imfname_10565249.pdf

Fit for long-term consumption?

Another key consideration with food supplements containing botanical ingredients is food safety. Here there are some key differences with herbal medicines.

As medicinal products are intended (mainly) for treating and preventing disease, they are usually not intended for long term consumption. Even though the long term consumption of certain medicines may be harmful, or they may be toxic when mixed with certain substances (alcohol for example) or consumed by certain consumers, in balance they are seen as effective ways to treat or prevent the disease in question. Efficacy is balanced with safety⁵.

Food supplements are, in contrast, intended to be consumed in a similar way to food, and could therefore be consumed for a long time, even for decades by certain consumers. In this case there is no such trade-off between efficacy and safety for these products.

There are currently no overarching warnings required for food supplements at European level other than 'keep out of reach of children' and 'do not exceed daily dose'. In some EU member states, food supplements have to be notified to the authorities before sale. In some – such as the UK - there is no such requirement.

Safety is a key principle of general food law (notably the Food Safety Act 1990 and Regulation (EC) 178/2002) and is an area where no food business operator (FBO) would want to be found lacking. With no specific regulation on plant based foods in Europe, and

no single list of permitted herbs and plants, it becomes the responsibility of FBOs to be able to demonstrate, if challenged, that the product they sell is safe and provides sufficient information to the consumer to make informed decisions about purchase and usage.

Onus falls on FBOs to go 'above and beyond' regulation

In this confusing world of botanical ingredients, it is not only vital to understand the national guidance and regulations at the country level, but also to go above and beyond the regulations. Companies need to assess proactively the food safety risks associated with food supplements containing botanical ingredients. Correct classification and labelling at the start of a formulation process can save paying a high cost later through product recalls and other sanctions.

⁵ MHRA Yellow Card Scheme <https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/>

How Leatherhead can help

If you are unsure as to the status of a botanical you want to use, we have a department of over 30 advisors, covering all major international markets, who are ready to help. We can also provide training on food supplement legislation and give advice on additives, flavourings and ingredients, as well as label and formulation checks.

About the author

Luke Murphy manages one of the three Regulatory teams at Leatherhead and also advises on UK, Ireland and EU food legislation. He has a BSc in Food Science from the University of Leeds and five years of experience in the food industry including product development roles at Mars Petcare and Unilever Beverages, and three years as a technologist for Leathams Ltd. Luke joined Leatherhead Food Research in April 2006. He is also a member of the IFST food law steering group and sits on the BRDO Business expert group (Food Standards and Labelling).

About Leatherhead Food Research

Leatherhead Food Research provides expertise and support to the global food and drink sector with practical solutions that cover all stages of a product's life cycle from consumer insight, ingredient innovation and sensory testing to food safety consultancy and global regulatory advice. Leatherhead operates a membership programme which represents a who's who of the global food and drinks industry. Supporting all members and clients, large or small, Leatherhead provides consultancy and advice, as well as training, market news, published reports and bespoke projects. Alongside the Member support and project work, our world-renowned experts deliver cutting-edge research in areas that drive long term commercial benefit for the food and drink industry.

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