Plant and herbal ingredients (botanicals)

"European bureaucracy versus humanity's most important dietary component"

Relevant legislation

Traditional Herbal Medicinal Products Directive (THMPD; Directive 2004/24/EC); Human Medicinal Products Directive (HMPD; Directive 2001/83/EC, as amended); Food Supplements Directive (FSD; Directive 2002/46/EC, as amended); Novel Foods Regulation (NFR; Regulation 258/1997, as amended); Nutrition and Health Claims Regulation (NHCR; Regulation 1924/2006, as amended)

What's the current situation?

- Plant and herbal species and ingredients, collectively known as 'botanicals', can be foods, food supplements, herbal medicines or pharmaceutical medicines under European Union (EU) legislation
- Many botanicals are ingredients found in conventional foods and are covered by EU food law
- Increasing numbers of botanicals are classified as novel foods under the NFR, which requires pre-market authorisation of any food or food constituent considered not to have been used 'significantly' in the EU prior to 15th May 1997. This includes an altered profile of natural constituents in a botanical, for example, where a novel preparation method is introduced
- The extremely broad scope and definition of a medicine given in the HMPD allows regulators to classify many botanicals in supplements and functional cosmetics as medicines – unless they are "clearly" (7th recital of amending Directive) foods, supplements or cosmetics. If in doubt, medicines law reigns supreme (Article 2.2)
- Unlike vitamins and minerals, the EU has decided against fully harmonising botanicals in food supplements, so botanical food supplements are regulated by national rules in individual EU Member States
- Manufactured herbal medicines can be placed on the EU market either as medicines with a full marketing or traditional use authorisation under the terms of the HMPD, or with a traditional herbal registration (THR) via the THMPD
- Compared with the pharmaceutical drug registration scheme, the THMPD has been simplified by replacing the requirement to prove efficacy via human clinical trials with evidence of long-standing safe use
- The future of health claims about botanicals is very uncertain. The process is currently on hold pending an EU decision, after objections were raised when the European Food Safety Authority (EFSA) initially rejected 97% of botanical health claims

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What's the problem?

- Through several mechanisms, the THMPD locks out a very large number of products associated with non-European traditions, such as Indian Ayurveda, Tibetan, traditional Chinese medicine (TCM) and Amazonian systems: it is restricted to products designed for minor, self-limiting conditions without practitioner oversight; 'long-standing safe use' is defined as 30 years' continuous safe use worldwide, including at least 15 years' use in the EU; non-herbal ingredients (e.g. minerals) are excluded if their inclusion amount is significant; and the application process and quality control requirements are extremely strict and expensive for polyherbal products
- The THMPD ideally suits products from the European phytopharmaceutical school, many of which are single-herb or limited combinations extracted using alcohol or acetone, stabilised in a base containing artificial polymers and preservatives
- Regardless of tradition, the THMPD application process is highly cumbersome and costly, largely thanks to the data requirements for quality and safety set by the European Medicines Agency (EMA) – which also sets quality and safety requirements for conventional drugs
- Since the advent of the THMPD, national regulators are increasingly assuming that it is the only possible route to market for botanical products, ignoring the more lenient food supplement route altogether
- When botanical products subsequently fail to negotiate the strict THMPD scheme, and are squeezed out of the food supplement regime, they 'fall between two stools' of EU food and medicine legislation – and are consequently illegal
- The main risks for botanicals presently selling as food supplements within the EU is their re-classification by regulators as either unregistered medicines or unauthorised novel foods
- Dietary simplification leading to decreased consumption of phytonutrients is a major contributor to the epidemic of chronic diseases, including obesity, type 2 diabetes, heart disease and cancer – and lack of access to botanicals of all sorts will only worsen the situation.

Solutions

- Eat a rainbow of fruit and veg every day to provide a diverse range of phytonutrients in your diet
- A proposed ANH-Intl judicial review of the difficult situation facing botanicals in the EU aims to 'repair' problems and allow consumers continued access to a diverse range of botanicals, including those from different traditional systems of healthcare
- Work to prevent regulators from unjustly classifying botanicals as medicines or novel foods
- Apply pressure for mutual recognition to prevent botanicals sold as food supplements in one EU Member State from being classified as medicines or novel foods in another
- In the long term, separate EU legislation is required for practitioners of traditional systems of medicine.