In focus

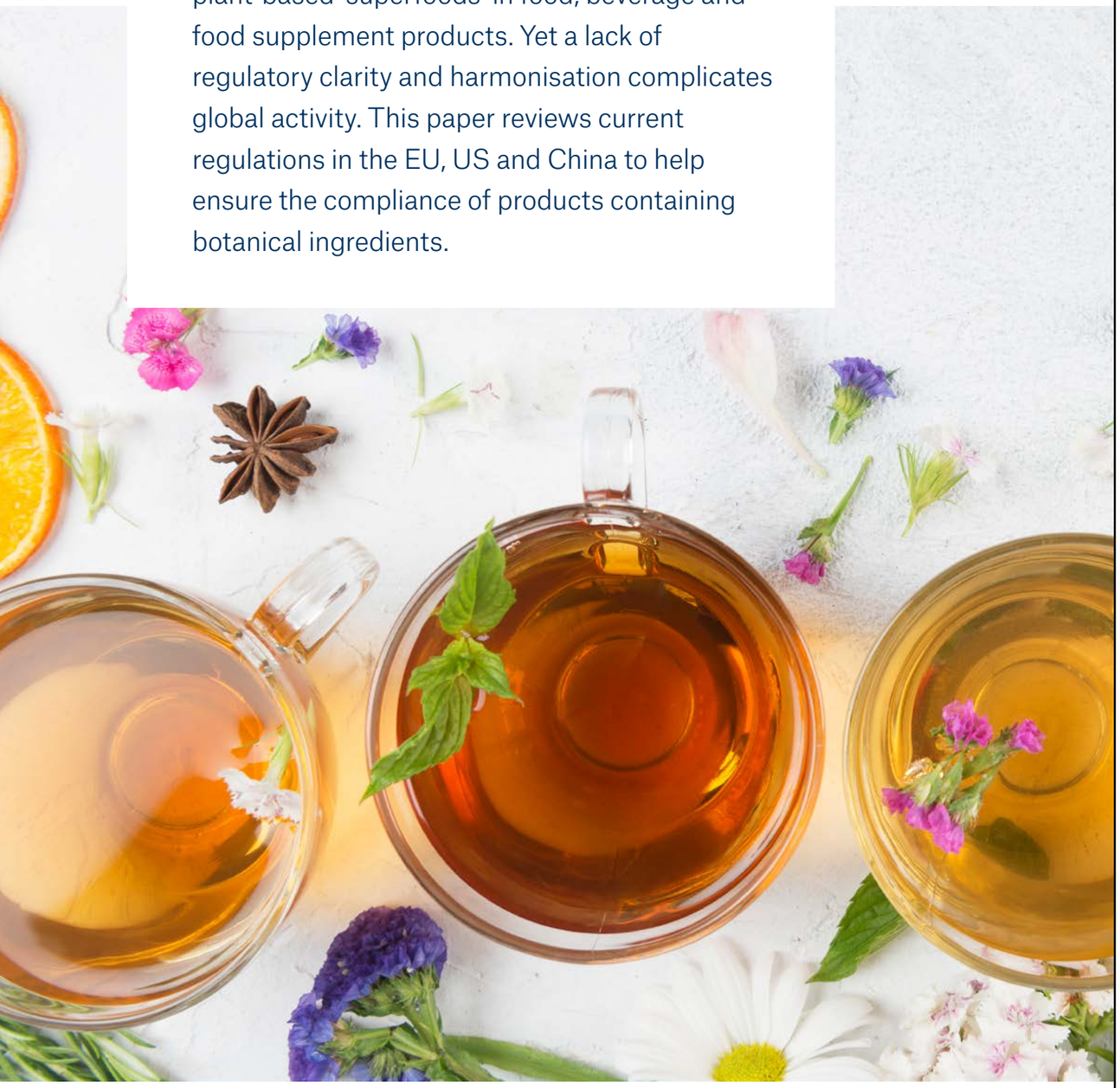
Botanicals: a consumer and regulatory dichotomy

Bringing clarity to botanicals regulation for food, beverages and supplements in the EU, US and China

leatherhead food research

a **science group** company

Consumer interest in botanicals is high, and manufacturers are incorporating a wide range of plant-based ‘superfoods’ in food, beverage and food supplement products. Yet a lack of regulatory clarity and harmonisation complicates global activity. This paper reviews current regulations in the EU, US and China to help ensure the compliance of products containing botanical ingredients.



Surging demand for botanicals

With growing consumer demand for natural products and greater awareness of superfoods’ potential health benefits, botanicals are a hot topic in the food and beverage sector. These plant-based commodities can contain active components that make them useful or desirable in many scenarios.

For instance, some botanicals may have a biological or physiological effect that is beneficial to humans. Mint is a good example with its contribution to the normal function of the intestinal tract. Others provide a natural alternative to synthetically produced substances. Take the stevia plant; its naturally sweet leaves contain steviol glycosides which are commonly used to replace artificial sweeteners such as aspartame. In some circumstances botanicals perform a functional role, like baobab powder which is used for its thickening properties.

What are botanical ingredients?

Botanicals are derived from plants, herbs, spices and their oils or extracts. They can come from various parts of a plant including the roots, bark, leaves, seeds or flowers.

Considerations for the use of botanicals

While market demand is strong, the regulatory landscape for botanical ingredients is complex. The classification of these ingredients and their associated health claims is regulated under country-specific laws which are not harmonised across markets. There are also differences in pre-market registration systems.

The situation is further complicated by the technical implications of adding botanicals to food and beverage matrices. The quantity used, interactions with other ingredients and the impact on product stability all need to be considered. Botanicals' bioavailability and efficacy also demands attention.

There are four key regulatory classifications related to botanicals:

1. **Technological ingredient**
   Colour or colouring adjunct, sweetener, thickener, stabiliser, flavouring agent or adjuvant, flavouring

2. **Nutritional ingredient**
   Nutritional food ingredient, food/dietary supplement, novel food, 'generally recognised as safe' (GRAS) substance or health food ingredient

3. **Therapeutics and medicines**
   Traditional herbal medicine or ingredient with pharmacological, immunological or metabolic action, or medical diagnostic properties and/or presented as having properties to restore, correct or modify physiological function in humans

4. **Cosmetics**
   Ingredients which are rubbed, poured, sprinkled or sprayed on human body parts such as skin, hairs, nails, lips or teeth for cleaning, perfuming, protecting purposes or changing their appearance

What is the current regulatory status for botanicals?

Technological ingredient

Many plants and plant products are used in food, beverages and food supplements to perform specific technological functions. These can range from flavouring, colouring and sweetening to anti-oxidation. Positive lists for the use of these ingredients are country specific and vary between the EU, US and China.

Nutritional ingredient

In the EU, use of botanicals in food and beverage products is subject to Member State rules. Belgium, France and Italy have published their own botanical list (the BELFRIT list) covering botanicals authorised for use in food supplements. However, there is not a corresponding list for general foodstuffs. Where no national legislation exists within an EU Member State, general safety provisions apply.

China has its own lists of permitted and prohibited ingredients (including botanicals) for use in food and beverages. These lists are not exhaustive though, with the exception of lists of authorised botanicals used in 'Health Foods' or as novel foods.

In the US, there are no specific positive lists of botanicals for use in foodstuffs as nutrients. Instead, permissibility is based on whether they have been recognised as food additives, GRAS substances or dietary ingredients. This depends on the application and evidence supporting their safe use in food.

Therapeutics, medicines and cosmetics

Therapeutic levels of certain plants with well-established medicinal properties are generally covered by country-specific legislation on medicinal products. This would preclude their use in food and beverage products or food supplements.

Medicinal products are registered separately in EU Member States, the US and China alike.

Similarly, any botanical ingredients used in cosmetic products must comply with country-specific cosmetic legislation.

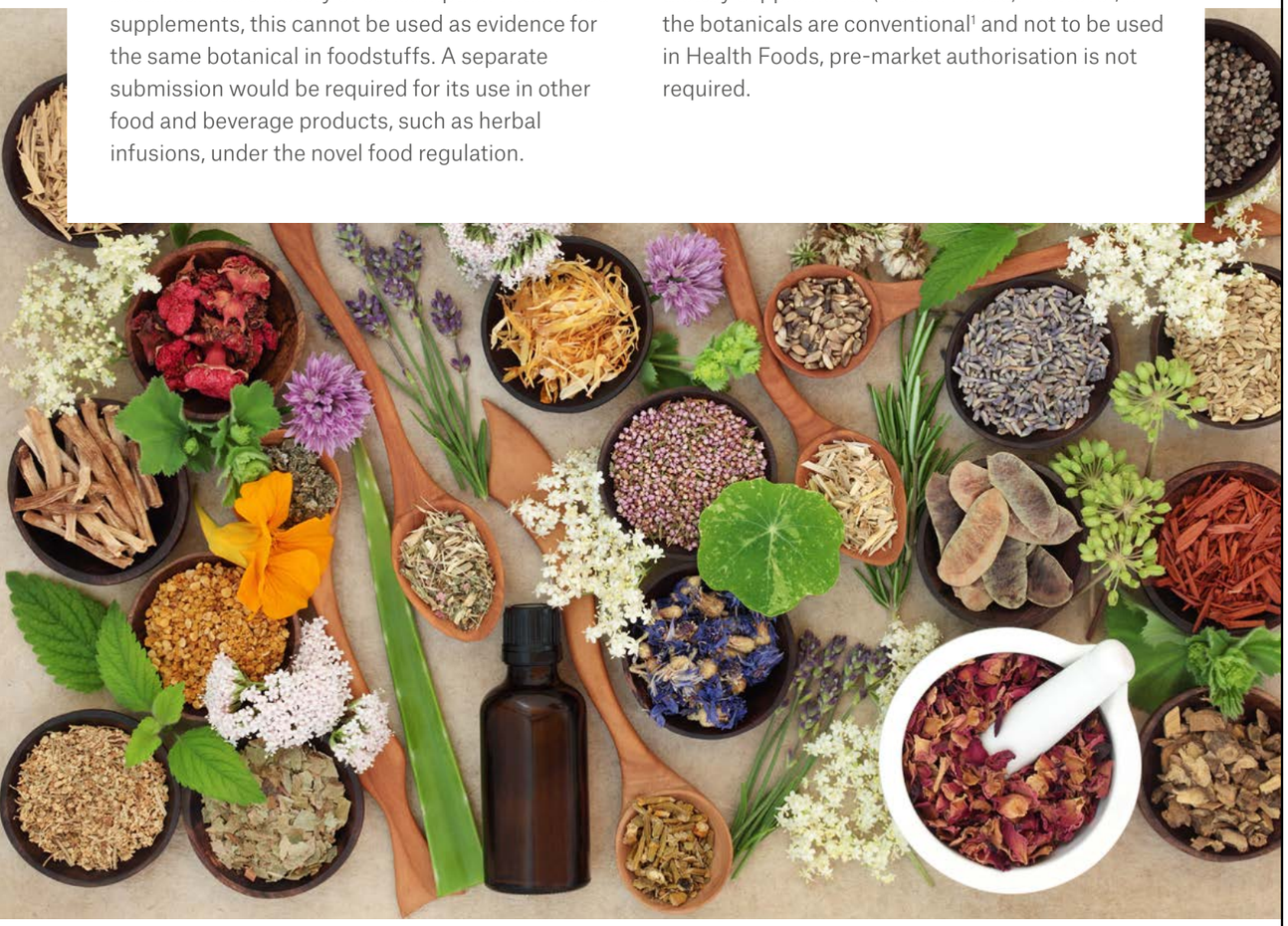
Pre-market registration of botanicals for food use

It is important to note that some botanicals need to undergo a pre-market registration specific to each market entry.

Botanicals with no significant history of consumption in the EU before 15 May 1997 are considered novel foods and therefore require pre-market approval (e.g. baobab fruit pulp). If a botanical has a history of consumption within food supplements, this cannot be used as evidence for the same botanical in foodstuffs. A separate submission would be required for its use in other food and beverage products, such as herbal infusions, under the novel food regulation.

Access to the US market depends upon the classification of a botanical as a food additive, GRAS substance or a dietary ingredient. Each of these falls under separate US-specific regulatory registration processes.

China also has its own pre-market authorisation for novel foods and some notification procedures for dietary supplements (Health Foods). However, if the botanicals are conventional[1] and not to be used in Health Foods, pre-market authorisation is not required.



[1] i.e. conventional botanicals not on the restricted botanical lists used as ingredients in general foods and beverages.

Health claims for botanicals

Health claims are defined and controlled under different regulatory regimes in the EU, US and China. But in all markets, claims indicating or implying that a food can prevent, treat or cure a human disease are prohibited on foodstuffs.

In the EU, some botanicals such as wheat bran fibre, walnut and beta glucan from oat and barley can be overtly associated with health benefits in foodstuffs. Their health claims have been approved for gut transit, improvement of endothelium-dependent vasodilation (elasticity of blood vessels) and maintenance of normal blood cholesterol levels respectively. However, numerous other botanical health claims have been in limbo for nearly a decade.

Around 2,000 botanical health claims are 'on hold' following 500 negative European Food Safety Authority opinions. These relate to lack of characterisation of the botanical and/or failure to demonstrate a cause and effect between consumption and the claimed health benefits, such as 'red clover can contribute to the maintenance of normal cholesterol levels in the blood'.

These 'on hold' botanical claims may be used while they are under assessment. However, relevant scientific data must be gathered to justify use of the claim. A clear summary of the botanical-health relationship is also required, including appropriate conditions of use. When their status is finally determined, some 'on hold' botanical claims may have to be removed from food labels in the EU.

Some of the claims currently on hold are clearly medicinal and should not be used. To date, there has been no communication regarding an amendment to the EU nutrition and health claim regulation which could unlock the current situation.

In the US, claims can relate to structure/function or health.

Structure/function claims for foods and dietary supplements do not require pre-market approval. In terms of conventional foods, this relates to effects derived from nutritive value, whereas for dietary supplements claims may also focus on non-nutritive effects. Manufacturers of dietary supplements must notify any structure/function claims to US authority and include a mandatory disclaimer on their labelling. Food manufacturers are not required to do this.

Health claims are subject to pre-market approval, and the same regulatory pathways exist for foods and dietary supplements. These include Nutrition Labelling and Education Act of 1990 (NLEA) claims, health claims based on 'authoritative statements' and qualified health claims (QHCs).

In China, Health Food functionality claims are only permitted on the labels of products classified as Health Foods. Typical functions that have been authorised in China include 'enhancing immune function' or 'improving memory'. Products that are not marketed as Health Food must not bear any indication or implication of health benefits.

Technical factors to consider

Creating products with botanical ingredients can be an exciting prospect, but there are technical challenges as well as regulatory complexity.

Formulation

When formulating a recipe, it is important to consider interactions between botanicals and other ingredients. Such interactions could cause unfavourable complexes that may impact product appearance, stability or bioavailability.

Quality, stability and shelf life

A botanicals' quality and stability must remain constant following exposure to processing, packaging and storage. Shelf life and stability within food or beverage matrices must consider physicochemical, biochemical and microbiological stability factors under normal environmental conditions (e.g. in terms of temperature, light, oxygen, moisture and relative humidity).

Bioavailability and efficacy

The bioavailability of botanicals in processed foods may reduce or even inactivate any expected health benefits. Processes such as enzyme-catalysis, fermentation and heat treatment may be detrimental to efficacy. Furthermore, bioavailability can be affected by *in-vivo* factors such as exposure to stomach acid before reaching the gut.

Safety and levels/limits of botanicals

The EU has published useful guidance[2] surrounding safety assessments for certain botanicals, their different parts and various usage levels. Outside of this guidance, national legislation at EU Member State level applies. It's important to consult this to determine whether a given botanical is considered a food or a medicinal ingredient depending on its dosage.

In the US, products using botanicals as dietary ingredients must contain 100% of the volume or weight declared on the label, excepting any deviation attributable to the analytical method. Products containing less than this amount would be deemed misbranded and in violation of the law. However, the law is less strict for naturally-occurring ingredients, which must be present at 80% of the declared value.

So, if a manufacturer uses vitamin C isolated from a natural source and sold as a dietary supplement, its presence in the final product must directly match what is declared on the label. However, if rose hips are added to the product, the vitamin C is naturally-occurring, so the requirement is that it must reach at least 80% of the declared value.

In China, only botanicals authorised as novel foods are attributed a maximum daily intake.

[2] Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (2009)
Scientific Opinion on a Qualified Presumption of Safety (QPS) approach for the safety assessment of botanicals and botanical preparations (2014)

What does the future hold?

There are many regulatory challenges associated with the use of botanicals in food, beverages and food supplements. Inconsistent categorisation and variations in the way health claims are regulated mean great care must be taken to avoid breaching legislation and damaging brand reputation.

When it comes to accessing specific markets, there are various potential routes. For instance, you might undergo pre-market registration for novel foods in the EU or for dietary supplements in the US.

An understanding of botanical ingredients' regulatory status and permitted health claims must be central to any product strategy. It also facilitates future product development that both satisfies consumer demand and complies with target market regulations.

How can Leatherhead help?

We offer a comprehensive service working with clients around the world to manage opportunities and challenges associated with new food products.

Our blend of expertise, contacts and processes makes complex regulatory matters more straightforward. We follow a robust and strategic process to support clients accessing different markets for new ingredients and products by:

- Assessing the classification of an ingredient under food law to determine whether it requires pre-market approval in global markets
- Assessing the feasibility of launching a new food product in global markets via comprehensive research and assessments of the available safety data
- Supporting the submission of EU pre-market approval dossiers and US GRAS notifications (our consultants have experience in submitting and reviewing dossiers, and our toxicologists can manage relevant studies)
- Advising on new ingredients' successful integration into formulations
- Understanding consumer views on new food products and how best to market them
- Advising on specific food labelling requirements (we cover regulations in 20+ languages and 150+ markets globally)

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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. Leatherhead Food Research is a trading name of Leatherhead Research Ltd, a Science Group Company.

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Science Group plc (AIM:SAG) is a science-led advisory and product development organisation. The Group has three divisions:

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- Regulatory & Compliance: helping clients in highly regulated markets to launch, market and defend products internationally, navigating the frequently complex and fragmented regulatory ecosystems.
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With more than 400 employees worldwide, primarily scientists and engineers, and speaking more than 30 languages collectively, the Group has R&D centres in Cambridge and Epsom with more than ten additional offices in Europe, Asia and North America.

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