



Between Food and Medicine: Navigating Food Supplement Regulation in the UK and EU

Levels, claims, nutrition labelling & botanicals

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About Ashbury

Founded in 2011.

Trusted regulatory,
technical & training
consultancy.

Specialists in:

- Multi-category
- Multi-country product
- Labelling compliance
- Retail own-brand compliance processes



Today's agenda

Consumer perceptions and the current market in EU and GB

UK FSA communications and market figures

What is a food supplement?

Definition, dose form, overlaps with foods & medicines

Ingredients

What's permitted, restricted and banned

Borderline products

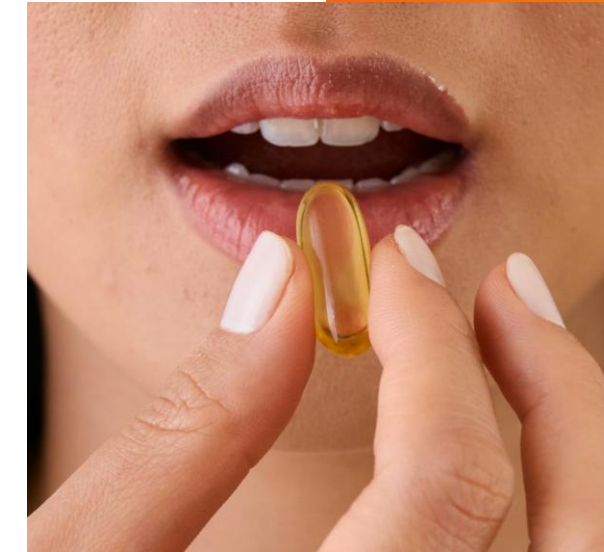
Medicines vs supplements; THMPs in the EU & GB

Nutrients & declarations

What counts as a nutrient; on-pack declarations

Health & nutrition claims

Authorised, on-hold botanical claims; rulings



The regulator is now talking directly to your customers

JANUARY 2026

FSA launches consumer guidance on what a food supplement is — and what it is not

Why now: New Year demand, social-media health advice and growing confusion between supplements and medicines.



Defines a supplement: a concentrated source in dose form that tops up — never replaces — a varied diet



Reminds consumers supplements cannot claim to prevent, treat or cure disease



Advises buying from reputable sellers and checking safe intake levels where these exist



Directs safety and labelling concerns of consumers to Local Authorities

What's next: FSA-commissioned UK consumer and market-insight research (May 2026 – Mar 2027) to shape future policy and risk assessment

A booming market — and a widening compliance gap

£34.2bn

Europe food supplements market, 2025 — forecast £47.8bn by 2030
(7.0% **Compound Annual Growth Rate CAGR**)

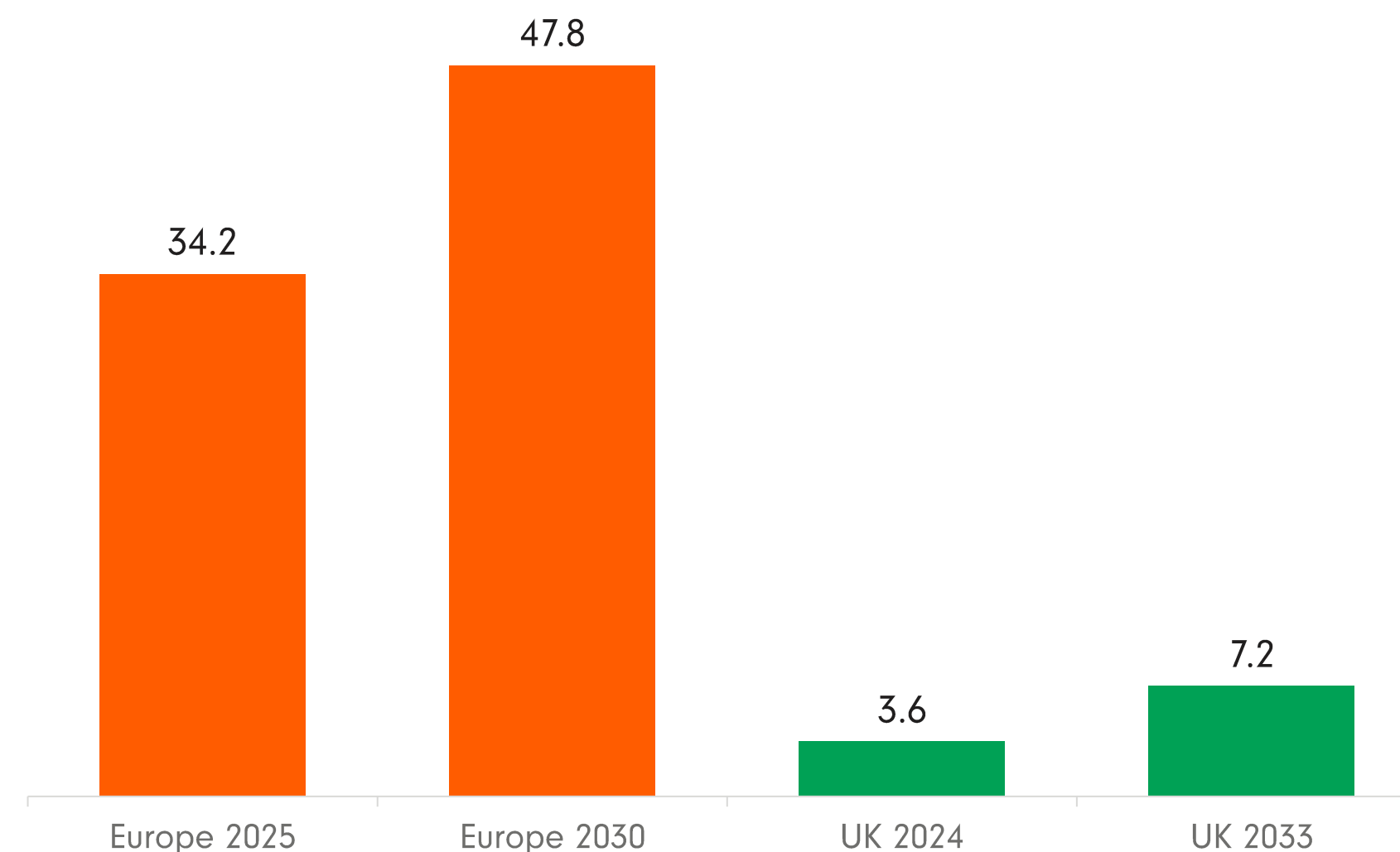
8.1%

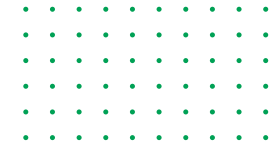
UK CAGR 2025–33: £3.6bn (2024) to £7.2bn; UK flagged as Europe's fastest-growing market

>86%

of ads in every health category the ASA reviewed were medium or high compliance risk (309,000 ads, Oct 2026)

Market value forecasts (£bn)





What is a food supplement?

Between food and medicine: the legal definition, dose form and the categories next door



What makes a product a food supplement?

Legal definition: any food the purpose of which is to supplement the normal diet, which is a concentrated source of vitamins, minerals or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form.

Dir. 2002/46/EC Art. 2; Food Supplements (England) Regs 2003 reg. 2 and devolved equivalents



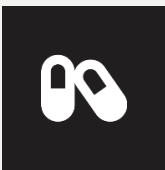
Purpose

Supplements — never replaces — the normal diet; aimed at the general healthy population



Concentrated source

Vitamins, minerals or other substances with a nutritional or physiological effect (not psychological)



Dose form

Capsules, tablets, pills, sachets of powder, ampoules, drop bottles — measured small units



Sold & represented as such

Labelled 'food supplement'; dose form alone does not make a food a supplement

Food excludes medicinal products, cosmetics and narcotic or psychotropic substances (Reg. 178/2002 Art. 2) — none of these can be a supplement.

Where supplements meet other categories

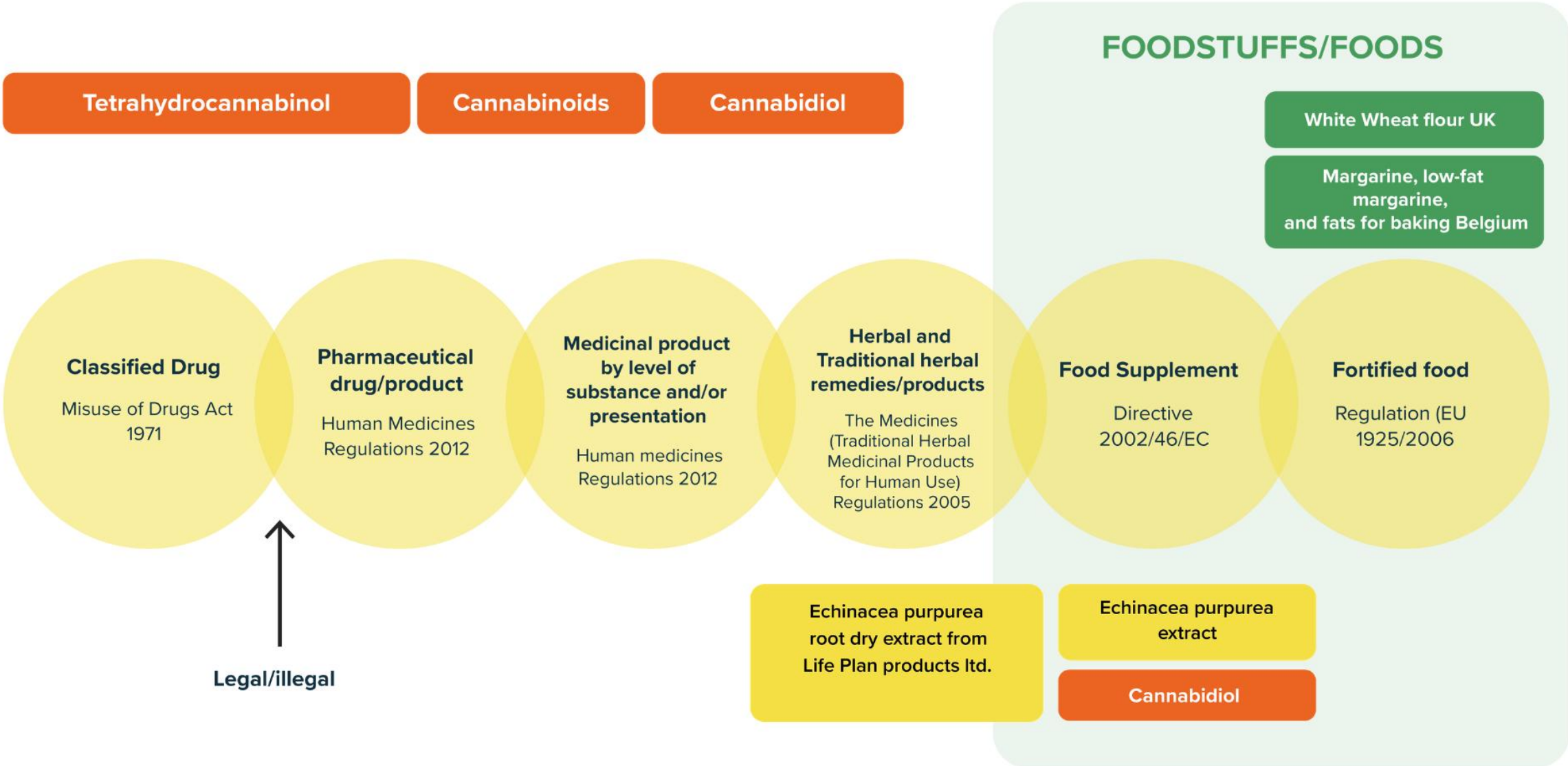
Category	Legal basis	How it differs from a food supplement
Fortified foods	Reg. (EC) 1925/2006	Normal foods with added nutrients; only Annex III (restricted/banned substances) applies to supplements
Beverages	Bioconcepts v HMRC [1993]; Kalron Foods v HMRC (2007)	Drinks taken to hydrate, quench thirst, fortify or give pleasure are beverages (UK VAT precedent)
Foods for specific groups / FSMP	Reg. (EU) 609/2013; Reg. 2016/128	For defined groups; FSMP used under medical supervision – mutually exclusive with supplements (C-760/21)
Medicines	Dir. 2001/83/EC; HMR 2012	Medicinal presentation or pharmacological, immunological or metabolic action (Section 03)

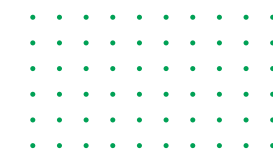
The test: what is the product for, and who is it for? Purpose and target consumer decide the category – and every regulatory question that follows.

Where substances cross other categories

Illustration of interaction with legislative controls that may be relevant to substances used in food supplements.

Basic references to legal control instruments only are given.
Basic descriptions of indicative products/substances/foods are given.





Ingredients

Permitted, restricted and banned – under EU and GB rules



Composition: three gates for every ingredient



Gate 1

Vitamins & minerals

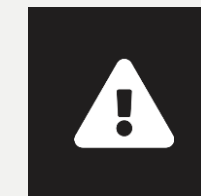
- Only Annex I nutrients in Annex II forms (Dir. 2002/46/EC, as amended by Reg. 1170/2009); purity criteria apply
- GB: Food Supplements (England) Regs 2003, Schedules 1 & 2, and devolved equivalents
- New forms only via application (Commission; FSA/FSS)



Gate 2

'Other substances'

- Must have a nutritional or physiological effect
- Not novel (pre-15 May 1997 history) or authorised: EU Union list vs GB register
- Safe (Art. 14 Reg. 178/2002) and not a medicine by function



Gate 3

Restricted & banned

- Reg. 1925/2006 Annex III: Part A banned, B restricted, C under scrutiny
- EU: monacolins (red yeast rice) <3 mg/day; green tea EGCG <800 mg/day
- GB: Kava-kava and Tryptophan Regs; MHRA herbal prohibition orders

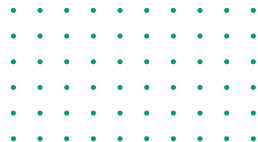
Maximum Vit and Mineral levels: no harmonised EU or GB numbers

	2002	Art. 5 of the Directive envisages EU maximum amounts
	2005–25	Two decades of stalled drafts and divergent national views
	Dec 2025	AGRI-FISH Council urges a formal proposal in 2026
	Mid-2026	Commission timetable: consultation Q3 2026, adoption Q1 2028
	Oct 2026	Commission now says no consultation is planned in 2026

Divergence to design around today

Vitamin D	BfR (DE) 20 µg/day vs EFSA UL 100 µg/day
Vitamin C	France proposed 208 mg vs up to 1,000 mg elsewhere
GB	No statutory limits; EVM (2003) Safe Upper Levels used as guidance
Models	EHPM (2021), FSE (2014), FSAI (2024) reference tables
Method	UL minus diet & fortified-food intake = residual for supplements

Minimums trigger claims — not composition



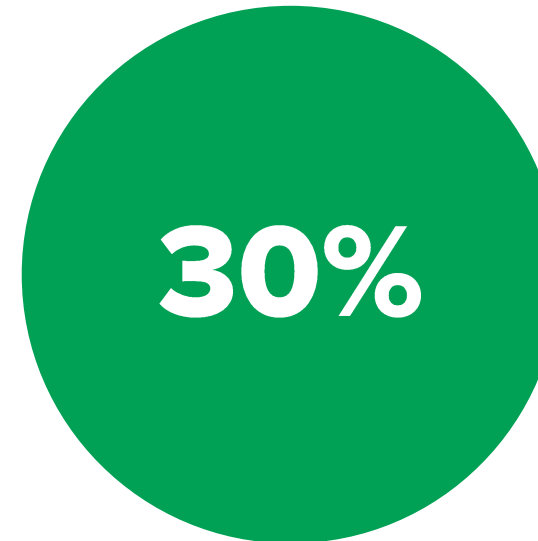
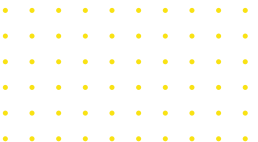
None

Legal minimum to be a supplement — but it must deliver a nutritional or physiological effect



15%

NRV per daily portion: 'source of' and the threshold for any vitamin/mineral claim



30%

NRV per daily portion: threshold for 'high in' claims

Other substances: the dose must meet the authorised conditions of use — e.g. glucomannan 3 g/day in three 1g doses before meals; DHA 250 mg/day. Token 'label-dressing' doses invite challenge as misleading and undermine the physiological effect that makes the product a supplement at all.



Botanicals: four regulatory models



Positive lists

Italy (DM 10 Aug 2018, as amended), France (Arrêté 24 June 2014), Belgium (RD 31 Aug 2021) — BELFRIT roots, but warnings and limits differ



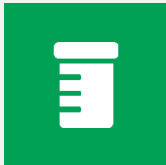
Reference lists

Germany, Austria, Switzerland: BVL 'Stoffliste' (3rd ed., Feb 2025) — non-binding but highly influential



Case by case

No list: safety (Art. 14 GFL), novel food status and the medicine borderline decide



Medicine-led

Plants classed as medicinal or pharmacopoeia-listed (e.g. France's Jan 2026 List A/B update) close the food route

EU-wide tools: Reg. 1925/2006 Annex III (Art. 8 procedure); EFSA Compendium of botanicals of possible concern; mutual recognition (Reg. 2019/515).

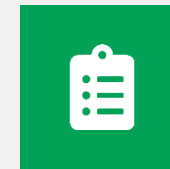
GB: no botanical list — MHRA borderline decisions, herbal prohibition orders and the THR register.

Novel foods and other substances: EU vs GB



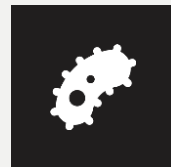
The novel food test

Not consumed to a significant degree in the EU before 15 May 1997 (Reg. 2015/2283). EU Union list (Reg. 2017/2470) and GB register have diverged since 2021.



Read the conditions

Phytosterols/stanols: GB conditions of use. CBD: no EU authorisation; GB FSA public list. Panax notoginseng & Astragalus extract: EU-authorised with conditions.



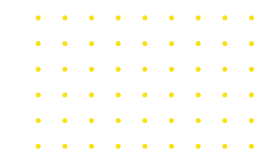
Probiotics & micro-organisms

EFSA QPS list (June 2023 update) as safety starting point; FSAI 2024 risk review. 'Probiotic' is generally a health claim – some states (e.g. Italy) allow it nationally.



Other substances

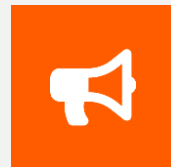
Amino acids, enzymes, essential fatty acids, carriers and additives: check novel status and approved status respectively plus purity criteria.



Borderline products

Medicines vs supplements: when has a product crossed the line?

Medicine or supplement: how to tell



By presentation

- Explicit and implied claims across label, web, social, reviews and influencers
- Pack, dose form and look resembling licensed medicines
- MHRA Guidance Note 8 and the Blue Guide set the GB test



By function

- Pharmacological, immunological or metabolic action at the stated dose
- Assessed case by case on current science, use and risk
- A THMP in one state can be a food supplement in another

Key CJEU rulings

C-319/05 Commission v Germany (2007)

Garlic capsules with no effect beyond normal food use are not medicines by function

C-140/07 Hecht-Pharma (2009)

'By function' needs capacity to significantly modify physiological functions in normal use

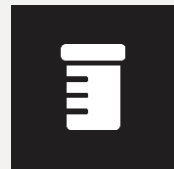
C-27/08 BIOS Naturprodukte (2009)

Classification weighs dose, manner of use, familiarity and risks, case by case

C-760/21 (2023)

FSMP and food supplement are mutually exclusive; classify case by case

THMPs vs food supplements in the EU and GB



Traditional herbal medicinal products (THMPs)

- Herbal actives only; for use without medical supervision
- 30 years' traditional use, incl. 15 in the EU (Dir. 2004/24/EC) or GB
- EU: national registrations; EMA HMPC monographs
- GB: MHRA Traditional Herbal Registration and THR certification mark



Same plant, different status

- Red clover for menopause: medicine route in Poland (Pharmaceutical Act 2001), supplement elsewhere
- EMA rhubarb root monograph: a laxative indication is medicinal
- If a registered herbal medicine exists for an indication, that claim on a supplement signals medicinal presentation

MHRA Guidance Note 8 borderline checklist: claims (explicit and implied) · pharmacological, metabolic or immunological action at the dose · primary purpose · similarity to licensed medicines · labelling, packaging, ads, web, social and reviews

Nutrients & declarations

The structure of supplement declarations



What counts as a nutrient?

Supplements Directive

Art. 2(b)

Vitamins and minerals – nothing else

FIC & claims Regulation

FIC Art. 2(2)(s)

Protein, carbohydrate, fat, fibre, sodium, Annex XIII vitamins and minerals, and their components

‘Other substances’

Reg. 1925/2006 Art. 2(2)

Nutritional or physiological effect but not nutrients – declared numerically, no NRV

Why it matters: a ‘nutritional effect’ under the Directive is wider than a ‘nutrient’ under the claims Regulation. It decides what you declare, whether %NRV applies, and which claims are available.

Supplements follow Article 8, not Annex XV



What does not apply

- FIC Art. 29(1)(a): the mandatory nutrition declaration does not apply to food supplements
- No energy and 'big 7' table required
- NHCR Art. 7: where a claim is made, supplements give the Art. 8 information instead



What does apply

- Amount of each vitamin, mineral and other active substance per recommended daily portion, in numerical form (Art. 8(1))
- %NRV for vitamins and minerals (Art. 8(2)); 'no NRV established' for others
- Values are averages from the manufacturer's analysis (Art. 8(3)); EU 2012 tolerances: vitamins +50%/−20%, minerals +45%/−20%
- Art. 6(3) particulars: 'food supplement', category names, daily portion, do-not-exceed warning, not a substitute for a varied diet, keep out of reach of young children
- FIC still applies: allergen emphasis, 1.2 mm x-height (0.9 mm under 80 cm²), QUID

Worked example: what an expert reviewer sees

Per daily dose (1 capsule)	Amount	%NRV*
Vitamin D3	25 µg	500%
Vitamin K2 (as menaquinone-7)	75 µg	100%
Magnesium	112.5 mg	30%
Saffron extract (Crocus sativus stigma)	30 mg	†

**Nutrient Reference Value †No NRV established
Illustrative panel — not a real product*



Vitamin D 25 µg: acceptable in GB and many markets, but above Germany’s BfR 20 µg recommendation



Magnesium at 30% NRV: ‘high in’ territory; authorised function claims available



Saffron: no authorised claim — mood claims are high risk (see Section 05); check national plant lists



Panel is per daily portion, not per 100 g; values must reflect analysis within tolerance

Health & nutrition claims

Compliant use of Nutrition and Health claims



The Health claims ladder: where each statement sits

Medicinal: prevent, treat or cure disease

Prohibited for food (Dir. 2002/46 Art. 6(2); FIC Art. 7(3)); risks medicine status by presentation (Dir. 2001/83 Art. 1(2); HMR 2012 reg. 2)

Disease risk reduction (Art. 14)

Authorised only; must state the disease has multiple risk factors

Function claims (Art. 13)

Register wording and conditions of use, per daily portion

General, non-specific (Art. 10(3))

'Supports vitality' — only with an accompanying authorised specific claim

Nutrition claims (Annex)

'Source of', 'high in' — Annex conditions apply

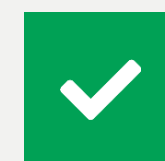
Plus 'on-hold' botanical claims: transitional use only where Art. 28(5)/(6) conditions are met — narrow and interpreted market by market.

Using Health claims compliantly: the expert checklist



Register match

Claim is on the EU register/GB NHC register for that nutrient or substance



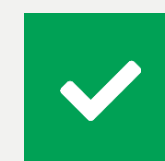
Conditions of use

Met per daily portion, e.g. $\geq 15\%$ NRV for vitamins and minerals



Equivalent meaning

Rewording keeps the meaning; no amplification ('boosts', 'maximises')



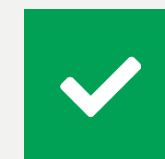
Art. 10(2) statements

Balanced diet, quantity and pattern of use, who should avoid, excess risk.
Per C-657/24 *Kyberg Pharma* does not need to be reproduced in written advertising when it already appears on the product's labelling.



Art. 10(3) pairing

General claims sit next to a specific authorised claim (Schwabe)



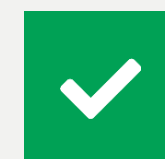
Whole presentation

Imagery, brand names, testimonials, influencer and AI personas all count



No HP endorsements

Art. 12(c) NHCR bars individual health-professional recommendations



Diet adequacy

Never imply a varied diet cannot supply enough nutrients (Dir. Art. 7)

EU case law shaping Health claims practice

2014

C-609/12 Ehrmann

Art. 10(2) mandatory information attaches to health claims once the lists apply

2016

C-19/15 Innova Vital

NHCR covers commercial communications aimed at health professionals

2020

C-524/18 Dr Willmar Schwabe

General claims need a specific authorised claim; a clear reference (e.g. asterisk) can link them

2025

C-386/23 Novel Nutriology

Botanical health claims banned until authorised, unless a transitional regime applies

2026

C-721/24 Vista-Life Pharma

Directions can themselves amount to health claims where they are linked to a beneficial health effect.

Takeaway: Commission delay is not permission – and competitors (e.g. VSW in Germany) are part of your enforcement risk

EU and National cases – ongoing change in 2026

Claims liability

C-250/26 *Marnen* (Dutch Council of State)

Can consumer reviews posted independently on a seller's site trigger the "medicinal product by presentation" criterion of Directive 2001/83

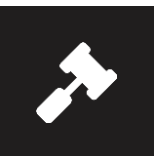
What is a claim

OLG Köln *MenoGlück* (16 January 2026, Germany)

A product name can be a health claim.

GB: the ASA is the de facto claims enforcer

- 

Minerva Wellness (2026)
Menopause/PCOS treatment implied; ‘adaptogenic herbs’ an unauthorised specific claim
- 

Real Health Supplements (2025)
Customer testimonials on back pain and depression treated as disease claims
- 

ShroomIQ (2026)
Kids’ gummies implying ADHD/anxiety benefits; AI ‘experts’ still count as endorsements
- 

The Turmeric Co. (2026)
Even blurred testimonials can imply disease claims
- 

Huel (Sept 2026)
General health claim without a specific authorised claim; irresponsible ‘replace all food’ message

ASA ‘Pulse’ study, Oct 2026

309k

paid-for health ads analysed

53%

of mushroom-supplement ads rated high risk

16.5k

women’s hormonal health ads – the largest category

17

upheld supplement rulings in 2026 to 22nd Oct

Sources: ASA rulings; NutraIngredients (5 Oct 2026); The Grocer (Sept 2026); HealthSpark PR ruling count (to 22 Oct 2026).

Actions for successful selling into GB and/or the EU

01.

Classify first

Food, THR drug, medicine or supplement — in every target market

02.

Formulate to the strictest

Lowest national limit and narrowest plant list you will sell into

03.

Modular claims

Anchor on authorised vitamin/mineral claims; market-specific botanical copy

04.

Govern all channels

Label, web, social, influencer, AI and testimonials are one presentation

05.

Build EU-ready now

SPS alignment brings EU rules to GB-only businesses

06.

Watch the horizon

EU maximum levels, EFSA botanicals guidance, on-hold resolution



In-market expertise: formulations & claims



Formulation review

Ingredients, forms, doses and plant parts checked against each market’s lists and limits



Claims & copy check

Label, web, social and influencer copy tested against registers, case law, and ASA practice



Labels & translation

Market-ready artwork from local specialists — 125+ experts, 35+ languages

Book a pre-launch formulation and claims review with Ashbury’s in-market regulatory team



Thank you

Questions?

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Position at 25th October 2026. General guidance, not legal advice.