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COMPLIANCE BRIEF

Understanding the Regulatory Framework for Food Supplements in the UK and EU

Practical regulatory guidance for Great Britain, with Northern Ireland, Ireland and European Union considerations.

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At a glance

Food supplements are regulated as foods where they meet the applicable legal definition. Their development and sale require more than compliance with the legislation specifically titled "food supplements". General food law, ingredient controls, claims, labelling and national market rules must also be considered.

The principal regulatory points for businesses operating across Great Britain, Northern Ireland and the European Union are:

- Great Britain has food supplement regulations applying separately in England, Scotland and Wales, together with an amended GB framework for permitted vitamins, minerals and their sources.
- The European Union uses Directive 2002/46/EC as its food supplement framework, alongside EU-wide regulations and national implementing or supplementary measures.
- Northern Ireland continues to apply relevant EU food supplement law under the Windsor Framework, with separate domestic enforcement arrangements.
- Ireland and other EU Member States may impose national requirements in areas that are not fully harmonised, including notification and certain ingredient restrictions.
- Novel foods, additives, claims, general food safety, hygiene and labelling must be assessed in addition to supplement-specific requirements.
- A product compliant in one market cannot automatically be assumed compliant in another.

This brief explains how these layers of law fit together and provides a practical market-by-market assessment framework.

How to use this brief

Use this document when selecting target markets, designing a formulation or planning a product launch. The review begins by identifying the intended markets and the legal requirements relevant to the product category, ingredients, dosage, presentation and claims.

This brief outlines the principal regulatory frameworks and explains the differences businesses encounter when supplying Great Britain, Northern Ireland, Ireland and other European Union markets.

1. What is a food supplement?

1.1 Definition and presentation

The EU framework describes food supplements as foods intended to supplement the normal diet, consisting of concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, and marketed in dose form. The concept includes tablets, capsules, measured portions of powder and small-volume liquids. The corresponding GB regulations use a substantially similar definition.

The legal categorisation is determined by the product as marketed, not solely by a business choosing to call it a supplement. Ingredients, dose, presentation, claims and the overall mode of use must all be considered. [1, 2]

1.2 Food supplement or medicinal product?

The food supplement framework does not apply to a product classified as a medicinal product. Where the presentation, intended use or relevant pharmacological characteristics raise a borderline issue, a product-specific classification assessment may be required. Food labelling cannot make an otherwise medicinal product lawful as a food supplement.

In particular, products marketed with claims to prevent, treat or cure human disease raise significant regulatory concerns. This is separate from the question of whether particular nutrition or health claims are permitted for foods. [1, 2, 3]

1.3 Recording a classification decision

A defensible initial classification should draw on the complete product specification and its proposed commercial presentation. The classification should be reassessed whenever the formulation, dose, target audience or claims change.

- Record the product type, dose form and recommended daily portion.
- Identify the intended physiological or nutritional purpose and the intended consumers.
- Review the product name, packaging, advertising and other claims for medicinal implications.
- Document unresolved classification questions and the need for any competent-authority advice.

2. The legal framework by urisdiction

The source of a requirement matters. Directly applicable EU regulations, directives implemented through national legislation, and GB domestic or assimilated legislation must not be conflated.

Market	Principal supplement framework	Key additional considerations
England	Food Supplements (England) Regulations 2003, as amended; GB schedules under the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.	General food law, GB ingredient authorisations, claims, food information and safety duties.
Scotland	Food Supplements (Scotland) Regulations 2003, as amended; GB permitted-substance framework.	Scottish implementing and enforcement provisions; GB-wide substantive rules where applicable.
Wales	Food Supplements (Wales) Regulations 2003, as amended; GB permitted-substance framework.	Welsh implementing and enforcement provisions; GB-wide substantive rules where applicable.
Northern Ireland	Food Supplements Regulations (Northern Ireland) 2003, together with relevant EU food supplement law under the Windsor Framework.	EU rules applicable in NI, relevant UK arrangements and domestic enforcement.
Ireland / other EU Member States	Directive 2002/46/EC as amended, transposed or supplemented through national law.	EU regulations plus national requirements for certain ingredients, notifications, language and enforcement.

The UK Government's business guidance identifies the corresponding instruments for the four UK nations. This table is an orientation, not a substitute for checking each amended instrument and associated rules. [2, 3, 4, 5]

3. Great Britain: England, Scotland and Wales

3.1 National food supplement regulations

England, Scotland and Wales each have food supplement regulations dating from 2003, amended since their introduction. They implement or preserve the relevant supplement-specific controls in the GB legal framework, including the definition of a supplement, prepacked supply and designated labelling particulars. The precise domestic instrument and amendments applicable in the destination nation should be checked. [2, 3]

3.2 The GB lists of permitted vitamins and minerals

For GB, the lists of vitamins, minerals and their permitted chemical sources are found in the Schedules to the N*utrition* (A*mendment etc.*) (EU E*xit*) R*egulations 2019*, as subsequently amended. They must not be replaced in a GB assessment by automatically consulting the latest Annexes to the EU Directive. [4]

The inclusion of a vitamin, mineral or source in an applicable list is necessary where the positive-list rules apply, but it is not a blanket approval of any dose, formulation or intended claim. Safety, ingredient restrictions and other applicable law remain relevant.

3.3 General food law continues to apply

The GB version of Regulation (EC) No 178/2002 provides fundamental general food law obligations. Food information, hygiene, additives, novel foods, claims and other regulated products are governed by their respective GB frameworks. Businesses should use the legislation.gov.uk versions applicable in GB and the relevant FSA or FSS registers where those registers have become the operative authorisation source. [2, 4, 6]

For example, the FSA states that from April 2025 certain GB regulated-product authorisations, including novel foods, are primarily recorded in the official FSA/FSS registers instead of being introduced by a new statutory instrument for each decision. The EU Union list should not be assumed to describe current GB authorisations. [6]

4. European Union: harmonised rules and national variation

4.1 The EU food supplement Directive

Directive 2002/46/EC establishes the core EU rules for food supplements, including a common definition, permitted vitamins and minerals and their sources, and certain labelling requirements. Unlike an EU regulation, a directive operates through Member State measures implementing its requirements. [1, 7]

The latest consolidated text identified on EUR-Lex during this research is dated **26 November 2025**. Businesses should check that text and subsequent changes rather than rely on an older PDF or unamended annex. [1]

4.2 What is not fully harmonised

Directive 2002/46/EC does not provide a complete, uniform answer for every ingredient or quantity in every EU country. National approaches can differ for botanicals, other substances, maximum levels where applicable, product notification procedures, language and enforcement. EU-wide restrictions under other legislation must be considered as well. [1, 7, 8]

An ingredient used successfully in one Member State is not automatically acceptable in every other Member State. Any argument based on free movement or mutual recognition must be assessed against the product, the sector-specific framework and the destination country's requirements; it should not be presented as a general exemption from food safety controls.

4.3 EU-wide laws applying alongside the Directive

- **Regulation (EC) No 178/2002:** general food law, safety, operator responsibility and traceability.
- **Regulation (EU) No 1169/2011:** food information and labelling.
- **Regulation (EC) No 1924/2006:** nutrition and health claims.
- **Regulation (EU) 2015/2283:** novel food assessment and authorisation.
- **Regulation (EC) No 1925/2006:** restrictions and controls relevant to certain other substances, including the Annex III mechanism.
- **Regulation (EC) No 852/2004:** food hygiene requirements.

These laws may have been amended. Their operative consolidated versions and the latest relevant implementing acts must be checked for each new regulatory assessment. [7, 8, 9]

5. Northern Ireland and Ireland

5.1 Northern Ireland under the Windsor Framework

Relevant EU food supplement rules continue to apply in Northern Ireland under the Windsor Framework, alongside Northern Ireland domestic enforcement legislation and relevant UK-specific arrangements. Northern Ireland should not simply be treated as another GB market when assessing permitted substances or claims. [3, 10]

The legislation and practical route to market must be checked for the particular product. Where a business plans to supply Great Britain and Northern Ireland together, it should first identify each applicable legal regime and then assess whether one product specification and label can satisfy both.

5.2 Ireland and national notification

Ireland applies EU food supplement law and its national E*uropean Communities* (*Food Supplements*) R*egulations 2007*, as amended. The Food Safety Authority of Ireland (FSAI) states that a supplement marketed in Ireland for the first time must be notified through its online system, with the duty falling on the manufacturer or importer as appropriate. A notification is not a general regulatory authorisation or guarantee of product compliance. [8]

Notification procedures differ among EU Member States. A full country-by-country account is reserved for FC-CB-006, but notification must be checked before commercial launch in every intended destination.

6. Rules applying beyond supplement classification

A compliant classification and permitted vitamin source do not establish that the finished product is lawful. A cross-regime review is required.

Regulatory area	Principal question	Where to verify
Ingredient legality	Is the ingredient, form, process and intended use permitted, including any novel food status?	Current official GB or EU authorisation sources, novel food registers and applicable national rules.
Product safety	Is the proposed daily intake safe for the intended consumers, including potentially vulnerable groups?	General food law; official scientific and regulatory risk assessments; relevant restrictions.
Food information	Are the prescribed designation, mandatory statements, ingredients, allergens and quantities correctly declared?	Relevant GB FIC framework or EU Regulation 1169/2011 plus national measures.
Marketing claims	Is each nutrition or health claim permitted in the destination market, and are the conditions of use met?	GB claims register or EU claims register and accompanying legal rules.
Food business operation	Are hygiene, registration, traceability and import responsibilities addressed?	Official local, UK or EU competent authority guidance and applicable legislation.
Market access	Does the destination impose notifications, language rules or particular restrictions?	Destination-country competent authority and current national law.

Other briefs in this series examine formulation compliance (FC-CB-003), claims (FC-CB-004), operator responsibilities (FC-CB-005), notification (FC-CB-006) and packaging (FC-CB-007) in greater depth.

7. Worked example: a product sold in GB and Ireland

Illustrative scenario: A business proposes a capsule food supplement containing a vitamin, a plant extract and a permitted excipient, to be placed on the market in England and Ireland.

A sensible assessment sequence would be:

1. **Classify the finished product:** confirm that its composition, dose and presentation are consistent with food supplement status rather than a medicinal product.
2. **Check the vitamin and source separately:** verify the vitamin and permitted chemical form against GB lists and the current EU Directive annexes for Ireland.
3. **Investigate the plant extract:** confirm precise identity, process, novel food position, relevant national ingredient restrictions and the proposed daily intake.
4. **Assess claims and labelling:** verify claims for each market and prepare mandatory information, including any country-specific language or presentation requirements.
5. **Check market-entry formalities:** identify the responsible FBO, establishment responsibilities and the FSAI notification obligation for Ireland.
6. **Record the evidence:** maintain a dated assessment identifying every applicable source and unresolved question.

The product cannot be declared compliant merely because the same ingredients appear in another seller's product or because it has previously been marketed in one of the proposed markets.

8. Regulatory change and future alignment

The UK Government has announced negotiations on a UK-EU sanitary and phytosanitary (SPS) agreement intended to bring specified GB rules into alignment with EU requirements. Food supplements are identified as within the planned scope, and the Government's stated intended start is mid-2027, subject to negotiations and implementation. [10]

At the date of publication, the announced future arrangements were not operative legislation. Businesses should assess products against the law currently applicable in each market while monitoring any confirmed changes, commencement provisions and transition measures.

The possibility of future alignment does not remove the need to distinguish current GB and EU rules in a 2026 regulatory assessment.

9. Regulatory framework checklist

The following questions support the initial planning and jurisdictional assessment of a food supplement.

- The intended product has been assessed against the legal definition of a food supplement and potential medicinal classification.
- Every destination market has been identified individually, including GB, Northern Ireland and any EU Member States.
- The specific applicable food supplement instruments and their latest amendments have been identified.
- GB and EU vitamin/mineral positive lists and source lists have been checked separately where relevant.
- Ingredient composition, source, processing, dosage, novel food status and national restrictions have been assessed.
- General food safety and food business operator responsibilities have been identified.
- Labelling, claims and market-specific presentation requirements have been assessed.
- Notification and establishment-registration obligations have been checked separately.
- Evidence sources, dates, interpretations, uncertainties and responsible owners are recorded.
- A review trigger is in place for regulatory changes, reformulation, new claims or entry into additional markets.

10. Primary legislation and official guidance

The official legal instruments and competent-authority guidance below establish the principal framework discussed in this brief.

1. EU Directive 2002/46/EC, current consolidated version (26 November 2025)
2. Food Supplements (England) Regulations 2003, as amended, and equivalent 2003 instruments in Wales and Scotland
3. UK Government: Food supplements, guidance for businesses; implementing legislation guidance
4. Nutrition (Amendment etc.) (EU Exit) Regulations 2019: GB schedules of permitted vitamins, minerals and sources

5. Food Supplements (Wales) Regulations 2003 and Food Supplements (Scotland) Regulations 2003
6. Food Standards Agency: GB regulated product authorisations and novel food register guidance
7. European Commission: Food supplements overview and scope of harmonisation
8. Food Safety Authority of Ireland: food supplement legislation and notification
9. EU Regulation (EC) No 178/2002: general food law, consolidated 1 January 2026
10. UK Government: UK-EU SPS agreement, legislation in scope and preparation (2026)
11. Food Supplements (Scotland) Regulations 2003, as amended
12. Food Supplements Regulations (Northern Ireland) 2003, as amended

Further official sources relevant to individual assessments: Regulation (EU) No 1169/2011; Regulation (EC) No 1924/2006; Regulation (EU) 2015/2283; Regulation (EC) No 1925/2006; Regulation (EC) No 852/2004; Northern Ireland Food Supplements Regulations 2003; and the implementing food supplement law of each destination Member State. These must be checked in the most current version for a particular product.

Conclusion

Food supplement regulatory compliance is a layered exercise. Supplement-specific legislation establishes a common framework, but general food law and market-specific rules can determine whether a particular product, ingredient, label or claim is acceptable.

The appropriate starting point is therefore a documented, jurisdiction-specific assessment of the formulation, classification, labelling, claims and route to market. Food Cortex's subsequent Compliance Briefs address these areas in greater practical detail.