foodcortex

COMPLIANCE BRIEF

Formulation Compliance: Ingredients, Permitted Substances and Novel Foods

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

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At a glance

The regulatory acceptability of a food supplement must be established by reference to the **specific formulation, intended conditions of use and destination market**. Formulation review is therefore an early-stage control, preceding artwork approval, manufacturing commitment and commercial supply. The presence of an ingredient in a competing product does not demonstrate that the same substance, preparation or dose is lawful for another operator or market.

- Confirm the exact identity, source, specification, manufacturing process and proposed daily intake of every ingredient.
- Check the applicable **GB** and **EU/Northern Ireland** lists of vitamins, minerals and their permitted sources separately.
- Assess botanical materials, medicinal and culinary mushrooms, amino acids and other substances against national restrictions, general safety law and relevant specific measures.
- Assess novel food status and the authorised use conditions of any relevant novel food in each intended market.
- Check additives, carriers, excipients, contaminants, allergen issues and the potential medicinal classification of the finished product.
- Record conclusions, evidence, unresolved questions and approval gates in a controlled formulation assessment.

How to use this brief

Use it as a formulation assessment framework at concept stage and whenever a recipe, supplier, ingredient preparation or intended market changes. The sections that follow provide the principal formulation assessment considerations for commercial development and market entry.

1. Define the product before assessing ingredients

1.1 Product identity and dose form

EU Directive 2002/46/EC defines food supplements as dose-form foods intended to supplement the normal diet and comprising concentrated sources of nutrients or other substances with a nutritional or physiological effect. Corresponding concepts apply in Great Britain through domestic legislation. A product sold as a gummy, capsule or measured liquid is not automatically a food supplement merely because its marketing uses that description. [1,2]

The starting record should identify the product category, intended consumers, recommended portion, maximum foreseeable consumption, markets, claims and distribution channels. Formula development and regulatory assessment must use the same controlled version of the recipe.

1.2 Food or medicine?

Products presented as treating or preventing disease may fall outside the food supplement framework, and the medicinal-product borderline can also depend on composition, pharmacological effects and overall presentation. Changing the label to say “food supplement” does not itself resolve classification. Borderline cases require a product-specific assessment, potentially involving the relevant competent authority. [1,3]

2. Verify the actual ingredient

2.1 Identity is more than a common name

For each ingredient, the compliance dossier should establish its **unambiguous identity**: chemical designation or botanical genus, species and plant part; the material supplied; manufacturing and processing method; active or characteristic constituents; intended function; and specification limits. For extracts, the extraction solvent, drug-extract ratio or equivalent characterisation, concentration, standardisation and residual solvent profile may be determinative. These particulars are not interchangeable with a marketing name. Missing identity information should result in an explicit qualification or request for further evidence, rather than an assumption of compliance.

For example, a conventional powdered food, a concentrated botanical extract and an isolated constituent from the same plant may require different regulatory assessments. Do not treat them as interchangeable on the strength of a shared plant name.

2.2 Ingredient evidence file

An appropriate evidence package will normally comprise the controlled supplier specification; manufacturing and processing information; composition, identity and purity criteria; relevant batch certificates of analysis; allergen status; contaminant and microbiological controls; and supporting stability evidence. The depth of evidence required should be proportionate to the ingredient risk and intended use. Supplier declarations such as “EU compliant” may assist enquiries but cannot establish compliance without identifying the relevant legislation, preparation, dosage and markets. Where an assessment depends on unverified supplier data, that dependence should be recorded.

3. Vitamins and minerals: separate legal lists

3.1 EU and Northern Ireland

Article 4 of Directive 2002/46/EC permits only vitamins and minerals listed in Annex I and only their sources in Annex II, subject to the Directive’s conditions. The Directive has been amended: use the **current consolidated annexes**, not a saved 2002 extract. Northern Ireland continues to apply relevant EU food supplement law under the Windsor Framework, subject to applicable arrangements. [1,2]

The positive lists specify eligible **nutrients and source substances**, not a general safety clearance for any level of addition. The permitted source, chemical identity, applicable specifications and total daily intake must be considered separately. Safety assessments may need to take account of age, pregnancy, concomitant exposure from other foods and other food supplements, and relevant national provisions. Scientific upper-level opinions are important risk-assessment evidence but should not automatically be represented as statutory maximum permitted amounts.

3.2 Great Britain

England, Scotland and Wales operate under their respective Food Supplements Regulations 2003, as amended, and the applicable schedules of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019. These GB lists must be consulted separately from the EU Directive annexes. [2,4]

A live example of why amendment control matters is the 2026 changes to the GB Schedule 2 listing for magnesium L-threonate monohydrate, introduced through separate instruments and dates for the GB nations. An ingredient list or regulatory register may therefore require **country-by-country effective-date checking**, even within Great Britain. [4]

4. Botanicals, mushrooms, amino acids and other substances

4.1 Areas not fully harmonised

The EU food supplement framework harmonises certain vitamin/mineral requirements, but it does not provide a single positive list authorising all botanicals, amino acids or other physiologically active ingredients across every Member State. National rules and restrictions, together with general EU food law, must be checked. [1,5]

The legal position for botanicals and mushroom-derived ingredients must be assessed against the exact species, plant or fungal part, extraction or cultivation method, standardisation, dose and intended use. A national botanical list may be advisory, restrictive, conditional or linked to particular preparations. Neither the presence of a plant in an official reference list nor its use in another Member State establishes unrestricted authorisation for all extracts or for Great Britain. The distinction between lawful ingredient use and permissible **health claims** must also be maintained.

4.2 Botanical lists and fungal ingredients

Several countries publish botanical reference lists, national conditions or restrictions. The legal force of a list differs: an entry may describe customary use, identify a permitted plant part, prescribe warnings, or restrict a specific preparation. The applicant should therefore establish what the list actually determines and whether later legal measures alter that position. A plant appearing on one country's list should not be taken to constitute EU-wide authorisation.

Mushrooms are subject to the same need for precise identification. **Species, fruiting body, mycelium and extracted constituents must not be treated as interchangeable materials.** As a practical EU illustration, the Netherlands Food and Consumer Product Safety Authority (NVWA) identifies *Cordyceps militaris* as an unauthorised novel food and contrasts it with *Cordyceps sinensis* (now also classified as *Ophiocordyceps sinensis*), for which the Commission's Novel Food status catalogue records a history of use in food supplements. This is not an authorisation for every extract or for ordinary food uses: material, processing and intended food category remain material to novel food status. The GB position must be established independently; in September 2026 the UK Government stated that *C. militaris* was likely novel in GB based on the evidence then available. [14,15,16]

4.3 Conditions beyond ingredient identity

Regulation (EC) No 1925/2006 and applicable GB provisions may impose restrictions on certain substances. Other relevant measures may concern contaminants, specific plant toxins or medicinal-product classification. Relevant national prohibitions or limits must be checked against the product's destinations. [3,5]

5. Novel food assessment

5.1 The threshold question

Regulation (EU) 2015/2283 concerns foods or ingredients meeting the novel food definition, including those lacking significant EU food-use history before **15 May 1997**, where no applicable exclusion applies. The inquiry is specific to the ingredient and its production process, composition and intended use. [6]

The history-of-consumption test must address the **specific food or substance** and, where relevant, the process and food category concerned. Food supplement use before 15 May 1997 may in certain circumstances support non-novel status for supplement use only, not extension to ordinary foods. Conversely, substantial concentration, isolation or a materially different manufacturing process may give rise to a separate novel food question. Historical use of a botanical source is not sufficient evidence of a comparable consumption history for every extract or isolated constituent.

5.2 Demonstrating non-novel status and Article 4 consultations

Absence from an authorisation register or novel food catalogue does not establish non-novel status. The starting point under Article 4 of Regulation (EU) 2015/2283 is the food business operator's obligation to verify whether the food falls within the Novel Food Regulation. Where a non-novel position is claimed, it should be supported by evidence of significant consumption as food within the EU before 15 May 1997, taking account of the particular preparation and intended use. Unsupported assumptions that a food is permitted until a regulator establishes otherwise expose operators to enforcement and withdrawal risk. The Commission's Novel Food status catalogue expressly states that operators must be able to demonstrate relevant historical consumption. [6,14]

Where uncertainty remains following the operator's assessment, Article 4 provides a route for consultation with the competent authority of the Member State in which the food is first intended to be marketed. Commission Implementing Regulation (EU) 2018/456 establishes the consultation procedure and dossier requirements, including identity, production process, history-of-use evidence and supporting documentation. An Article 4 consultation addresses **status**; it is distinct from an application for authorisation of a novel food. GB operates its own arrangements and competent-authority process, so an EU status decision should not be assumed to dispose of a GB case. [17,18]

5.3 EU authorisations and conditions

For the EU, cross-check the Commission's Union list under Implementing Regulation (EU) 2017/2470 and its amendments. The entry may specify manufacturing source, purity, permitted food categories, maximum amounts, additional labelling and exclusive/data-protection arrangements. The Commission's Novel Food Catalogue is a useful official screening resource, **not** itself a definitive authorisation instrument. [6,7]

5.4 Great Britain and Northern Ireland

Great Britain has a separate novel food authorisation system. Since **1 April 2025**, applicable ministerial authorisations are reflected in the GB regulated-product register, which is a primary source for current GB novel food authorisations. Do not use an EU Union-list entry as proof of GB approval, or vice versa. Northern Ireland continues to apply relevant EU novel food rules. [8]

Where status is genuinely uncertain, record the evidence gap and consider the appropriate authority consultation process; do not classify the ingredient as lawful merely because an application appears in a public register.

6. Additives and formulation excipients

The review must extend to **all** constituents, including processing aids and excipients where relevant to the legal assessment, not simply the substances highlighted on the front label. For additives such as bulking agents, sweeteners, colours, carriers, coating agents and capsule-shell materials, determine the functional role in the finished product and whether the substance is acting as a food additive. Assess the appropriate food category, authorised technological function, restrictions and specifications. A substance identified by an E number is not automatically permissible in every supplement format or at every level.

In the EU, Regulation (EC) No 1333/2008 and its annexes govern permitted food additive uses; in GB, the official FSA/FSS regulated-product register is a key current authorisation source, with applicable food-category conditions. The status and function of a substance cannot be inferred from its E number alone. [9,10]

In the EU additive framework, food category **17.1** concerns food supplements in solid form, excluding those for infants and young children, while **17.2** concerns liquid-form supplements. The distinction is relevant to permitted additive entries and conditions. Some uses are subject to a numerical maximum; others are permitted at q*uantum satis*, which is not an unrestricted right to add the substance but remains subject to the applicable definition and good manufacturing practice. Annex II restrictions, carry-over provisions, purity specifications and any condition applicable to the exact product format must be checked. GB authorisations and conditions must be evaluated separately. [9,10] Where the legal classification of a capsule-shell constituent is disputed, document the interpretation and rationale rather than presenting an unresolved convention as settled law.

7. Safety and quantitative assessment

7.1 Contaminants and market-specific requirements

The contaminant assessment must identify both the relevant product category and the **legislation applicable in the destination market**. In the EU and Northern Ireland, Commission Regulation (EU) 2023/915 establishes maximum levels for specified contaminants in foods, including certain categories of food supplements. The GB legal position must be verified against the corresponding GB-applicable contaminants legislation and amendments; EU replacement legislation should not be assumed to have automatically replaced GB provisions. Pesticide residues, microbiological criteria and specific plant toxins may require separate assessment. [11,12,13]

A certificate reporting compliance with a generic heavy-metals panel cannot substitute for the complete contaminant assessment of a botanical extract, marine-sourced ingredient or another higher-risk raw material. Analytical scope, detection limits and the point in the supply chain at which limits apply should be documented.

7.2 Intake and safety rationale

Food cannot be placed on the market if unsafe. Review the full recommended daily exposure and reasonably foreseeable use, especially where multiple ingredients have overlapping physiological effects. Compare ingredient evidence with relevant safety opinions and national measures without presenting risk-assessment reference values as automatic legal maxima. [11]

Assess vulnerable populations, contraindications and interacting nutrients. Consider contaminants, allergens, stability, microbial risks, residual solvents and cross-contact risks. Where a claim depends on a particular daily nutrient amount, formulation and claims assessments should be reconciled without assuming that a permitted claim proves ingredient safety at the chosen dosage.

8. Case study overview: a multi-ingredient supplement for men

Consider a proposed capsule supplement positioned for adult men with a marketing focus on performance and endurance. The initial concept includes B vitamins, selected amino acids and a botanical preparation such as W*ithania somnifera* (ashwagandha). Regulatory review begins with the intended formulation, the actual daily portion, the intended consumers, the proposed claims and the countries of sale, not with the marketing narrative alone.

- **Vitamins and minerals:** each added vitamin or mineral must be supplied from a permitted source in the appropriate GB or EU/NI positive list, with relevant specification, purity and intake criteria satisfied. A named nutrient does not confer permission to use an unlisted source compound.
- **Amino acids and other substances:** establish the precise chemical or biological identity, intended function, daily intake, any applicable novel food status and national restrictions. Their inclusion in supplements marketed elsewhere provides no substitute for an assessment of the destination market.
- **Botanicals:** the botanical species, plant part and specific preparation must be characterised. For ashwagandha, assessment should distinguish root, leaf and other plant parts, extraction process and composition and take account of country-specific restrictions and current competent-authority safety positions. Denmark, for example,

prohibits the sale of food containing ashwagandha; that position cannot be extrapolated to all EU countries. [19]

- **Additives:** a solid capsule formulation generally directs the additive assessment to **category 17.1** in the EU framework, with a separate assessment of the GB provisions. Each additive's function, permissions, numerical limits or q*uantum satis* status, and applicable format restrictions must be established. A liquid alternative may instead engage category 17.2.
- **Safety, claims and presentation:** assess cumulative daily intake, contaminants, allergen and manufacturing controls, and whether any proposed endurance or performance claims are specifically authorised for the substance concerned and satisfy their conditions of use. The overall positioning must not imply treatment of a medical condition.

The case demonstrates how individual legal controls operate together. An apparently conventional multi-ingredient formula can require distinct decisions on nutrient sources, botanicals, novel foods, additives, safety and market-specific claims before final pack copy is prepared.

9. Pre-manufacture formulation checklist

- Product definition, intended market and consumer group are documented.
- Current ingredient specifications match the assessed recipe and supplier.
- GB and EU/NI vitamin/mineral source lists are checked separately, including amendments.
- Botanicals, mushrooms, amino acids and other substances have a market-specific regulatory assessment.
- Novel food status, authorisations and any conditions of use are substantiated.
- Additives, processing aids and excipients are checked for relevant permissions.
- Safety, contaminants, allergens and daily intake are assessed and documented.
- Legal and technical unknowns have an owner and escalation route.
- Manufacturing, claims and artwork cannot proceed on an unapproved formulation.

10. Primary legislation and official sources

The following official regulatory sources provide the legal framework and current competent-authority information referred to in this brief.

1. Directive 2002/46/EC on food supplements (consolidated text)
2. UK Government: Food supplements legislation guidance
3. MHRA: A guide to what is a medicinal product
4. Nutrition (Amendment etc.) (EU Exit) Regulations 2019: schedules
5. Regulation (EC) No 1925/2006: addition of vitamins, minerals and other substances
6. Regulation (EU) 2015/2283 on novel foods
7. European Commission: Union list of authorised novel foods
8. FSA/FSS: GB novel food authorisations register and guidance
9. Regulation (EC) No 1333/2008 on food additives
10. FSA/FSS: GB food authorisations register
11. Regulation (EC) No 178/2002: general principles of food law
12. Commission Regulation (EU) 2023/915: current EU contaminant maximum levels
13. GB-applicable Regulation (EC) No 1881/2006 on contaminants (as amended)
14. European Commission: Novel Food status catalogue and documentary evidence
15. Netherlands NVWA: 2025 enforcement investigation concerning Cordyceps militaris
16. UK Parliament: 2026 answer on Cordyceps militaris novel food status
17. European Commission: Consultation process on novel food status
18. Commission Implementing Regulation (EU) 2018/456 on Article 4 consultations
19. Denmark: Veterinary and Food Administration guidance on ashwagandha

Conclusion

A defensible formulation review is based on exact ingredient identity and intended use in clearly defined markets. **Permitted ingredient**, **non-novel ingredient**, **safe dose** and **lawful finished product** are different conclusions requiring different evidence. A controlled assessment completed before manufacturing is the most efficient point at which to identify unacceptable risks and costly changes.