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COMPLIANCE BRIEF

Food Supplement Safety, Manufacturing and Food Business Responsibilities

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

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At a glance

Food supplements are foods for the purposes of general food safety and hygiene legislation. Their manufacture, importation, storage and distribution must therefore be managed through appropriately designed and documented controls. **Contract manufacture does not, of itself, transfer all legal responsibility from the brand owner or the operator placing the product on the market.** Responsibilities must be identified for each food business operator and reflected in the relevant contractual and operational arrangements.

- Identify the food business operators responsible for each stage of manufacture, import, storage, distribution and sale.
- Apply suitable hygiene procedures and a documented food safety management system based on HACCP principles.
- Establish supplier qualification, specifications, traceability and appropriate testing and release controls.
- Assess safety of the **finished product**, including dose, contaminants, allergens, stability and intended users.
- Maintain a functioning withdrawal, recall and authority-notification process.
- Distinguish food business **establishment registration** from any separate **product notification** requirement.

How to use this brief

This is a scoping and operational-controls document for food supplement businesses, private-label suppliers and contract-manufacturing arrangements. It draws on current food law and official guidance, with particular attention to the practical responsibilities of food supplement businesses.

1. General food safety requirements

Article 14 of Regulation (EC) No 178/2002 prohibits placing unsafe food on the market. Article 17 places primary responsibility for meeting relevant food-law requirements on the food business operators at all stages within their control. This general framework operates in the EU, Northern Ireland and, in its GB-applicable form, Great Britain. [1]

Food can be considered unsafe if injurious to health or unfit for human consumption. Safety assessment must consider normal conditions of use, information provided to consumers, probable immediate and longer-term effects and sensitivities of particular consumer categories where relevant.

The use of ingredients that individually appear conventional is not sufficient to establish the safety of a **finished dose-form product**. Evaluate the actual daily consumption level and combined exposure.

2. Food business operators and responsibility allocation

2.1 Manufacturing and selling roles

A supply chain may include the ingredient manufacturer, contract supplement producer, packing facility, importer, brand owner, fulfilment provider, distributor and retailer. Each operator needs clarity about activities within its own control and any relevant legal role. [1,2]

A technical or manufacturing agreement should define specification ownership, supplier approval, deviation handling, batch disposition, complaint investigation, recall communication and records access. It is an important operational control but cannot displace statutory obligations owed by each relevant food business operator. The scope of responsibility should be checked against the actual supply chain, particularly where manufacture is outside the intended sales market.

2.2 Establishment registration and other permissions

Article 6 of Regulation (EC) No 852/2004 requires operators to notify competent authorities of establishments under their control for registration, subject to applicable arrangements. In England, Wales and Northern Ireland, FSA guidance states that food businesses generally must register with the local authority **at least 28 days before trading**. Scotland has its own registration guidance and enforcement arrangements. [2,3]

Registration of a food-business establishment is **not** the same as notifying a supplement product in an EU Member State. Specific operations or food types may need further permission; the responsible authority should be checked.

3. Hygiene and HACCP-based management

3.1 Legal hygiene requirements and good manufacturing practice

Regulation (EC) No 852/2004 establishes food hygiene obligations, including procedures based on HACCP principles where applicable to the relevant operator. The legal requirement should be distinguished from additional **good manufacturing practice (GMP)** arrangements adopted under company standards or guidance. GMP can be an appropriate means of demonstrating robust process control, but a voluntary industry certificate is not a statutory approval of the supplement or its composition. [2]

3.2 Process-specific controls

The controls established by each operator should reflect the activities carried out, the hazards associated with its ingredients and processes, and the size and nature of the operation. Contract manufacture requires clear coordination of hazard management and evidence of applicable controls, not an assumption that every safety responsibility passes to the supplier. [2]

Documented controls should address the actual process: raw-material acceptance, weighing, mixing, capsules or tablets, cleaning, cross-contact, storage, water, pests, employee hygiene, packaging and distribution. Identify hazards requiring prevention, elimination or reduction and define monitoring, corrective action and verification.

HACCP does not mean that every process step must be called a critical control point. The hazard analysis should justify the chosen preventive measures and monitoring arrangements.

4. Formulation safety and product specifications

4.1 Raw-material qualification

Specifications should identify the ingredient and relevant compositional markers, manufacturing origin, acceptance tolerances, microbiological status, contaminants, allergens, authenticity and storage needs. Additional checks may be appropriate for concentrated botanicals, high-dose nutrients, novel ingredients or vulnerable intended consumers.

Use supplier certificates and audits as evidence to be verified, not as an automatic transfer of responsibility. Record specification versions, deviations, outcomes and corrective actions.

4.2 Finished-product controls

A suitable finished-product specification should address identity, nutrient/active levels, unit-weight consistency, contamination, organoleptic or physical properties, packaging integrity, shelf life and appropriate release criteria. Testing intensity is risk-based and should be capable of detecting relevant failures rather than simply generating routine certificates.

Do not equate a laboratory result for a single batch with compliance across a changing supply chain. Stability, intended storage and meaningful batch records are equally important.

5. Allergens, contamination and consumers

5.1 Relevant contaminants rules

The applicable contaminant regime must be established separately for GB and EU/NI markets. Commission Regulation (EU) 2023/915 sets maximum levels for certain contaminants in foods in the EU; the GB-applicable legislation and any differences must be checked independently. A product-specific assessment should distinguish contaminants associated with the relevant botanical, mineral, marine or other source from hazards requiring general testing only where justified. Product category, units, sampling method and the stage at which limits apply matter. [7,8]

5.2 Verification of finished-product compliance

Regulation (EU) No 1169/2011, as applicable in the market, governs declaration and emphasis of specified allergens used as ingredients or processing aids, subject to the law's rules. Appropriate controls should also address unintended allergen cross-contact. Allergen risk cannot be settled by a generic "may contain" warning instead of preventive measures. [4]

Potential supplement-specific risks include excess exposure to particular vitamins or minerals, misidentified botanicals, undeclared pharmacologically active substances, pesticide residues, heavy metals, microbial contamination and unsuitable directions for sensitive consumers. The relevant hazard set depends on the exact formulation and supply chain.

6. Traceability and incident response

6.1 Traceability and retention

Traceability under Article 18 of Regulation (EC) No 178/2002 requires operators to be able to identify the businesses from which food or relevant substances were supplied and the businesses to which products were supplied, subject to the applicable rules. Effective batch-level systems should additionally enable timely identification of affected lots, dates, destinations and remaining stock. Records should be accessible within a timescale compatible with urgent incident response. [1]

6.2 Withdrawal, recall and competent-authority contact

The traceability arrangements described above must enable timely identification and location of affected lots when a food-safety concern arises. [1]

Article 19 addresses withdrawal of unsafe food that has left the operator's immediate control, competent-authority notification and, where necessary, effective consumer recall. Waiting for definitive laboratory confirmation can be inappropriate where available facts already give reason to believe that food is unsafe. [1]

Maintain a documented incident process defining initial triage, batch traceability, stock blocking, authority contacts, escalation, retailer communications, recall execution, effectiveness checks and subsequent corrective action. Periodically test retrieval of actual supply-chain records.

7. Importing and distributing across markets

The regulatory requirements governing entry from third countries, border procedures, product categories and the responsible importing operator must be assessed for the specific route. Packaging, labelling and claims should be aligned to the destination market before placing products on sale. Northern Ireland continues to apply relevant EU food law under the Windsor Framework, while GB has its own applicable rules; do not assume one set of controls resolves the other. [3,5]

Ireland and other EU Member States may also require food supplement product notifications or national ingredient checks in addition to food-business registration and general safety law. [6]

8. Illustrative contract-manufacturing handover

A brand commissions tablets from an external producer. The manufacturer makes and tests the product, but the brand controls the sales presentation and appoints the distributor. A useful handover requires an agreed, approved master formulation, ingredient/source specifications, batch and test documentation, dated claims and artwork masters, identified FBO details, distribution traceability and an escalation procedure for non-conformities. Neither party should assume that the other has performed a legal review of the finished product.

9. Operational compliance checklist

- Each FBO, legal role and contact point is identified.
- Necessary establishment registration/permission is confirmed.
- HACCP-based systems, procedures, hazard records and training are documented.
- Ingredient, supplier and finished-product specifications are current.
- Safety assessment considers dose, intended users and all relevant hazards.
- Labelling and allergens are verified against the approved recipe.
- Batch genealogy and one-step-back/one-step-forward records work in practice.
- A rapid withdrawal/recall and authority-notification plan is testable.
- Import, NI/EU market and notification requirements are allocated.
- Changes, non-conformities and complaints trigger documented review.

10. Primary legislation and official guidance

The following legislation and official guidance address the food safety and operator obligations discussed above.

1. Regulation (EC) No 178/2002: General Food Law, traceability and withdrawal
2. Regulation (EC) No 852/2004 on food hygiene
3. UK Government: Register a food business
4. Regulation (EU) No 1169/2011 on food information
5. UK Government: Food supplements legislation guidance
6. Food Safety Authority of Ireland: Food supplements legislation
7. Commission Regulation (EU) 2023/915 on maximum levels for certain contaminants
8. GB applicable Commission Regulation (EC) No 1881/2006, as amended

Conclusion

Food business operators retain responsibility for ensuring that products placed on the market meet the applicable safety and food information requirements. Contractual outsourcing of manufacturing or distribution does not, of itself, remove statutory obligations. A defensible operating system combines verified product design, suitably controlled manufacture, reliable traceability and the ability to act promptly when problems emerge.