EHPM Quality Guide

- Executive Summary

2022

Food supplements are defined by Directive 2002/46/EC as a specific category within the vast family of food products, and are described as *"[...] foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect"*.

Food supplements must comply with the safety and quality requirements applicable to all foodstuffs, as foreseen by harmonised EU legislation, and compliance is mandatory for all operators within the EU. As with all other foodstuffs, food supplements must be safe to use and truthful about the benefits they claim to deliver.

The EU Food Safety framework outlines the following obligations for Food Business Operators, with further detail to be found in guidance on the implementation of the requirements of General Food Law:

- **Safety:** operators shall not place on the market unsafe food or feed
- **Responsibility:** operators are responsible for the safety of the food and feed which they produce, transport, store or sell
- **Traceability:** operators shall be able to rapidly identify any supplier or consignee
- **Transparency:** operators shall immediately inform the competent authorities if they have a reason to believe that their food or feed is not safe
- **Emergency:** operators shall immediately withdraw food or feed from the market if they have a reason to believe that it is not safe
- **Prevention:** operators shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points
- **Co-operation:** operators shall co-operate with the competent authorities in actions taken to reduce risk

While safety may be the overriding principle in the production process of a food or food supplement product, quality and safety are so closely interlinked as to be all-but synonymous – and quality cannot be simply 'added in' during a product production run. Appropriate quality standards must be in place from the very beginning of the development and throughout the production process, from the selection of the raw materials to the finished product and beyond, to post market surveillance, so as to ensure the quality, safety and effectiveness of the food supplement.

The EHPM Quality Guide (first published in 2007), comprehensively describes the requirements for the production of food supplements in the European Union, from product concept through to manufacturing, quality control, packaging, distribution and storage. Specifically, it details both the legal and the recommended production requirements to help maintain safe and consistent production. The Checklists which accompany the Guide are intended as helpful tools to establish a company's level of performance, or that of its suppliers or contract manufacturers, relative to the quality requirements.

This third edition (2022) of the EHPM Quality Guide updates the overall quality requirements for food supplements and, importantly, incorporates a greatly enhanced section on the production of botanical food supplements, preparations which have a rich history of use in Europe. Botanicals are *material, preparations or substances obtained from plants or other vegetative organisms*, which are constituted by complex matrices.

The Guide covers the specific requirements for their use in food supplements, from the raw material through to the finished product, taking into account recent developments in manufacturing processes and latest best practices. A new *"EHPM Botanical Suppliers' Questionnaire"* accompanies this section - a checklist of the essential data that food supplement businesses require in the processing of botanicals and botanical preparations, including the information required from botanical preparation suppliers and across the supply chain.

The EHPM Quality Guide also comprises updated information on EU and, where applicable, national regulatory requirements for ingredients, labelling, and placing products on the market - and the role of mutual recognition.

Specific sections of the updated EHPM Quality Guide 2022, which has been written with the intention that it can be used by companies operating in any EU Member State or country that is a member of the European Economic Area (EEA), cover:

- **Legislation:** the requirements for the manufacture of food supplements as detailed in European Union legislation, including the incorporation of national best practice from several EU Member States

- **Quality and quality management:** defined as coordinated activities to direct and control an organisation with regard to quality, including details of requirements, specifications, guidelines and characteristics that products and processes should consistently meet in order to ensure their quality matches expectations; and that they are both fit for purpose and meet the needs of their users. Recommendations are given on the achievement of this goal via an integrated system which includes Quality Assurance, Quality Control and Good Manufacturing Practice.

- **Premises and equipment:** detailed requirements based on the principles that buildings should be located, designed, constructed, adapted and maintained to suit the operations carried out in them; that they should facilitate the protection of materials and products from contamination or deterioration; that equipment should be designed, constructed, adapted, located and maintained to suit the processes and products for which it is used.

- **Personnel and training:** the measures necessary to ensure that, compatible with the size and type of business, there are sufficient personnel at all levels with the ability, training experience and, as appropriate, the professional and technical qualifications for the tasks assigned to them; also that their duties and responsibilities are clearly explained and recorded as job descriptions or by other suitable means, and that formally authorised and documented deputies have been assigned to cover the absence of key personnel. Training must also include both general best practice and the statutory requirements for personal hygiene for food business operatives.

- **Product and process development, from the selection of raw materials through manufacturing, processing and packaging, to the finished product, warehousing, storage, transport and distribution:** the essential checks to be made when developing a new product or making changes to an existing product so as to ensure that the final product complies with current legislation regarding safety and legality and also that it meets consumer expectation within the intended circumstances of use. The testing and inspection procedures necessary to enable the monitoring of relevant parameters and the application of corrective action, should results fall outside specified limits.

- **Manufacture and Product Master Manufacturing Instructions:** the necessary procedures to ensure that the operations and processes used in manufacture, together with the premises, equipment, materials, personnel and services provided, are capable of consistently yielding finished products which conform to their specifications and are suitably protected against contamination or deterioration. Defined and documented manufacturing procedures, including associated activities and precautions, to ensure that all concerned understand what has to be done, how it is to be done, who is responsible, and how avoid mistakes which could affect food safety and quality.

- **HACCP:** how to set up and implement a Hazard Analysis Critical Control Point (HACCP) system and the documentary requirements to ensure that food supplement manufacturing processes correspond with the obligations of a HACCP system and can demonstrate full traceability, from raw material through to finished product. A systematic approach to the identification and assessment of the hazards and risks associated with the manufacture, distribution and use of a particular foodstuff, and the definition of means for their control which should be used by all levels of food businesses to help satisfy themselves and their customers that their products are safe - in an efficient, reliable and cost-effective way which focusses on hazard prevention throughout the food chain rather than relying on end-product testing.

- **Documentation and traceability:** all ingredients intended for use in food supplements must comply with the traceability requirements of Regulation (EC) No 178/2002 which defines traceability as the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution. Recommendations are given on what should be documented and how documentary evidence of traceability should be retained and maintained.

- **Post-marketing surveillance:** how to ensure an organised and coherent system and methodology to deal with complaints, product withdrawal and recalls and emergency procedures, as required under EU Regulation (EC) No. 178/2002.

- **Internal audits:** to monitor implementation and compliance with best practice, and to propose necessary corrective measures, including personnel matters, premises, equipment, documentation (including the HACCP system), production, quality control, distribution of products, and arrangements for dealing with complaints and recalls.

Designed to steer companies through the various quality and safety control processes that are needed to ensure the manufacture of safe and consistent food supplements – from 'farm to fork' - the overall aim for this third edition of the EHPM Quality Guide for Food Supplements is to help food business operators and food supplements manufacturers in particular, to comply with the EU legislation and other requirements applicable to their products in terms of quality and safety, as well as to ensure production of high-quality and safe products.

Implementing the EHPM Quality Guide is therefore the best way for food supplements operators to ensure both the safety and the satisfaction of the growing number of European citizens who use food supplements every day.

About EHPM

WHO ARE WE?
The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975 and since then EHPM has been the voice of the food supplement sector in Europe. Through its 14 National Associations and 12 Member Companies, EHPM represents approximately 1,600 health product manufacturers and distributors, the majority of whom are small and medium-sized enterprises (SMEs), in 17 European countries.

WHAT WE DO?
EHPM proactively develops concrete proposals and tools, such as this Quality Guide, through its technical working groups and task forces to help improve the EU regulatory framework for food supplements and to **establish and promote industry best practices for product quality, safety, and efficacy**.