ehpm
European Federation of Associations of Health Product Manufacturers

EHPM Quality Guide

2022

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Chairperson's letter

Dear Reader,

Food supplements are defined by Directive 2002/46/EC as a specific category within the vast family of food products. 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 regarding the benefits they claim to deliver.

Some specific issues related to food supplements—in particular, the use of botanical ingredients with a history of safe use and of positive effects on essential physiological functions—have not yet been addressed in EU legislation. Specifically, defining the conditions under which health claims can be made for botanical ingredients remains subject to the discretion of individual Member States.

In early 2020, EHPM launched its manifesto for the food supplement sector in Europe "Food Supplements for healthier citizens & a stronger economy in the EU". The manifesto comprehensively presented safety, quality, sustainability, transparency for consumers as EHPM's priorities and it sparked a prolific period of proactive initiatives and publications.

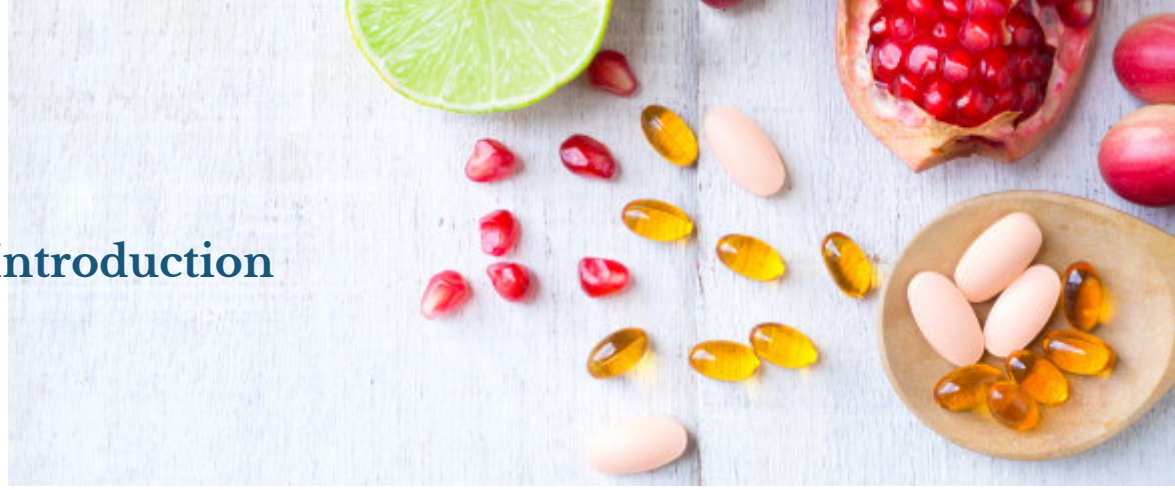
In the same year, the EHPM proposal for the assessment of health claims on botanical food supplements in the EU was published. This "graded approach" re-prioritises consumer choice and develops tailored assessment methodologies for botanicals, which are constituted by complex matrices.

The update of the EHPM Quality Guide falls within this general framework and will be soon followed by the publication of the EHPM Botanicals Safety Paper.

The EHPM Quality Guide is not only about HACCP and traceability. It covers all aspects of food supplement quality. Implementing the EHPM Quality Guide is therefore the best way to ensure both the safety and the satisfaction of the growing number of European citizens who use food supplements for supporting their well-being.

I would like to thank EHPM's national associations and members for the invaluable contribution that they have made to the preparation of this Quality Guide. As Chairman of EHPM, I understand the importance of the application of stringent quality standards for our industry. EHPM, its member associations and their member companies are passionately committed to providing consumers with safe, science-based, high-quality products as well as accurate and helpful information about the nutritional value and use of the food supplement products they choose to use. I encourage all companies active in the food supplement sector in Europe to use the EHPM Quality Guide as a reference document for auditing their manufacture, production and distribution procedures.

Antonino Santoro
EHPM Chairperson



1 - Introduction

Food Supplements are defined by European Union (EU) Directive 2002/46/EC as a specific category within the vast family of food products, 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 general quality and safety requirements applicable to all foodstuffs. The quality and safety of food supplements are covered 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 regarding the benefits they claim to deliver.

This Quality Guide covers all aspects of food supplement quality, including the incorporation of national best practice from several EU Member States concerning botanical preparations. Implementing the EHPM Quality Guide is therefore the best way for food supplements producers to ensure both the safety and the satisfaction of the growing number of European citizens who use food supplements every day.

2 - How to Use This Guide

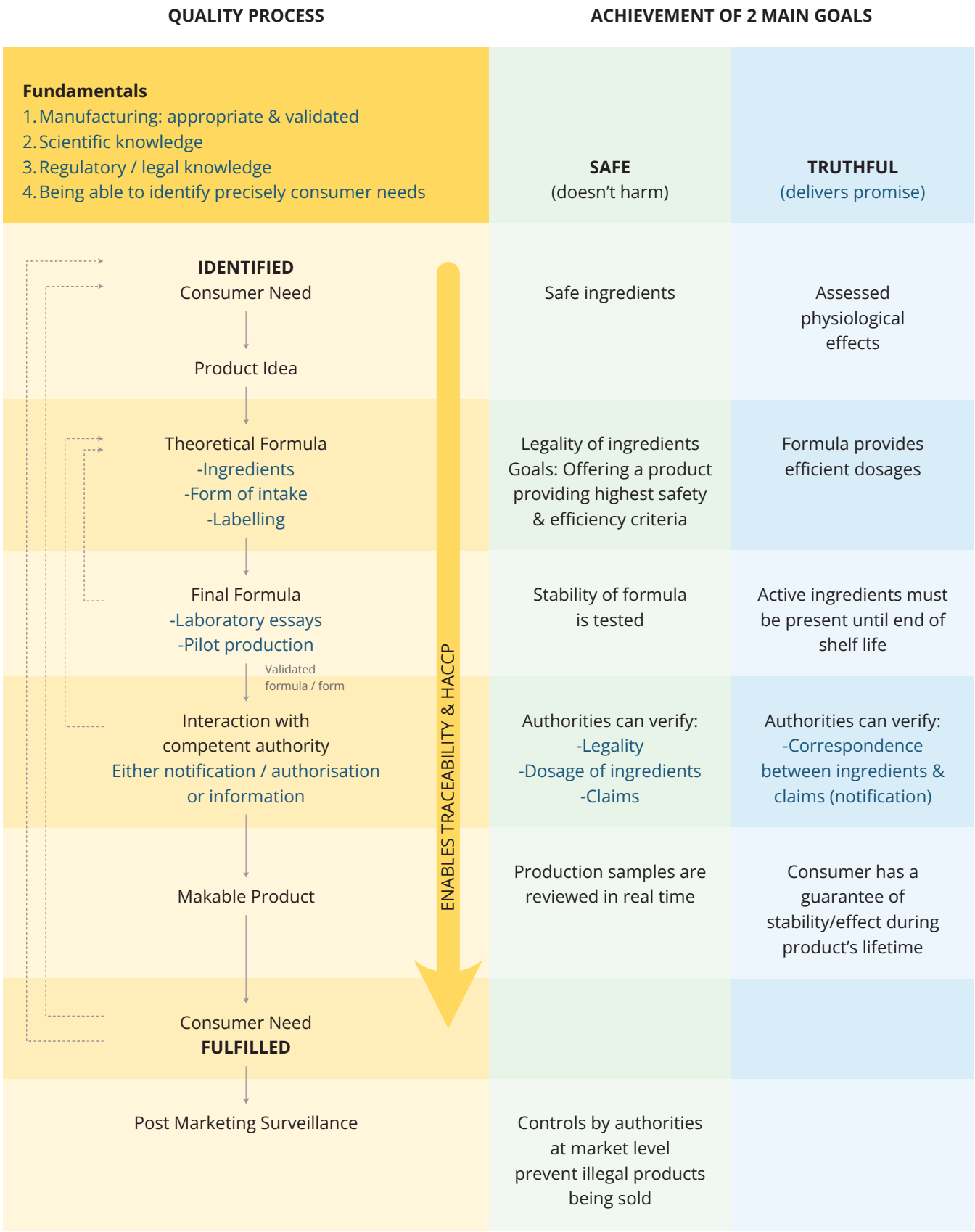
This Quality Guide is designed to steer companies through the various quality and safety control processes that are needed to ensure the manufacture of safe and consistent food supplements. When you have completed studying the guide, the checklists provided with the Guide are intended as helpful tools that you can use to establish your own level of performance, or that of your suppliers or contract manufacturers, relative to the quality requirements. These checklists are available on the EHPM website www.ehpm.org and manufacturers are encouraged to use them to manage their own quality performance and also to ensure that their contract manufacturers and raw material suppliers meet the required standards.

The diagram on the next page illustrates the optimal process to be followed in the development of a food supplement product. The diagram highlights the various factors that need to be taken into account from the product development stage all the way through to the placing of products on the market.

This Guide is focussed on common requirements applicable to the manufacture of food supplements across all countries. Readers are encouraged to study the conceptual approach outlined in the following page closely; the remainder of the Guide will then outline the practicalities of implementing the steps outlined in the diagram.

In studying the diagram please note:

- The development process starts with the identification of a consumer need (Identified) and ends with a corresponding product placed on the market (**fulfilled**).
- Each step addresses two basic goals:
    - Food Supplements (FS) must be **safe** (no potential harm to health of people consuming them due to composition and/or process).
    - FS must be **truthful** (a product claim for the enhancement of health due to a physiological effect must have sufficient supporting evidence to justify the claim).
- Manufacturing a FS implies that the production processes correspond to the obligations of risk management (**HACCP**) and being able to trace back the origin of a quality problem (**traceability**).
- The process incorporates **post-marketing surveillance** via an organised system for collecting and processing consumer comments or complaints regarding the product.


QUALITY PROCESS
ACHIEVEMENT OF 2 MAIN GOALS
Fundamentals
1. Manufacturing: appropriate & validated
2. Scientific knowledge
3. Regulatory / legal knowledge
4. Being able to identify precisely consumer needs
SAFE
(doesn't harm)
TRUTHFUL
(delivers promise)
IDENTIFIED
Consumer Need
Product Idea
Safe ingredients
Assessed physiological effects
Theoretical Formula
-Ingredients
-Form of intake
-Labelling
Legality of ingredients
Goals: Offering a product providing highest safety & efficiency criteria
Formula provides efficient dosages
Final Formula
-Laboratory essays
-Pilot production
Validated formula / form
Stability of formula is tested
Active ingredients must be present until end of shelf life
Interaction with competent authority
Either notification / authorisation or information
Authorities can verify:
-Legality
-Dosage of ingredients
-Claims
Authorities can verify:
-Correspondence between ingredients & claims (notification)
Makable Product
Production samples are reviewed in real time
Consumer has a guarantee of stability/effect during product's lifetime
Consumer Need
FULFILLED
Post Marketing Surveillance
Controls by authorities at market level prevent illegal products being sold
ENABLES TRACEABILITY & HACCP

3 - Introduction to EU and National Regulatory Requirements for Food Supplements

This Quality Guide 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)[1]. The requirements set out in the guide aim to incorporate not only the relevant EU legislation, but also national best practice in the area of food supplements manufacture. It is important to note that, while legislation in European countries which are not members of the EU and/or the EEA is likely to be similar to that of the EU, national legislation in such countries should always be checked for any national differences.

The following links give access to the EU regulatory framework, applicable to all EU Member States, which underpins the content of this Guide:

Food supplements (europa.eu) Directive 2002/46/EC, "The Food Supplements Directive" and the harmonised list of vitamins and minerals that may be added for nutritional purposes in food supplements (**Annex I**), and the list of permitted sources (vitamin and mineral substances) from which those vitamins and minerals may be manufactured (**Annex II**).

EUR-Lex - 52016XC0730(01) - EN - EUR-Lex (europa.eu) The implementation of food safety management systems covering prerequisite programmes (PRPs) and procedures based on the HACCP principles.

Legislation (europa.eu) EU Rules regarding Food Hygiene covering all stages of the production, processing, distribution and placing on the market of food intended for human consumption.

EUR-Lex - 02004R0852-20090420 - EN - EUR-Lex (europa.eu) Regulation (EC) No 852/2004 on Food Hygiene.

EUR-Lex - 32021R0382 - EN - EUR-Lex (europa.eu) Regulation (EU) 2021/381 amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, redistribution of food and food safety culture.

Food Supplement regulation in the EU is as yet not fully harmonised and there are some particular areas of potential national difference, including:

3.1 - INGREDIENTS

The regulatory structure in place for food supplements in the EU and EEA is not entirely harmonised. The level of vitamins and minerals that can be used in food supplements per daily intake varies across EU Member States and there are also diverging national rules in place on which other substances can be used in food supplements and at what intake. As an example, melatonin can be used in food supplements in Italy but can only be used in medicines in Ireland.

3.2 - LABELLING

Directive 2002/46/EC on food supplements provides a level of harmonisation on labelling requirements and the procedure for placing products on the market. It also lists the vitamins and minerals and their chemical forms that can be used in food supplements.

1 - Iceland, Liechtenstein and Norway

However, the levels at which they can be used are regulated at national level until such time as the European Commission produces a proposal to harmonise levels across the EU.

Aside from the Food Supplements Directive, general EU food labelling law is also applicable to food supplements. In this respect, Regulation (EC) No 1169/2011 Food Information to Consumers (FIC) has a direct impact on the labelling of food supplements through its provisions, for example, on minimum font size.

3.3 - PLACING PRODUCTS ON THE MARKET

The process for placing a product on the market is set out in Directive 2002/46/EC on food supplements. However, the way that process has been implemented varies significantly between EU Member States (MS).

In some MS, a simple notification of the product label to the relevant national authorities is sufficient, whereas in others the notification process foreseen in the food supplements directive has in effect become an application process where a fee is levied, a product dossier must be submitted and, depending on whether all ingredients meet national requirements or not, even some form of authorisation may have to be secured before a product can be placed on the market.

There are also some MS that do not require a notification before a product is placed on the market and some with a mixed approach whereby vitamin and mineral food supplements require simple notification but products containing other substances go through an authorisation system. Some MS also charge an administration fee for products that go through their notification and/or authorisation systems. The table below provides a breakdown by EU Member State plus the UK. However, we also advise operators wishing to place their products on the market to liaise with National Authorities to verify the system in place at that time.

Member State	Administration Fee	No Pre-Marketing Obligation	Notification System
Austria		√	
Belgium	√		√
Bulgaria			√
Croatia	√		
Cyprus			√
Czech Rep.			√
Denmark			√
Estonia			√

Member State	Administration Fee	No Pre-Marketing Obligation	Notification System
Finland	√		
France			√
Germany			√
Greece	√		√
Hungary			√
Ireland			√
Italy	√		√
Latvia			√
Lithuania	√		√
Luxembourg			√
Malta	√		√
Netherlands		√	
Poland			√
Portugal			√
Romania	√		√
Slovakia			√
Slovenia			
Spain	√		√
Sweden		√	
UK		√	

3.4 - MUTUAL RECOGNITION

While 3.1 – 3.3 above highlight some of the differences in national rules applicable to food supplements, one important piece of EU legislation is specifically designed to facilitate the free movement of goods in the EU. The mutual recognition principle ensures market access for goods that are not, or are only partly, subject to EU harmonisation legislation. It guarantees that any good lawfully sold in one EU country can be sold in another. This is possible even if the good does not fully comply with the technical rules of the other country (although there may be exceptions where public safety, health or the environment are concerned). Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another country came into force in April 2020 and replaces Regulation (EC) No 764/2008. It defines the rights and obligations in relation to the mutual recognition principle for competent authorities and businesses when selling goods in another EU country.

For further guidance on the general application of the Mutual Recognition Regulation, see https://ec.europa.eu/docsroom/documents/44930

4 - Quality Management

4.1 - GENERAL PRINCIPLES

As a general principle, quality management is defined as coordinated activities to direct and control an organisation with regard to quality. It encompasses details of requirements, specifications, guidelines and characteristics that products and processes should consistently meet in order to ensure their quality matches expectations; they are fit for purpose and they meet the needs of their users. Standards are an essential element of a quality management system. While many European companies have adopted ISO principles, the essential point is that there should be a comprehensive system so designed, documented, implemented and controlled, and so furnished with personnel, equipment and other resources as to provide assurance that products will be consistently fit for their intended use. The attainment of this quality objective requires the involvement and commitment of all concerned, at all stages of manufacture, storage and distribution.

The quality objective will be achieved by an integrated system including Quality Assurance, Quality Control and Good Practice. These three aspects of quality are defined as follows:

4.2 - GOOD MANUFACTURING PRACTICE

The basic requirements of Good Manufacturing Practice are that:

- All manufacturing processes should be clearly defined and known to be capable of achieving the desired ends.
- All necessary resources and facilities are provided, including:
  - Appropriately trained personnel
  - Adequate premises and space
  - Suitable equipment and services
  - Correct materials, containers and labels
  - Approved procedures (including cleaning procedures)
  - Suitable storage and transport
- Operators are trained to carry out the procedures correctly.

4.3 - QUALITY ASSURANCE

Quality Assurance is the part of quality management focussing on increasing the ability to fulfil quality requirements. ISO standards are often used to achieve this. The objectives of Quality Assurance will be achieved when processes have been defined and documented, which, when followed, will yield a product that consistently complies with its specification and the quality expected, and when the finished product:

- Contains the correct ingredients in the correct proportions
- Has been correctly processed, according to the defined procedures
- Is of the purity required
- Is enclosed in its proper container, which
- Bears the correct label (or is otherwise suitably marked or identified) and

- Is stored, distributed and recommendations given for its subsequent handling in accordance with the recommended storage conditions, so that its quality is maintained throughout its designated or expected life

Quality Assurance normally covers the following points:

a. Procedures are written in instructional form, in clear and unambiguous language, and are specifically applicable to the facilities provided.

b. Records are made during manufacture (including packaging), which demonstrate that all the steps required by the defined procedures were in fact taken, and that the quantity and quality produced were those expected.

c. Records of manufacture and distribution which enable the complete history of a lot to be traced, are retained in a legible and accessible form.

d. A system is available to withdraw or recall from sale or supply any lot or products, should that become necessary.

e. The quality assurance procedures of the suppliers of raw and packaging materials should be monitored, preferably with regular audits. A Supplier Quality Assurance procedure should be developed to define the criteria for selection, approval, review and ongoing approval to ensure that purchased products and services meet the organisation's requirements.

f. There needs to be rapid feedback of information in the form of summaries of quality performance data (accompanied, where appropriate, by advice) to manufacturing personnel, enabling prompt adjustment or corrective action to be taken when necessary; and to the purchasing function in respect of raw material lots

g. Customer/consumer complaint samples should be examined, the causes of defects investigated where possible, and appropriate measures advised for corrective action to prevent recurrence (see Chapter 14).

h. Due heed must be taken of new developments in EU food legislation, especially those requiring changes in compositional standards and labelling requirements which may necessitate changes to specifications for raw materials or finished products.

i. A continual review of Quality Assurance systems should be undertaken to ensure that they remain effective. This should be done by documented self-inspections.

4.4 - QUALITY CONTROL

Quality control (QC) is the part of quality management focussed on fulfilling quality criteria of a manufactured product. Quality Control activities include sampling and testing, specification setting, the documenting of test results and the operation of release and quarantine procedures. Such processes ensure that the appropriate tests are conducted on raw materials, packaging components and finished products, confirming that they are within defined acceptance criteria and can be released for manufacturing or sale. In addition, they also ensure that materials are held or quarantined until their quality has been established, or that they are rejected if they fail to meet their acceptance criteria.

To achieve effective control of quality:

a. The authority and responsibilities of the Production Management and the Quality Control Management functions respectively should be clearly defined so that there is no misunderstanding. Quality Control Management must be separated from Production Management and be empowered to make independent decisions on product quality; where possible there should be separate reporting structures.

b. Adequate facilities and staff should be available for sampling, inspecting and testing starting materials, packaging materials, intermediate, bulk and finished products, and where appropriate, for determining environmental quality.

c. Samples of starting materials, packaging materials, intermediate products, bulk products and finished products should only be taken by personnel adequately trained and using methods approved by the person responsible for Quality Control.

d. Results of the inspection and testing of materials, and of intermediate, bulk or finished products should be formally assessed against specification by the person responsible for Quality Control (or a person designated by him) before products are released for sale or supply.

e. Product assessment should include a review and evaluation of relevant manufacturing (including packaging) documentation.

f. Sufficient reference samples of starting materials and finished products should be retained (the latter in the final pack for the finished product) to permit future examination if necessary.

See also Chapter 16

4.5 - SERVICE LEVEL AGREEMENTS

A key element in guaranteeing that the quality and safety standards set out in this guide are met is the conclusion of Service Level Agreements (SLAs) with subcontract manufacturers and raw material suppliers. An SLA is essential to clearly define the responsibilities and commitments of the parties to it.

A good SLA helps ensure that raw materials and finished products are covered by adequate full specifications (as outlined in the other sections of this guide). Best practice requirements should be clearly emphasised and quality control, record transfer, coding, rejection, dispute and complaint procedures be identified and agreed. Items of possible confidentiality should be identified and any appropriate safeguards be mutually agreed.

Checklists for subcontract manufacturers and raw material suppliers can be downloaded from the EHPM website www.ehpm.org. These checklists can be used to:

- Establish what areas need to be addressed in SLAs with potential raw material suppliers or sub-contract manufacturers;
- Verify that existing raw material suppliers and sub-contract manufacturers are in compliance with their SLAs.

See also Chapter 17.9

5 - Food Premises and Equipment

5.1 - GENERAL

Buildings should be located, designed, constructed, adapted and maintained to suit the operations carried out in them and to facilitate the protection of materials and products from contamination or deterioration. Equipment should be designed, constructed, adapted, located and maintained to suit the processes and products for which it is used and to facilitate protection of the materials handled from contamination or deterioration.

5.2 - GENERAL REQUIREMENTS FOR FOOD PREMISES

a. Premises must be designed to allow cleaning and maintenance to be carried out to a high level.

b. Layout, design, construction and size should be such as to:

- Permit hygienic cleaning, good food hygiene practices, and suitable temperature/humidity conditions where necessary;
- Prevent cross contamination in the premises and contamination from external sources such as pests.

NOTE: The Revised Codex General Principles for Food Hygiene (5.2) contain helpful advice on pest control, see www.fao.org/fao-who-codexalimentarius/sh proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf

c. Facilities that must be provided:

- Availability of washbasins, lavatories
- Adequate supply of potable water
- Ventilation
- Lighting
- Drainage facilities
- Changing facilities for staff

5.3 - GENERAL REQUIREMENTS IN ROOMS WHERE FOODSTUFFS ARE PREPARED, TREATED, OR PROCESSED

a. Construction and design. Consideration must be given to smooth, crevice-free and easily cleanable:

- Floor surfaces
- Wall surfaces
- Ceilings and overhead fixtures
- Windows
- Doors
- Surfaces in contact with food.

b. Facilities. Consideration must be given to facilities for cleaning tools and equipment, where necessary.

5.4 - PREMISES

5.4.1 - GENERAL PREMISES AND BUILDINGS

Premises should:

- Provide sufficient space to suit the operations to be carried out;
- Allow an efficient flow of work;
- Provide suitable internal storage areas;
- Facilitate effective communication and supervision;
- Be sited with due regard for the provision of services needed and to avoid contamination from adjacent activities. In existing premises, effective measures should be taken to avoid such contamination;
- Be maintained in a good state of repair. The condition of buildings should be reviewed regularly, and repairs effected where necessary. Special care should be exercised to ensure that building materials of construction, repair or maintenance operations are not allowed to affect adversely product quality or integrity;
- Be constructed and maintained with the object of protecting against the entrance and harbouring of vermin, birds, insects, other pests and pets. There should be either trained personnel to oversee infestation control or a professional infestation control company should be employed for regular inspection, advice and treatment if required;
- Be maintained in a clean and tidy condition (including processing areas, laboratories, stores, passageways and external surroundings).

Manufacturing areas should not be used as a general right of way for personnel or materials, or for storage (except of materials in process).

Access to fire exits must not be blocked or restricted at any time.

5.4.2 - VENTILATION AND LIGHTING

Buildings should be effectively lit and ventilated, with appropriate air control facilities (including temperature, humidity and filtration where necessary) suitable both to the operations undertaken within them and to the external environment. Air supply and extraction trunking should be designed so that contaminants are not introduced into products. All lighting appliances should be completely covered by shatterproof plastic diffusers to contain any pieces of glass in the event of shattering. Brittle Material procedures should be developed detailing the action to be taken in the event of any breakage or damage to glass, ceramic or hard plastic items.

Fans should be positioned in order to avoid contamination hazards caused by either intake of noxious vapours, gases or solids, or release of materials which could contaminate [other] products, and with due regard for the local environment and the avoidance of nuisances such as odour, noise or dust emissions.

Pipework, light fittings, ventilation points and other services in manufacturing areas should be sited to avoid creating recesses which are difficult to clean. Services should preferably run outside the processing areas. They should be sealed into any walls and partitions through which they pass.

Piping must be identified and the flow direction should be reported.

Working conditions (e.g. temperature, humidity, noise levels) should be such that there is no adverse effect on the product, either directly or indirectly, via the operator.

5.4.3 - FLOORS, WALLS AND CEILINGS

Floors in manufacturing areas should be made of impervious materials, laid to an even surface and free from cracks and open

joints in areas where product is exposed. They should be of adequate construction and material for the wear and tear and conditions of manufacture encountered.

Drains should be of adequate size and should have trapped gullies and proper ventilation. Any open channels should be shallow to facilitate cleaning.

Walls should be sound and finished with a smooth impervious and easily cleaned surface.

Windows should be of toughened glass or plastic, adequately screened and secured, and with ledges sloped away from the glass at an angle to prevent items being left on them. Materials should be chosen so as to avoid tainting or otherwise contaminating food materials.

Doors should have smooth and non-absorbent surfaces in order that they are easy to clean and, when necessary, disinfect.

Ceilings should be so constructed and finished that they can be maintained in a clean condition. Suspended ceilings should not permit the accumulation of dirt and should be so installed as to reduce condensation, the formation of mould and the release of loose particles.

The coving of junctions between walls, floors and ceilings in critical areas is recommended.

5.4.4 - CLEANING AND SITE HYGIENE

All operations should be carried out in such a way that the risk of contamination of one product or material by another is minimised.

There should be written cleaning procedures and schedules for manufacturing and storage areas, external areas and vehicles used in the distribution supply chain. A Site Hygiene Plan should be developed to ensure a hygienic manufacturing site, thus minimising the risk of potential product contamination. This plan should be regularly reviewed. [see: Regulation (EC) 852/2004]

Vacuum or wet cleaning methods are to be preferred. Compressed air, hoses, pressure cleaners, brooms and brushes should be used with care, so as not to incur the risk of product contamination.

4.4.4.1 - WASTE

Waste material should not be allowed to accumulate. It should be collected in suitable receptacles for removal to collection points outside the buildings and disposed of at regular and frequent intervals. Disposal of printed packaging materials or raw materials and rejected products should be carefully controlled and a reconciliation carried out on quantities used and/or produced.

5.4.5 - RECEIVING AND DESPATCH AREAS

Protection from the weather should be provided for receiving and despatch areas, and for materials or products in transit.

Where appropriate, a defined de-boxing/ debagging area should be provided for those raw materials or packaging materials which arrive in external packaging.

5.4.6 - PERSONNEL HYGIENE FACILITIES

Cloakrooms must be provided and be separate from, or partitioned from, manufacturing areas.

Provision must be made for separate accommodation for clothing and footwear not being worn during working hours.

Adequate sanitary conveniences (flush toilets) must be provided and kept clean, complying with the detailed requirements of the regulations, including notices instructing users to wash their hands after using the convenience. Toilets must not open directly to manufacturing areas.

Rest and refreshment rooms should be separate from other areas.

Hand-wash basins and accompanying facilities (hot and cold water or temperature controlled hot water, soap or detergent, nail brushes and clean towels or other suitable drying facilities) must be provided and kept clean, at convenient places accessible to food handlers.

First aid materials as specified in the Hygiene Regulations must be provided in a place readily accessible to authorised First Aiders.

5.5 - EQUIPMENT

Equipment should be designed and arranged so as to protect the contents from external contamination and should not endanger a product through contamination from leaking glands, lubricant drips and the like, or through inappropriate modifications or adaptations.

5.5.1 - SURFACES AND MATERIALS IN CONTACT WITH FOOD SUPPLEMENTS

All surfaces and materials in contact with food supplements:

Must comply with the Materials and Articles in Contact with Food Regulation (EC) 1935/2004;

- Should be inert to the food supplements under the conditions of use and should not yield substances which might migrate or be absorbed into the food supplements;
- Should be microbiologically cleanable, smooth and non-porous so that particles are not caught in microscopic surface crevices and become difficult to dislodge;
- Should be visible for inspection or the equipment should be easily dismantled for inspection, or it should be demonstrated that routine cleaning procedures eliminate the possibility of contamination.

All surfaces in contact with food supplements should be readily accessible for manual cleaning or, if not readily accessible, then easily dismantled for manual cleaning, or if clean-in-place techniques are used, it should be demonstrated that the results achieved without disassembly are the equivalent of those obtained with disassembly and manual cleaning.

All interior surfaces in contact with food supplements should be so arranged that the equipment is self-emptying or self-draining.

Exterior surfaces of equipment not in contact with food supplements should be so arranged to prevent harbouring of soils, micro-organisms or pests in and on the equipment, floors, walls and supports.

There should be detailed written instructions for cleaning and sanitising. Specified materials, methods, safety precautions and suitable facilities should be provided.

5.5.2 - PLANT AND EQUIPMENT

Plant and equipment should be cleaned and serviced after use. Any faults should be recorded.

Any missing components such as nuts, springs, clips, etc. should be reported immediately. All lots produced since the previous check should be quarantined until the missing item is found or the lots have been shown to be clear (e.g. by metal detection or sieving).

Procedures describing the action to be taken for the control of foreign body contamination should be formally documented, and personnel should be actively encouraged to report without delay any incident of contamination or potential contamination of the product.

Plant and equipment should be checked for cleanliness and integrity before every use and to this end should be designed with sound, secure, quick-release systems for inspection and disassembly.

Appropriate precautions for ventilating fumes from power driven equipment, heaters, etc. should be taken.

5.5.2.1 - MAINTENANCE

Preventive maintenance should be considered for all equipment and components. A maintenance procedure, based upon risk assessment, should be established covering both preventive and responsive maintenance. This procedure must be highlighted to maintenance and machine servicing contractors.

Procedures should be in place to ensure that all product produced since the last satisfactory check can be identified, isolated and retested should the inspection and testing equipment be found to be functioning incorrectly.

5.5.2.2 - CALIBRATION

Regular calibration of all measuring equipment (weight, volume, temperature, etc.) should be carried out using suitable standards. Detailed records of the calibrations should be maintained and routinely audited to ensure that all calibration is up to date and that the equipment is working to the required level of accuracy. Once a piece of equipment has been calibrated it should only be adjusted by authorised personnel according to prescribed procedures, with any adjustments being formally recorded.

5.5.2.3 - WATER

Only potable water should be used as a minimum standard for all uses in production. Higher standards (such as de-ionised water) may be required for certain operations.

6 - Personnel and Training

6.1 - GENERAL

Compatible with the size and type of business there should be sufficient personnel at all levels with the ability, training experience and, where necessary, the professional and technical qualifications, appropriate to the tasks assigned to them. Their duties and responsibilities should be clearly explained and recorded as job descriptions or by other suitable means. Formally authorised and documented deputies should be assigned to cover the absence of key personnel.

6.2 - TRAINING (GENERAL)

Training should cover not only specific tasks, but best practice generally, and the importance of and factors involved in personal hygiene. Training should be given to each new employee upon employment and then repeated, revised and enhanced as applicable, with consideration given to any language or literacy difficulties. Refresher training should be given on a regular basis particularly in the case of poor hygiene practices being identified.

In addition to the training of employees involved in production and quality control, appropriate training should be given to all those who have any contact with the manufacturing areas or activities, such as office, maintenance and cleaning staff.

Persons* involved in the training of food handlers and in the administration of internal and external audits should be trained to a nationally recognised standard where applicable.

Training should be planned and recorded for each individual employee.

*Persons - in this context allows personnel or external consultants to be used.

6.3 - THE TRAINING OF FOOD SUPPLEMENT HANDLERS

Food businesses must ensure that food supplement handlers are supervised and instructed and/or trained in hygiene matters commensurate with their work activity.

Food businesses are responsible for identifying the detailed measures necessary and relevant to their own operation. These measures should ensure that all potential food handlers, including supervisors and managers, have the knowledge necessary for them to play their part in handling food hygienically so that the health of the consumer is properly safeguarded. What is appropriate in one business will not necessarily be appropriate in another. For example:

- Some businesses have a high turnover of casual labour making formal training difficult, but making good instruction and supervision very important.
- The nature and type of supervision necessary will depend on the number of food handlers within the unit of the business and the nature of their work.

The supervision and instruction and/or training needs must relate to the work undertaken by food handlers themselves and those in the nearby environment and the risks to food safety presented by their activities. In deciding on the relative risks presented, food businesses should consider:

a. The nature of the food supplements with which the operators work, for example, food supplements in capsule, tablet, liquid or powder form, each of which have different levels of concern.

b. How operators handle food supplements. What processing or preparation is being undertaken? Are there risks which the food handler needs to be aware of? What are they, not forgetting microbiological, chemical or foreign body hazards? This may include, for example:

    - Ensuring that staff are aware, when handling supplements in forms such as gelatine capsules, of the need for high personal hygiene standards. Food handlers should, where necessary, be aware of procedures to keep toxic substances, such as cleaning materials, separate from ingredients and products, or of procedures on a production line to check for and reduce the risk of foreign bodies such as glass or metal in products.

6.4 - PERSONAL HYGIENE

Chapter 6 of the revised Codex General principles for Good Hygiene contains helpful guidance on the requirements, including:

- Personal cleanliness and clothing;

- Infected food handlers: The Codex General Principles (7.2) contain helpful advice on these requirements.

See: www.fao.org/fao-who-codexalimentarius/sh proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf

6.4.1 - STATUTORY REQUIREMENTS

These are as follows:

a. Personnel must keep as clean as is reasonable all parts of their person, clothing or overclothing liable to come into contact with the food; must keep any open cut or abrasion on any exposed part of their person covered with a company issued detectable blue metal strip plaster, which must be issued, signed out and checked at the end of production to ensure it is still in place. Normal plasters applied to wounds received outside of the workplace must be removed and replaced with the company issued plasters. If a plaster is lost during production, this must be reported immediately to the relevant manager and the procedures for the control of foreign body contamination must be followed.

b. Personnel must not spit, smoke, use snuff or chew gum in any food room or room in which there is open food. Food and drink must not be taken into or consumed in production areas.

c. Personnel must wear sufficient clean and washable or disposable overclothing (including headgear and, where appropriate, neck-covering and/or beard snood).

d. Persons suffering from, or carriers of, certain kinds of infection (typhoid, paratyphoid, any other salmonella infections, or amoebic or bacillary dysentery or any staphylococcal infection, which could include an infected cut) likely to cause food poisoning, must not be allowed to handle food; personnel suffering from any such infection must inform the manufacturer who must in turn immediately inform the relevant Health Authority if required.

6.4.2 - BEST PRACTICE REQUIREMENTS

In addition to the statutory requirements, Best Practice (adapted to national requirements) may involve:

a. The provision of safety footwear and suitable protective overclothing, and the laundering thereof.

b. The provision of a separate and suitably equipped changing room.

c. Pre-employment medical checks or certification so that no person suffering from or a carrier of any of the specified kinds of infection is employed as a food handler. Visitors and contractors should be verbally requested, prior to entering a production area, to inform the relevant staff member of any recent illness that may pose a risk of contamination to products. Contractors should be asked to read the hygiene requirement specific to that part of the operation in which they are working.

d. The use of a personal medication procedure to control personal medicines such as decongestant nasal sprays and those for diabetes or asthma.

e. The active encouragement of personnel to report infections and skin lesions, and the encouragement of supervisory personnel to look out for signs and symptoms of such conditions.

f. The following of "return to work" procedures after illness or holidays abroad with emphasis on diseases contracted during the period abroad.

g. The prohibition of the wearing of wrist watches and jewellery except for plain wedding rings or plain sleeper earrings (without studs) for pierced ears in "open food" areas. There should be a clear policy on the type of jewellery permitted for medical, ethnic or religious reasons and the controls in place to reduce the risk of product contamination and ensure employees' health and safety.

h. Where the risk exists, the carrying of loose items (including mobile phones) in the production areas should be restricted or prohibited. Outerwear (coats or overalls) should not have external pockets.

i. The removal of protective clothing before break periods and on leaving the production area.

j. The keeping of fingernails clean, short and unvarnished. False fingernails or nail varnish should not be worn due to the risk of foreign body contamination.

k. The use of procedures for hand washing, ensuring personnel wash hands before commencing work, on return to the production area, after toilet and rest breaks and after handling waste or cleaning. Antibacterial cream should be applied to hands after washing in areas of high microbiological sensitivity.

l. The use of a procedure to control the issue of gloves to prevent them being a source of foreign body contamination. Personnel training should include the understanding that the wearing of gloves does not reduce the need for adequate hand washing.

m. The use of "Brittle Material" procedures in the event of breakage of glass or hard plastic lenses in spectacles.

7 - Product and Process Development

7.1 - GENERAL

A HACCP study should be applied (see section 12) from the earliest stages of product and process development to eliminate or minimise potential hazards and to aid the incorporation of effective control parameters into the product design.

Basic checks need to be made when developing a new product or making changes to an existing product 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. Testing and inspection procedures should be developed to enable the monitoring of relevant parameters and the application of corrective action, should results fall outside specified limits.

Continued attention should be paid to any changes in legislation to ensure that existing products maintain compliance in all areas of production (see 4.4).

The following sections provide a guide to the necessary checks that need to be made when developing a new product.

7.2 - SELECTION OF RAW MATERIAL

Each ingredient should be characterised by a positive identification e.g. macroscopic microscopic chemistry, and should be linked to a specification with all identification details and other parameters required to confirm the characteristics of the ingredient.

a. The product specification:

- Product specifications should be developed so as to facilitate full characterisation of the ingredients along with limits or ranges of all the relevant parameters that allow control of the composition of active ingredients and all applicable legal requirements.

- Limits and unofficial ranges should be realistic in the context of an assessment of the risk.

b. Composition and activity of the ingredients:

- The composition and recommended intakes of the product must be based on the use and/or the specific knowledge of the product, and in the common use of the ingredient. Once the composition of a product has been set, the relevant active components of the ingredients should remain within an acceptable range in each batch/lot. The acceptable range is determined by the chemical ingredient analysis and active components set out in the specifications.

- Records of analyses of batches/lots must be retained and must be compared regularly.

- Where results fail to comply with the acceptable range, the batch/lot must be quarantined and cannot be released for use, unless there is warranted documentation.

- Vegetable ingredients in powder or extracts that are outside the chemical

specifications may not be used for the production of plant-based food supplements, unless there is warranted documentation.

c. Extraction Solvents: (for further information on extraction solvents, see EUR-Lex - 32009L0032 - EN - EUR-Lex Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. See also 17.3.2 for further information on botanical material).

- All the extraction solvents used for the preparation of extracts of botanical ingredients for use in food supplements must comply with the legislation on extraction solvents for use in food and residue limits must not be exceeded. This legislation lists the permitted solvents, and for a number, conditions of use and maximum residue levels.

- The selection of the appropriate solvents and solvent ratios is an important aspect of the extraction process. Solvent ratios are normally defined in terms of the ratio of the solvents (e.g. aqueous/ethanol 60:40). In some cases the percentage of the major solvent can be given (e.g. ethanol 40% v/v).

- The type, concentration and quality of each extraction solvent will affect the spectrum of components obtained from a given amount of botanical material and can have an impact on the safety of the preparation.

- A detailed knowledge of the chemistry of the botanical material is required before the solvent(s) can be selected. The chemistry of the material has to be reviewed in the context of its aqueous (water) extractable components and its alcohol/organic solvent extractable components. Frequently, both forms of solvent and the ratio of the solvents will need to be adjusted to the proportions of the relevant extractables.

- Once the solvents and solvent ratios have been selected, the substance profile of the native extract should be compared with the phytochemical profile of the starting material to verify that the solvent is appropriate.

- Once a solvent system is selected and verified it should not be changed, as any changes could result in a significantly different extract.

- Once the solvent ratio/concentration has been established, the acceptable tolerances for the variation in the ratio should be defined. The tolerance is the variation either side of the target quantity. For example, a ± 5% tolerance on a 60:40 ratio would be from 65:35 to 55:45.

- It cannot be assumed that a single tolerance is applicable for all botanicals. A justification for the tolerance applied should be available.

d. Aspects that should also be taken into consideration:

- The format of the product (e.g. Tablet, granule, effervescent, concentrates, etc.) must be appropriate and relevant to the active ingredients used.

- The format of the product must be inert or should not adversely affect the composition of the ingredient or its biological activity.

- Combination products must be properly tested before full commercial production to ensure that there are no problems of stability or other undesirable interactions caused by the mixture of ingredients.

- Particular aspects that must be considered when choosing vegetable ingredients are addressed in Chapter 17.

7.3 - CHECK LEGALITY OF INGREDIENTS FOR ALL INTENDED MARKETS

As indicated in section 3, when developing products for national markets within the EU it is crucial to take into account the overlap between national and EU legislative requirements for ingredients. For product ingredients, factors to be assessed are:

- Compliance with any compositional legislation
- All additives permitted and below maximum levels (regulation 1333/2008) and follow specifications (regulation 231/2012)
- Maximum levels checked in products (e.g. preservatives, antioxidants)
- Official approval obtained for novel ingredients (regulation 2015/2283)
- Vitamins and minerals form permitted (Regulation 1170/2009)
- Below maximum level of vitamins and minerals (national maximum level)
- Substances for nutritional or physiological purposes permitted (Regulation 609/2013 + national list)
- Flavourings: Regulation (EC) No 1334/2008 lays down the general requirements for the safe use of flavourings. Annex II lists substances which may not be added to food, and maximum levels of certain substances naturally present in flavourings and in food ingredients with flavourings properties.
- All components of compounded ingredients permitted
- Prohibited ingredients (such as novel ingredients) not present
- Composition does not infringe patents
- Irradiated status
- Presence of genetically modified organisms (GMOs)

7.4 - CHECK SAFETY OF INGREDIENTS

(See also Chapter 17.4 for special requirements for Botanical Ingredients. Note 17.4.4.1: ETO contamination and safety)

Raw materials and final product meet microbiological criteria:

- Formula considered for potential chemical interactions.
- Micronutrient levels (e.g. zinc, vitamin A) are within accepted safety levels and are appropriate for the Target population.
- Ingredients and final products comply with current legislation on contaminants.
- where applicable, safety checks have been carried out on individual and combinations of herbs.
- potential allergen sources identified/ substituted.

7.5 - CHECK STABILITY OF FORMULA

It is a legal requirement that products, including those based on botanicals, must meet the label claim throughout the period of declared shelf life and must meet the expectations of the consumer. Therefore, the person responsible for putting the food supplement on the market has to determine the length of time during which the product, after being packed for sale, will comply with its label claims.

The determination of this date is based on the date of production and takes into account data from:

- Stability studies on the actual product, either from real time testing or accelerated testing as determined most appropriate to the particular product by the manufacturer;
- Use of previous data from other stability studies made on similar products, where appropriate;
- Extrapolation of results from relevant bibliographic data.

If stability studies are necessary to estimate the shelf life of a botanical product (for example, in cases where there is no appropriate accumulated data as described in the section above), tests should be carried out on the final supplement product as sold to the ultimate consumer.

As product stability is dependent on the barrier properties and seal integrity of the packaging, all stability studies should be carried out in the selected packs. Any change in packaging can require a re-evaluation of stability.

The stability studies on the extract should be designed in such a way that changes to the chemical composition of the botanical(s) can be detected.

In particular, it is recommended that the following factors are checked under normal conditions of transportation and storage, both in sealed containers and after opening and during usage, to replicate the typical storage and manufacturing conditions of the extract user:

a. Organoleptic properties (taste, smell, presentation/appearance, and colour) and notably:
    - Colour and flavour stability.

b. Chemico-physical and microbiological properties, and notably:
    - That the final product does not permit microbiological growth
    - Fat stability (oxidation/rancidity in fish or vegetable oils)
    - Physical changes on storage (appearance, caking, hardness, agglomeration)
    - There are no interactions between ingredients (to confirm prior theoretical checks based on the chemistry of the components)
    - Levels of any relevant active constituents and extract composition profile are maintained within justified limits throughout the shelf life
    - Where relevant, the stability in use of the product/extract i.e. the stability of the product/extract after opening the pack and during the expected consumption period
    - Chromatographic fingerprinting to support the composition stability

These checks allow the operator to ensure that the expiry (Best Before End) date is valid for declared ingredients.

Additional guidance on shelf-life issues can be found in documentation available from The International Alliance of Dietary/Food Supplement Associations (IADSA). www.iadsa.org

7.5.1 - OVERAGES

Some ingredients in food supplements may be inherently unstable and their levels may reduce over the product's given shelf life. However, EU regulation requires that the total amount of the ingredient per recommended daily intake should be present in the product throughout its shelf life.

To solve this dichotomy an "overage", defined as the difference between the formulated and declared levels, may be added - the amount dependant on the

known stability of the ingredient in the product matrix.

It should be noted that that the total amount of the declared level of the ingredient per recommended daily intake must be well below any known safety concerns.

For further guidance, see: https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition-vitamins_minerals-guidance_tolerances_1212_en.pdf

7.6 - CHECK LEGALITY OF LABELLING

It is crucial to ensure that all mandatory information required under relevant legislation is provided on labelling.

7.6.1 - GENETICALLY MODIFIED ORGANISMS (GMOS)

In the case of labelling for genetically modified (GM) ingredients, it is essential to:

- Clearly indicate all ingredients produced from genetic modification.
- Ensure that the GM source is approved for use in foods.
- In the case of pre-packaged GM food/feed products, the list of ingredients must indicate "genetically modified" or "produced from genetically modified [name of the organism]".
- In the case of products without packaging these words must still be clearly displayed in close proximity to the product (e.g. a note on the supermarket shelf).
- **N.B.** These labelling requirements do not apply to GM food/feed products in a proportion no higher than 0.9% of the food/feed ingredients considered individually and if this presence is adventitious or technically unavoidable. For further detail, see: Traceability and labelling (europa.eu).

7.6.2 - Other essential labelling requirements

It is also essential that:

- Compositional statements (e.g. laxative statement, indication of sweeteners) are in compliance with legislation and in the appropriate position.
- All potential allergenic sources are identified and highlighted in the ingredients list. EU Regulation 1169/2011 on the Provision of Food Information to Consumers requires that the presence of allergens is labelled on the finished product.
- Appropriate warnings and/or advisory statements are made for micronutrient levels (e.g. iron, vitamin A), where required nationally.
- All components of compounded ingredients are listed in compliance with legislation.
- Requirements of the Food Supplements Directive are in compliance with legislation.
- Quantity Indication of Ingredients (QUID) is in compliance with legislation.
- Any products that have been legally irradiated or contain legally irradiated components should be labelled appropriately.
- Information is in the required native language(s) of the intended market.

7.7 - CHECK LEGALITY OF CLAIMS

- Check legality of intended claims under food law ensuring they do not contravene current legislation.
- Energy calculations are in compliance with legislation for macronutrients.
- Vitamin and mineral calculations are in compliance with legislation.

- Active components are correctly calculated, taking into account moisture, assay levels, etc.
- Minimum levels for claims can be met at the end of declared shelf life and can be met at the lower end of raw material specification ranges.
- Intake (dose)/response relationships for nutrients are in accordance with scientific studies.
- Claims are not misleading and can be substantiated by generally accepted scientific evidence.

7.8 - CHECK PROTECTION/ APPROPRIATENESS AND LEGALITY OF PACKAGING

(also see 7.4 above)

- Packaging should be appropriate for the product with light/moisture/oxygen barriers.
- Product contact surfaces of packaging should be in compliance with legislation.
- Packaging recoverability (e.g. recycling) should be in compliance with legislation.
- Check compliance with legislation for maximum levels for heavy metals (Directive 94/62/EC).
- Select appropriate packaging that will maintain stability of the product throughout shelf life.
- Packaging should not be misleading i.e. pack size should not be excessively larger than the contents volume.
- Packaging should conform to minimum safety and hygienic standards for the packed product and consumer.
- Statutory label information is legible, intelligible and in appropriate position according to legislation.

7.9 - CHECK THE PRODUCT CAN BE MADE SAFELY AND CONSISTENTLY

- Take into consideration tolerances on raw material specifications and the ability to meet claims at extremes of specification ranges.
- Check homogeneity can be achieved by the mixing process.
- Where appropriate, perform trials on production lot sizes to check de-mixing during in-process handling and packing.
- Ensure raw materials and products are protected from effects of moisture/ oxygen/light.
- Check tolerances on finished product specifications and the ability to meet claims at extremes of specification ranges.
- Check integrity of pack seals/barriers to ensure packaging consistently seals.

8 - Manufacture

8.1 - GENERAL

The operations and processes used in manufacture should, together with the premises, equipment, materials, personnel and services provided, be 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, are necessary to ensure that all concerned understand what has to be done, how it is to be done, who is responsible, and to avoid mistakes which could affect food safety and quality. This is provided in the Master Manufacturing Instructions for each product. All personnel responsible for decision-making or authorisation at any stage during the process should be formally defined.

8.2 - SUITABILITY FOR PRODUCTION

Before the introduction of Master Manufacturing Instructions for a product, trials should be carried out to establish whether the formulation, methods and procedures specified therein are suitable for factory production, and are capable of consistently yielding products within the Finished Product Specification. If necessary, amendments and further trials should be made until these conditions are satisfied.

Similar evaluation should be carried out in connection with any significant proposed change of raw material, plant or method.

Similar evaluation should be carried out periodically, to check that the Master Manufacturing Instructions are being followed, that they still represent an effective and acceptable way of achieving the specified product and that they are still capable of consistently doing so.

Tests should be conducted in accordance with previously defined procedures and a record made of the results. The necessity, extent and degree of the work will depend on the nature and complexity of the product and process as determined by the manufacturer.

8.3 - DOCUMENTATION

Production staff should follow defined and authorised procedures for each stage of each manufacturing process, i.e. the manufacture of a product should proceed in accordance with the Master Formula and Method, and/or with the Master Packaging Instructions, supplemented as necessary by Standard Operating Procedures. The details of the operation should be recorded on the Lot Manufacturing Record, or Lot Packaging Record.

Any deviation from defined procedures must only be by prior agreement, and must be recorded and agreed by the person responsible for production and the person responsible for quality control, or their assigned deputies.

Before any manufacturing operation begins, steps should be taken to ensure that the work area and equipment are clean and free from any starting material, packaging material, products, product residues or documents not required for the current operation.

At all times during processing, all materials, bulk containers and major items of equipment used should be labelled or otherwise identified with an indication of the product or material being processed, its strength (where applicable) and lot number. Where applicable, this identification should also indicate the stage of manufacture and status.

Operating instructions for production operators should be written in clear, unambiguous, instructional form and should form a key part of operator training. Due regard should be given to reading or language difficulties of some operators and that the significance of the instructions are fully understood.

Particular attention should be paid to problems that may arise in the event of stoppages, breakdowns or emergencies, and written instructions should be provided for action to be taken.

8.4 - RAW MATERIALS/INGREDIENTS

8.4.1 - SPECIFICATIONS

Each raw material/ingredient must have a specification and must comply with it.

8.4.2 - DELIVERIES

Each delivery lot should be given a reference code to identify it in storage and processing, and the documentation should be such that, if necessary, any lot of finished products can be correlated with the deliveries of the respective raw materials used in its manufacture and with the corresponding laboratory records. Deliveries should be stored and marked in such a way that their identities do not become lost, except in the case of bulk deliveries.

Any pallets or deliveries should be cleaned, if necessary, before entering the warehouse.

8.4.3 - QUARANTINE

Reception of raw materials/ingredients should be quarantined until inspected. Release can either be based on certificates of analyses provided by the supplier, or sampled and tested in accordance with agreed specifications, and released for use only on authority of an authorised person. Particular care should be taken where a delivery of containers appears from markings to include more than one lot of the supplier's production, or where the delivery is of containers repacked by a merchant or broker from a bulk supply. Where appropriate, immediate checks should be carried out for off-flavours, off-odours, or taints, and particularly in the case of additives, testing should include test of identity, i.e. establishing that the substance is what it is purported to be. (N.B. In a multi-container delivery it is impracticable to check the identity of the contents of every container on arrival but operators should be trained and encouraged to report immediately anything unusual about the contents when a fresh container is brought into use.)

The General Food Law Regulation (EC) No. 178/2002 requires operators to keep records of the suppliers of every lot of raw materials/ingredients received, as part of the traceability system. Records must be kept available for inspection by the competent authorities for the period required by national legislation.

Temporarily quarantined material should be located and/or marked in such a way as to avoid risk of its being accidentally used. Material found to require pre-treatment before being acceptable for use should be suitably marked and remain quarantined until pretreatment. Material found totally unfit for use should be suitably marked and physically segregated pending appropriate disposal.

In the case of a bulk delivery by tanker, preliminary quality assessment should be

made before discharge into storage is permitted, and systems should be in place so that the material can be traced to a certified source.

8.4.4 - STORAGE, ISSUE OF RAW MATERIALS, DOCUMENTATION

All raw materials/ingredients should be stored under hygienic conditions, and in specific conditions (e.g. of temperature, relative humidity) appropriate to their respective requirements as indicated in their specifications, and with due regard to any legislation relating to the control of hazardous substances.

Stocks of raw materials/ingredients in store should be regularly inspected and sampled/tested where appropriate, to ensure that they remain in acceptable condition.

In issuing raw materials/ingredients from store for production use, correct stock rotation should normally be observed, unless otherwise authorised or specified by Quality Control.

Authorised procedure and documentation should be established and followed for the issue of raw materials from store.

When a raw material/ingredient has been issued but not used as planned (e.g. because of a plant stoppage) Quality Control should advise as to its disposition.

8.4.5 - WEIGHING, DISPENSING, DOCUMENTATION

Depending on the product being manufactured, the ingredients involved and the nature of the process and equipment, the dispensing of the required quantities of ingredients could take various forms, including manual dispensing by weight or volume, or continuous metering by volume; the form(s) actually taken will be stated within the Master Manufacturing Instructions. In each case, the weighing and/or measuring equipment should have the capacity, accuracy and precision appropriate to the purpose, and the accuracy should be regularly checked.

Where lot quantities of an ingredient have to be dispensed manually into containers in advance, this should be done in a segregated area. Where manual pre-dispensing of relatively small and accurate quantities (for example of micronutrients or additives) is required, this should be done by, or under direct supervision of, suitably trained staff. All weighing should be checked by a second operator or by use of a validated computerised weighing control system.

Records should be kept enabling the quantities of materials issued to be checked against the quantity or number of Lots of products manufactured.

Where an operator controls the addition of lot quantities of one or more ingredients to a lot, the addition of each ingredient to a lot should be recorded at the time on a Lot Manufacturing Record, to minimise risk of accidental omission or double addition.

The final yield, and any significant intermediate yield, of each production lot should be recorded and checked against the expected yield within defined limits. In the event of a significant variation, steps must be taken to prevent release or further processing of the lot (or of any other lots, or products processed concurrently, with which it may have become admixed) until an adequate explanation can be found which permits release or further processing.

8.5 - PACKAGING MATERIALS

Each packaging material must have and must comply with its specification (including any legal requirements).

8.5.1 - ESSENTIAL REQUIREMENTS:

The packaging is in compliance with the requirements with the current EU legislation on packaging and packaging waste.

- The product is adequately protected during its expected life under normal conditions of storage and use (with a safety margin for adverse storage).
- In the instance of packaging coming into immediate contact with the product, there is no significant adverse interaction between product and packaging material, and that the packaging material complies with the requirements of the Regulation on Materials and Articles in Contact with Food.
- Where the packaged product undergoes subsequent treatment, whether by the manufacturer, caterer or consumer, the packaging adequately stands up to the processing conditions and no adverse packaging/product interaction occurs.
- The packaging is capable of providing the necessary characteristics and integrity where the preservation of the product depends on the pack.
- The packaging provides adequate protection to ensure the chemical and physical stability of the product during the declared shelf life, with an adequate safety margin for adverse storage.
- The finished pack will carry the statutory and other specified information in the required form and location. In the case of products containing known food allergens these must be clearly stated on the label in terms easily understood by the consumer.

Where packaging material carries information required by law (e.g. labels, printed packages, lithographed cans), Quality Control should ensure that the specification is updated as required to comply with new legal provisions, and that stocks of packaging materials that no longer comply are quarantined for modification (if possible and desired) or destruction.

When a new pack or label design is introduced for a product the obsolete packaging or labels should be destroyed and this disposal recorded.

Each label should contain a code which will cross-reference it to the formulation to ensure that changes in formulation are reflected in the label copy.

8.5.2 - DELIVERIES

Each delivery or lot of packaging should be given a reference code to identify it in storage and processing, and the documentation should be such that, if necessary, any lot of finished products can be correlated with the deliveries of the respective packaging materials used in its manufacture and with the corresponding laboratory records. Deliveries should be stored and marked in such a way that their identities do not become lost.

Packaging materials should be assigned a shelf life where appropriate.

8.5.3 - QUARANTINE OF PACKAGING MATERIAL

Deliveries of packaging material should be quarantined upon receipt and released for use only when the necessary quality assessment has been made. Operators should be trained and encouraged to report immediately anything unusual about the appearance, odour or behaviour of packaging materials issued.

Temporarily quarantined packaging material should be located and/or marked in such a way as to avoid risk of its being accidentally used before release. Material found totally unfit for use in packaging operations should be suitably marked and physically segregated pending appropriate disposal.

8.5.4 - STORAGE

All packaging materials should be stored in hygienic conditions, and as indicated in their respective specifications.

Stocks of packaging materials in store should be inspected regularly to ensure that they remain in acceptable condition.

8.5.5 - ISSUE OF PACKAGING MATERIAL AND RECONCILIATION

In issuing packaging material from store for production use, stock rotation should normally be observed, unless otherwise authorised or specified by Quality Control.

Authorised procedure and documentation should be established and followed for the issue of packaging materials from store, and for the return of part-used Lots of packaging to store. The return procedure should consider the need to re-seal part used boxes of packaging to prevent foreign body contamination.

All printed packaging components should be issued from and returned to a secure area with controlled personnel access.

There should be a procedure for the reconciliation of all printed packaging component stock from quantity issued, quantity used, wastage and that returned to store.

8.6 - PROCESSING AND PACKAGING

Where a company manufactures more than one product or more than one version of a product, and there is more than one production line, production layout should be such that confusion is avoided.

8.6.1 - CROSS-CONTAMINATION

Whether in single-line or multiple-line production particular care should be taken, in terms of production layout and practices, to avoid cross-contamination of one product by another. Multiple packaging lines should have adequate segregation in order to avoid cross-contamination.

On a production line, the name and appropriate reference to the product being processed/packaged should be clearly displayed.

8.6.2 - CHECKING THAT PACKAGING IS CORRECT

Where a company manufactures more than one product, or more than one version of a single product, the greatest care should be taken to check that the correct packaging is issued for the product to be manufactured, and that no incorrect packaging materials, left over from a previous production run of a different product or a different version, are left in the production area where they might accidentally be used. In no circumstances should primary food packaging be used for other than its intended purpose.

Where packaging is reference-coded and date-marked for use, care should be taken to ensure that only material carrying the correct date is used. Surplus material left from earlier production and bearing an invalid reference or date should not be left in the production area. Where the reference and/or date is applied during the manufacturing operation, care should be taken to check and ensure that the marking machine is set for the correct reference and date.

8.6.3 - PRODUCTION CHECKS

Before production begins, checks should be carried out to ensure that the production area is clean and free from any products, product residues, waste material, raw materials, packaging materials or documents not relevant to the production to be

undertaken; and that the correct materials and documents have been issued and the correct machine settings have been made. All plant and equipment should be checked as clean and ready for use.

Processing should be strictly in accordance with the Master Manufacturing Instructions subject to any variations approved, and by detailed procedures set out for operators in the Plant Operating Instructions.

Process conditions should be monitored and process control carried out by suitable means including, as appropriate, sensory, instrumental and laboratory testing, and online checking of correct packaging and date-marking. Where continuous recorders or recorder/controllers are in use, the charts should subsequently be checked by Quality Control and retained as process records.

There should be regular and recorded checks on the accuracy of all instruments used for monitoring processes (e.g. thermometers, temperature gauges, pressure gauges, flowmeters, and check weighers).

8.6.4 - CLEANING

Effective cleaning of production premises and equipment must be carried out.

8.6.5 - PERSONNEL

All persons working in or visiting the production area must comply with the requirements of personal hygiene, and adequate facilities must be provided, and appropriate clothing worn.

8.6.6 - GOOD HOUSEKEEPING

General “good housekeeping” should be practised, including prompt removal of waste material, precautions to minimise spillage or breakage, prompt removal and clean-up of any spillage or broken packaging occurring, and the removal of any articles that might enter the product as foreign matter.

8.7 - INTERMEDIATE PRODUCTS

After its preparation, an intermediate product should be quarantined until checked and approved by Quality Control for compliance with its specification. If required to be stored before further processing, it should be stored as designated in that specification, and suitably reference-marked and documented so that it can be correlated with the Lots of raw materials from which it was made and the lot(s) of finished products in which it is subsequently incorporated.

A lot of intermediate products found to be defective should remain quarantined pending reworking or recovery of material or outright rejection as the case may be.

8.8 - FINISHED PRODUCTS

Packed finished products should be quarantined until checked and approved by Quality Control for compliance with the appropriate Finished Product Specification and not released for sale until reconciled, approved and signed off by the appropriate person.

An approved batch/Lot of finished products should be suitably flagged to identify it and stored under the appropriate conditions (e.g. of temperature or relative humidity) stated in the Finished Product Specification. In order to conform to the traceability requirement of Regulation (EC) 178/2002 the identification mark must be provided in a traceability document to any retailer to whom part of that lot is sold.

Where a batch/Lot of finished products fails to meet the Specification, the reasons for failure should be thoroughly investigated.

Defective finished product should remain quarantined in a segregated area pending reworking or recovery of materials or disposal as the case may be.

8.9 - DISPOSAL OF WASTE AND EFFLUENT

It is essential when disposing of surplus raw materials, waste or reject product, process chemicals and laboratory reagents that attention is paid to the "Duty of Care" requirements for waste.

Waste management protocols should take the following into consideration:

- Waste minimisation
- Reusing the material wherever possible
- Waste recycling
- Waste disposal

All waste materials and effluent should be disposed of in accordance with current local regulations by a route appropriate to the class of material.

8.10 - SAMPLING AND TESTING

Sampling and testing are two important aspects of the quality management for food supplements. This enables manufacturers to verify and document the conformity of products at any stage of the manufacturing process, including raw materials. It is part of the traceability system.

Samples should be taken from each new batch/Lot of raw materials/ingredients, intermediate and finished products, taking account of the identified risks, using a statistically representative method and operating in adapted hygienic conditions in order to prevent contamination due to sampling. Testing should be performed in correspondence with an appropriate risk assessment.

All operations should be documented in an appropriate registration system.

a. Sample size

The sample size and sampling regime must be based on a risk assessment which should take into account the type of material to be analysed, its source, the batch/lot size and the number of containers.

European regulations mandate sample collection and sampling requirements for heavy metals, polycyclic aromatic hydrocarbons (PAHs), 3-MCPD, dioxins and PCBs and mycotoxins. These formal procedures should be applied to contaminants testing.

In the absence of legislative provisions on sampling and sample preparation, the methods to be used as a reference are the standards of the ISO (International Organisation for Standardisation) for sampling and sample preparation according to the guidelines of the Codex Alimentarius and if relevant the European Pharmacopoeia (2.8.20).

b. Frequency of Sampling and Testing

Sampling must be performed for all batches/lots. Testing should be performed in a statistically representative manner. For materials new to the manufacturing process, the testing should be made on all batches/lots. If analytical results show conformity with specifications in a persistent way, the frequency of testing could be reduced after a corresponding risk assessment.

This change should be documented in the quality management system. Changing of suppliers or of the geographical area for a same material as already used is equivalent to introducing a new material.

As a general principle, the frequency of testing should be reassessed after a regular review of the results, or when changes of suppliers, processes, specifications or other material factor occur.

c. Representativeness of Samples – Homogeneity Aspects

Samples should be representative of the quality of the whole batch/Lot of raw material or of intermediate or finished product which has to be analysed. The sample taking procedure should be defined considering the homogeneity characteristics of each physical form to be examined (example liquids versus powders versus pastes) and of the type of intermediate storage (bulk vs containers/ bags).

If a risk of settling (liquids) or of de-structuring (powders) exists, the material to be sampled should be mixed again in order to provide a homogenous mixture.

d. Traceability of Samples – see also 13.5 below

European food legislation prescribes that each operator in the supply chain within the EU is responsible for maintaining an appropriate traceability system including supplier and customer records for each batch/Lot of products or material. This applies equally to material of EU or non-EU origin.

9 - Recovery or Re-Working of Materials

Material may be recovered, reworked or reprocessed by an appropriate and authorised method, provided that the material is suitable for such treatment, that the resulting product complies with the relevant specification and that the related documentation accurately records what has occurred. Any impact on the shelf life of a batch/lot containing such recovered material must be taken into consideration.

Reworked or recovered material which might adversely affect product quality, efficacy or safety should not be used in subsequent lots.

The treatment of reworked or recovered material, and the means of their inclusion in a subsequent lot, should be specifically authorised and documented.

Limits, approved by Quality Control, should be established for the amount of any such material which may be added to a subsequent lot.

Lots incorporating reworked or recovered material should not be released until the lots from which the material originated have been tested and found suitable for use.

Methods of reprocessing should be specifically authorised and fully validated and documented once any potential risks have been evaluated and found negligible.

The need for additional testing of any Finished Product which has been reprocessed (or to which reworked or recovered material has been added) should be considered,

A finished product returned from the manufacturer's own stores or warehouse (for example, because, of soiled or damaged labels or outer packaging) may be relabelled, or bulked for inclusion in subsequent lots, provided that there is no risk to product quality and the operation is specifically authorised and documented. If such products are relabelled, extra care is necessary to avoid mix-up or mislabelling; any identifying marks and shelf-life indication on the original labels should appear unaltered on the new labels.

Finished products returned from the market which have left the control of the manufacturer should be considered for resale, relabelling or bulking with a subsequent lot only after they have been critically assessed by Quality Control. The nature of the product, any special storage conditions it requires, its condition and history, and the time elapsed since it was issued should all be taken into account in this assessment. Where any doubt arises over the quality of the product, it should not be considered suitable for reissue or reuse.

10 - Warehousing

10.1 - GENERAL

Effective warehousing operations should be designed to ensure that all products are easily accessible for load assembly as required; to ensure that aisles and assembly areas are planned so that unimpeded movement is possible to and from all parts of the warehouse; to facilitate proper stock rotation, particularly important in relation to short-life and date-marked foods; and to obtain maximum utilisation of available space, consistent with the foregoing requirements.

Storage and transportation of finished products should be under conditions that will prevent contamination, including development of pathogenic or toxigenic micro-organisms, will protect against undesirable deterioration of the product and the container, and assure the delivery of safe, clean and wholesome foods to consumers. This deterioration includes, but is not limited to, contamination from insects, rodents and other vermin, toxic chemicals, pesticides and sources of flavour and odour taint.

The buildings, grounds, fixtures and equipment of food warehouses and vehicles should be designed, constructed, adapted and maintained to facilitate the operations carried out in them and to prevent damage.

10.2 - ACCESS TO STORAGE AREAS

Access to material and product storage areas should be restricted to those working in those areas and to other authorised persons.

A suitable curtain should be provided at all entrances and exits in order to maintain the internal conditions of the warehouse at an appropriate level for the product therein.

10.3 - TEMPERATURE AND LIGHTING

Warehouse temperatures should be kept at an appropriate level to maintain the wholesomeness of the particular foods received and held in such areas. Temperature mapping and recording should be carried out to ensure even temperatures in product storage areas.

The lighting should be as high as possible above the product; the smaller the angle of the light source from ground level, the smaller is the shadow made by the stack.

Lights should be protected by shatterproof covers where appropriate.

10.4 - PRODUCT STORAGE

In order to provide effective protection from contamination, materials and products should be stored under conditions stated in their respective specifications. Particular attention should be paid to the avoidance of microbiological cross-contamination and tainting. Where special conditions are required, they should be regularly checked for compliance.

Materials and products should be stored in such a way that cleaning, the use of pest control materials without risk of contamination, inspection and sampling, retention of delivery identity or lot identity, and effective stock rotation can be easily carried out.

The stacking of products should have regard for all elements of safety. Pallets should be checked periodically for structural integrity. Where appropriate, corner boards should be positioned at the corner of each stack, both to make the corner "stand out" visually, and to protect the product from accidental impact damage by high-lift and powered pallet trucks.

Pallets should be placed in prescribed places; gangways should be used as such and not as temporary repositories for stocks. Pallets should be so spaced as to allow proper ventilation.

Products which have been recalled or returned, and lots which have been rejected for reworking or recovery of materials or disposal, should be so marked and physically segregated, preferably in an entirely separate storage facility.

Material deliveries and product lots temporarily quarantined pending the results of testing should be so marked, suitably segregated, and effective organisational measures implemented to safeguard against unauthorised or accidental use of those materials or despatch of those products. Segregation may be physical or logical (using suitable software and barcodes). Suitably validated control systems should be used.

All stored items should be marked with their identification to ensure that traceability is maintained.

If a lot of finished products is to be labelled at a later date, the greatest possible care should be exercised in maintaining its exact identity. The containers holding the product must bear a fixed label of contents and Lot number and the final product label must be marked with the appropriate shelf life. This information may be available from the documentation or identified from the product name and lot number.

10.5 - DAMAGED GOODS

Damaged goods should be placed in a designated place as they occur or are discovered. Care must be taken not to expose foods stored in the warehouse to contamination or infestation. The same may also apply to returns from customers. Damaged goods which cannot be repacked must be dealt with prior to disposal so as to prevent their re-entry into the food distribution chain.

Only products which have been properly inspected to ensure that the product and packaging are fully acceptable may be repacked into outer packaging in a suitable area/room. If it is necessary to repack goods of different production codes into the same outer packaging, the package should be marked with an age code which relates to the oldest packet in the case.

10.6 - CLEANING OF STORAGE AREAS

Effective cleaning of storage premises and equipment must be carried out at the frequency and using the methods and materials specified in well-designed cleaning schedules and instructions.

Storage areas should be regularly inspected for cleanliness and good housekeeping, and to identify Lots of products which have exceeded their shelf life or, in the case of date-marked products, leave insufficient time for retail display. These inspections should be formally documented, including any corrective action taken if necessary.

11 - Transport and Distribution

(See also 17.9.9)

All vehicles, containers, etc. should be free from rodents, birds and insects or contamination from them; free from odours, nails, splinters, oil and grease, accumulations of dirt and debris, and should be in good repair, without holes, cracks or crevices that could provide entrances or harbourage for pests.

Prior to loading, it is advisable that the vehicle interior (including walls, floor and ceiling) be inspected for general cleanliness, freedom from moisture, foreign materials, etc. which could cause product contamination or damage to the packages.

Vehicles bringing products to a warehouse should be inspected for evidence of damage (including that to any lighting or other “brittle material” items), or of insect or rodent infestations, objectionable odours, or other forms of contamination.

If damaged product is accepted on a vehicle, it must be kept separate from other products and handled in a manner which will not expose other foods on the vehicle, or subsequently the food warehouse, to contamination or infestation.

A procedure should be set up to deal with consequences of accidents and damage occurring when goods are in storage or distribution, e.g. salvage or condemnation following damage to goods in a road traffic accident.

Security precautions should include means of deterring and preventing any tampering with goods in storage and distribution.

Where warehousing or transport is contracted out, the premises, vehicles and conditions, where possible in practice, should be subject to checks to ensure that there is no risk of contamination or tainting.

Docks, railway sidings, bays, driveways, etc. when within the factory complex should be kept free from accumulation of debris and spillage.

Fire appliances should be suitable for use on the commodities concerned and a sufficient proportion of them should be capable of dealing with electrical and petroleum/fuel oil fires.

Fork lift and other trucks used within the warehouse should normally be battery driven or otherwise equipped to prevent fume or fuel contamination.

12 - Hazard Analysis Critical Control Point (HACCP)

12.1 - HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP)

HACCP is a practical technique which food businesses must use to help satisfy themselves and their customers that their products are safe. It achieves product safety in an efficient, reliable and cost-effective way, by focussing on hazard prevention throughout the food chain rather than relying on end-product testing. It is a structured approach to the following:

- Identifying the main risk areas in an operation
- Adopting the appropriate controls
- Ensuring the proper operation of these controls

HACCP systems can be applied to all levels of food business, from the smallest individual operator up to sophisticated multinational operations. Current legislation requires that "food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles", a statement which allows flexibility in the implementation of the HACCP principles, particularly with regard to the smaller food businesses.

HACCP systems are designed to accommodate changes, whether in raw material supply, equipment design, processing procedures or technological developments.

Definition

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.

12.2 - REQUIREMENT FOR HACCP

There is now a greater emphasis on Hazard Analysis Critical Control Point within the food industry, as companies are recognising the need to critically examine the nature of the business due to their responsibility for ensuring the protection of their consumers. This has been a legal requirement since 1 January 2006 under EU Regulation (EC) No. 852/2004 on Food Hygiene.

HACCP is also now expected by large retailers and supermarkets who require the HACCP process to be fully documented by their suppliers[2].

2 - See DG SANCO guidance document on the facilitation of the implementation of HACCP principles in certain food businesses, 16 November 2005

12.3 - SETTING UP A HACCP SYSTEM

HACCP can only be effectively implemented once all food hygiene requirements and Good Practices for food businesses are adhered to i.e. all controls, systems and procedures possible are in place in order to control hazards in a general way. Once this has been achieved the HACCP principles can be applied (see Figure 2 below). The HACCP system can be devised following the steps outlined in 12.3.1 to 12.3.13 (see also the example of practical application in Annex III).

12.3.1 - THE HACCP TEAM

This should include key personnel from all parts of the food business, e.g. a food technologist, microbiologist, production manager, quality assurance manager, engineer and purchasing manager. The support and commitment of all staff are essential to the success of the exercise. The team members need to have relevant experience, knowledge of the products and processes within the study and suitable training in how to undertake a HACCP study and the implementation of HACCP principles. At least one member of the team should have formal HACCP training but all team members need to be trained in how to utilise the HACCP principles. The team are also responsible for ongoing review and management of the HACCP system. The management of the HACCP system and the development and implementation of the food safety control system remain the responsibility of the manufacturing organisation.

In the event that external expertise is sourced to assist with either the development or maintenance of the HACCP system it is critical that the management team should not delegate responsibility to the external resource. The quality of the external expertise should be formally assessed including the amount of appropriate experience in the food industry and the provision of appropriate references from current clients.

12.3.2 - DESCRIBE THE PRODUCT

This will include the identity and quantities of active and other ingredients, the structure, processing and presentation form of the food, its packaging, storage and distribution conditions, required shelf life, instructions for use and any applicable microbiological or chemical criteria.

12.3.3 - IDENTIFY INTENDED USE

This will include how the customer will normally be expected to store and consume the product and needs to give consideration to any vulnerable groups within the population.

12.3.4 - CONSTRUCT PRODUCTION FLOW DIAGRAM

This should include details of all processing steps throughout the entire food chain, from receipt of raw materials to placing the end product on the market. This information should be put into a detailed flow diagram together with adequate technical data.

12.3.5 - VERIFICATION OF FLOW DIAGRAM

Visual inspection of the processing steps is required to ensure that they are a true representation of the processes. This verification should be carried out during normal operating hours, and the flow diagram must be amended, should any deviation from the steps be noticed.

12.3.6 - LIST ALL HAZARDS ASSOCIATED WITH EACH STEP AND LIST ANY PREVENTIVE MEASURES TO CONTROL HAZARDS

A hazard is anything that can harm the consumer and can include biological, chemical and physical hazards. Preventive measures are the actions that are required to remove or reduce the hazard occurrence to an acceptable level. In certain cases, a hazard analysis may show that hazards can be controlled simply by following all food hygiene requirements and best practices.

12.3.7 - DETERMINE THE CRITICAL CONTROL POINTS

Through the use of a HACCP decision tree (see Figure 3 below), the HACCP team identifies those steps that must be controlled to eliminate each hazard or minimise its likelihood. These are the Critical

Control Points (CCPs). It should be noted, however, that legislation recognises that "in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points".

12.3.8 - ESTABLISH TARGET LEVELS AND TOLERANCES FOR EACH CCP

Target and tolerance levels need to be specified for each preventive measure, taking into account potential fluctuations within the process, in order to be able to monitor the Critical Control Point in question and ensure that critical limits, corresponding to the extreme values acceptable with regard to product safety, are not exceeded. They should be set for observable or measurable parameters (e.g. moisture levels, pH, texture), and should be based on firm evidence that the chosen values will lead to process control. The legislation recognises, however, that "the requirement of establishing 'critical limits' does not imply that it is necessary to fix a numerical limit in every case".

12.3.9 - ESTABLISH A MONITORING SYSTEM FOR EACH CCP

This must be documented and will detect any loss of control at the Critical Control Points and provide information in time for corrective action to be taken. For each CCP, the HACCP team will decide what form of monitoring is to be done, when it is to be done and who is responsible to maintain control.

12.3.10 - ESTABLISH CORRECTIVE ACTIONS

Establish what corrective action must be undertaken when monitoring identifies a deviation from a documented target level.

This should include who is responsible for the implementation of the action, what action is to be undertaken to correct the deviation, what action is to be undertaken with regard to products manufactured whilst the deviation occurred and a written record of measures taken indicating all relevant information.

12.3.11 - VERIFICATION OF HACCP SYSTEM

This will involve finished product testing, inspection of operations, audits, review of records, confirmation that CCPs are kept under control and validation of target levels, etc. The verification should be carried out by someone other than the person responsible for the monitoring and corrective actions and needs to be fully documented.

12.3.12 - ESTABLISH RECORD KEEPING AND DOCUMENTATION

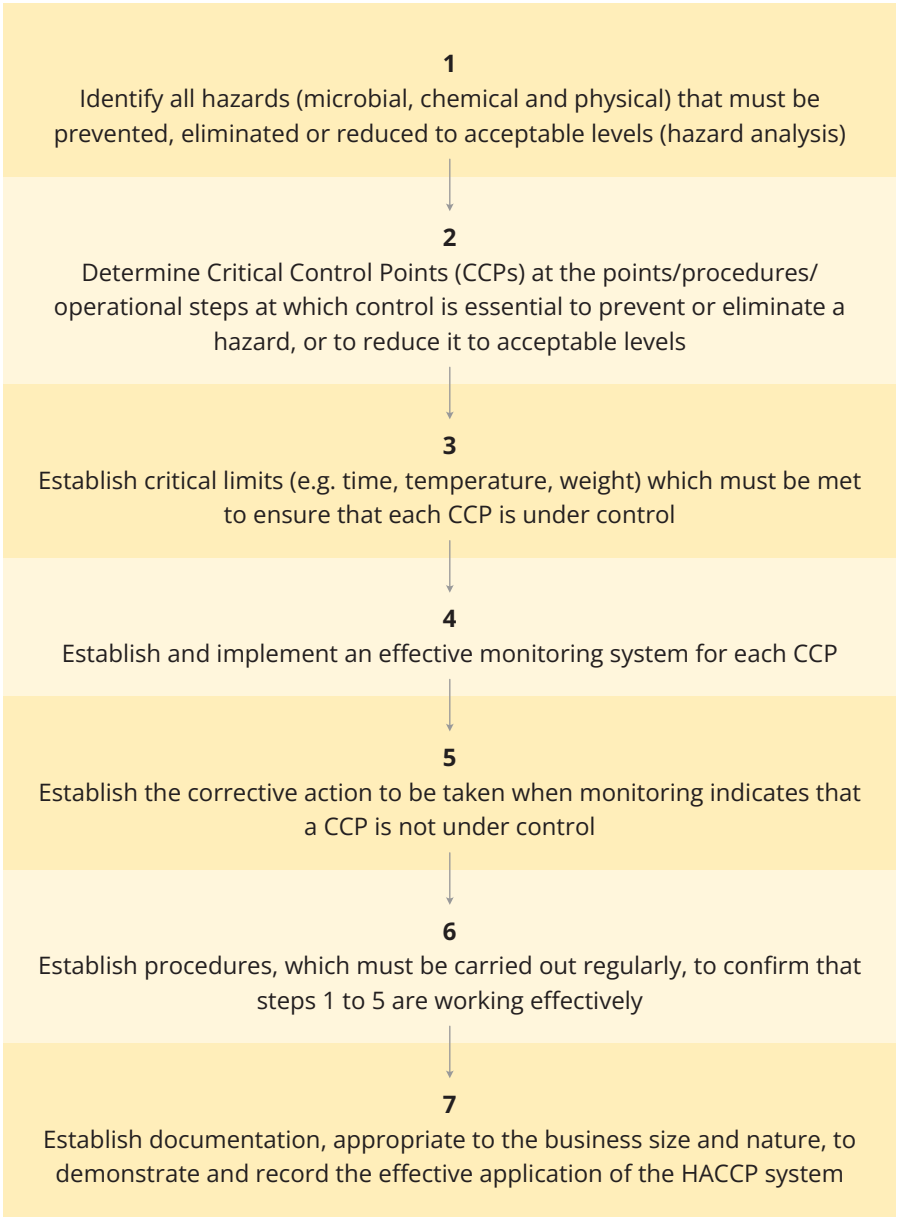
This requires good document control and a set procedure (appropriate to the nature and size of the business), which will ensure that HACCP activities keep pace with any proposed changes, e.g. to ingredients, processing procedures, etc.

HACCP-related record keeping can be limited to what is essential with regard to food safety, but it must be remembered that these records need to be sufficiently adequate to provide proof of "due diligence" to the relevant authorities should the need arise.

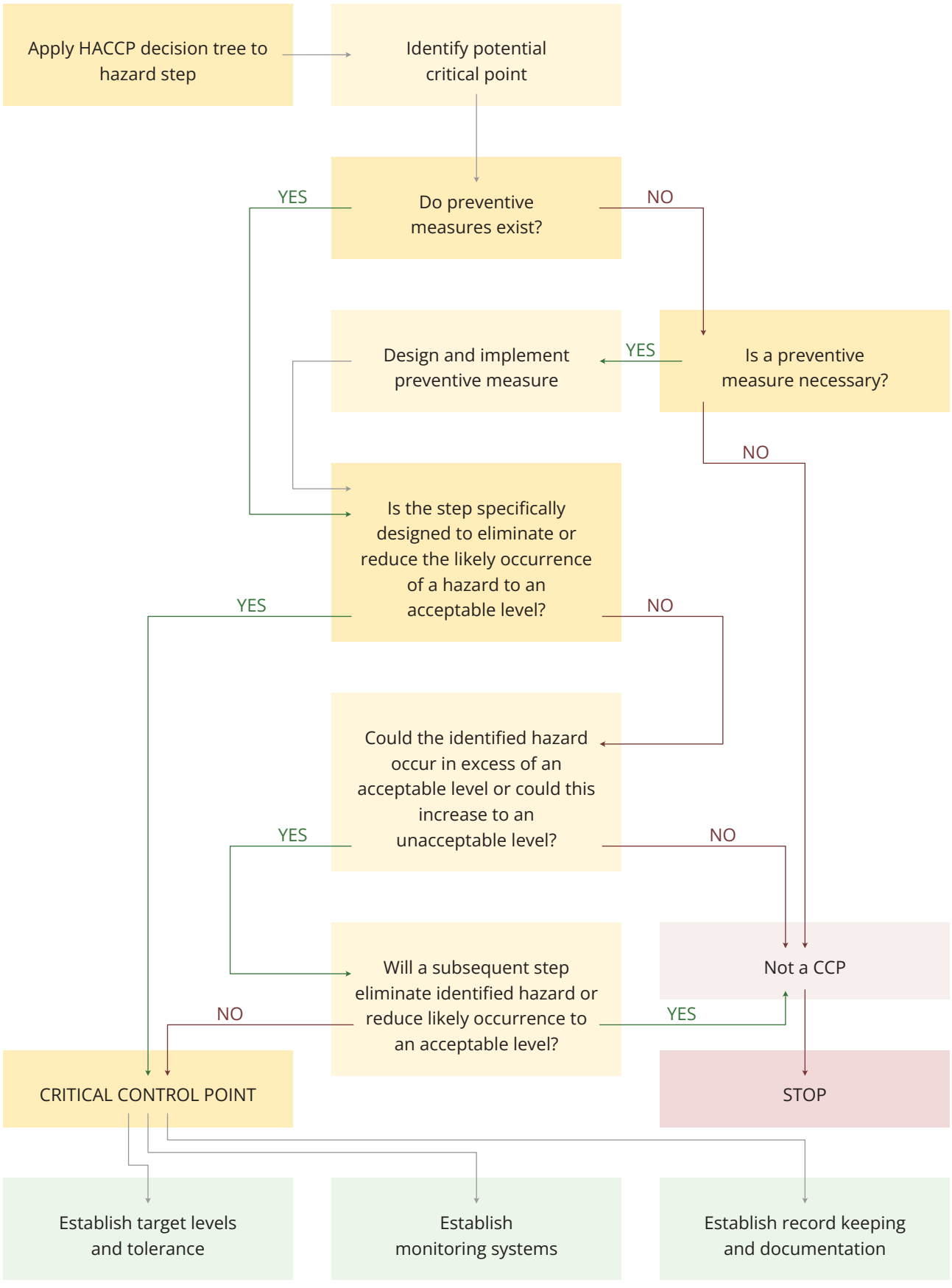
12.3.13 - REVIEW OF HACCP SYSTEM

The HACCP plan should be reassessed at least once a year to ensure it continues to provide a valid system for the identification, assessment and control of hazards and risks associated with the food supplement.

SEVEN PRINCIPLES OF A HACCP SYSTEM



HACCP LOGIC SEQUENCE: DECISION TREE



13 - Documentation

13.1 - GENERAL

Good and effective documentation is an essential and integral part of Good Practice and a fundamental element of a well-designed HACCP system. Its purposes are to define the materials, operations, activities, control measures and products; to record and communicate information needed before, during or after manufacture; to reduce the risk of errors arising from oral communication; and to permit investigation and tracing of defective products. The system of documentation should be such that as far as is practicable the history of each lot of products, including utilisation and disposal of raw materials, intermediates and bulk or finished products, may be ascertained and thus traceability maintained.

Where documentation is maintained electronically safeguards need to be in place to ensure the data is entered correctly and that sufficient back-ups are made so that, in the event of file alteration, corruption, deletion or destruction, the original data can be retrieved. The system should be protected against unauthorised access to the data. Procedures should be developed outlining the issue, cancellation or alteration of authorisation, and also for the action to be taken in the event of system failure or breakdown.

Any computer software used for controlling critical operations such as quarantine/ release status should be set up to only permit approved-personnel access and “change control”.

To facilitate proper and effective use of documents they should be designed and prepared with care, be free of errors and pay particular attention to the following points:

a. The title (which should be unambiguous), nature and purpose of the document should be clearly stated. The document should be laid out in an orderly fashion, and be easy to check. Where a document has been revised, systems should be operated to prevent inadvertent use of superseded documents.

b. It is an advantage if it is possible to revise part of a document without necessarily completely rewriting the whole document.

c. The way the document is to be used, and by whom, should be clearly apparent from the document itself. Other means provided to explain its use are of less value.

d. Where documents bear instructions, they should be written in the imperative, as numbered steps. They should be clear, precise, unambiguous and in language the user can understand. Such documents should be readily available to all concerned with carrying out the instructions.

e. Documents which require the entry of data should:

- Provide sufficient space for the entry, including space to record preventive and corrective actions taken following inspection as applicable;
- Allow adequate spacing between the entries;

- Show headings clearly indicating what is to be entered.

f. Persons making entries should do so in clear legible writing and should confirm the entry by adding their initials or signatures. A signed recorded observation is preferable to simply ticking in a box.

g. Manuscript entries should be made in ink or other indelible medium.

h. The size and shape of documents and the quality and colour of the paper used should be considered in relation to the typing/printing, reproduction and filing facilities available.

i. Reproduced documents should be clear and legible.

Sufficient training on how to complete the documents should be given to the relevant personnel and the effectiveness of the training should be regularly assessed.

Documents should contain all necessary, but no superfluous, data. Any headings, or places for entries, which cease to be used should be removed at the earliest opportunity.

If an error is made or detected on a document, it should be corrected in such a manner that the original entry is not lost and the correction initialled and dated. Where appropriate, the reason for the correction should be recorded. The application of correction fluid is not allowed.

Documents should be kept up to date. Any amendments should be formally authorised and signed. In the case of permanent amendments, the amended document should be replaced at the earliest opportunity by a newly prepared document.

The documentation system should include procedures for issue, authorisation, periodic review and revision.

An outdated or superseded document should be removed from active use, and a copy, marked that it has been superseded, retained for reference. Routine internal audits will help ensure that the correct versions of documents are being used.

It may be useful to prepare a manual which describes the overall Quality Assurance system, the procedures employed and the documents used. This should be fully integrated with the HACCP documentation and be available to all relevant staff.

13.2 - TYPES OF DOCUMENTS

Manufacturing formulae, processing and packaging instructions state all the starting materials used and lay down all processing and packaging operations.

Specifications describe in detail the requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.

Procedures give directions for performing certain operations e.g. cleaning, clothing, environmental control, sampling, testing, and equipment operation.

Records provide a history of each batch/Lot of products, including its distribution, and also of all other relevant circumstances pertinent to the quality of the final product.

13.3 - RETENTION OF DOCUMENTS

The retention period for documents is dependent upon their function. Consideration must be given to any legal requirements, including the provision of evidence of due diligence. As a general guide:

a. Batch/lot records should be retained for the shelf life of the product plus an additional year.

b. Weight and measures control records (as required by the Weights and Measures legislation) must be retained for a minimum of one year and one day.

A Controlled Records List should be used to provide an ongoing and constantly monitored system for removing the files of unwanted old data.

Fire risk should be assessed and consideration should be given to the use of a fireproof safe for the storage of electronic back-ups and, in the case of paper-only systems, master copies and key documents.

13.4 - CLASSES OF DOCUMENTS

The following lists are not exhaustive but do give an indication of the types of documents relevant to the production of food supplements:

a. Specifications, Instructions and Procedures

- Ingredient Specifications
- Packaging Materials Specifications
- Copy of order and/or terms of conditions of purchase
- Master Manufacturing Instructions (including standard recipes)
- Intermediate Specifications
- Bulk Product Specification
- Finished Product Specifications
- Quality Control (including Analytical and Microbiological) Procedures and Methods
- Standard Procedure for Product Recall
- Plant Operating Instructions
- Cleaning Instructions, Good Housekeeping and Pest Control Schedules
- Plant Maintenance Schedules
- HACCP plans

b. Records and Reports

- Records of receipt, examination, approval, and issue for use of Raw Materials and food packaging materials as required by law
- Records of the testing and release of Intermediates, Bulk Products and Finished Products
- Records of Process Control Tests
- In-Process Recording Instruments Charts
- Weight or Volume Control Charts
- Lot Manufacturing Records
- Customer Complaint Records
- Quality Control Summaries and Surveys
- Quality Audit Reports and Records
- HACCP Review Reports
- Training Records
- Superseded Documents

c. Programmes

- Production Programmes
- Training Programmes
- Quality Audits

d. Personnel data

13.5 - TRACEABILITY

All ingredients intended for use in food supplements must comply with the traceability requirements as given in the EU Regulation on General Food Law. Regulation (EC) No 178/2002 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.

The traceability of food supplements throughout the food chain allows identifying and addressing potential risks and protecting public health, so it is essential to ensure food safety. Faced with a Food Alert food traceability enables swift action for the withdrawal from the market of products or ingredients affected. The traceability requirement aims to ensure that companies can identify suppliers of raw materials or products and the immediate receptors of their products – as below:

From whom are the products received? Record the batch/lot number and/or the number of identification of raw materials or products received and know what will be done with them.

Link what goes into products with what comes out: Record entry, intermediate products, know what they are, how they have been processed, and when.

What products are delivered and to whom? Record the complete data of products delivered, customer data, data, data of all what has been sold and when.

To achieve this goal, companies must implement all those systems and procedures that are necessary to have this information. It is particularly impoxrtant to keep all documents and records up to date.

Given that in the EU foodstuffs can circulate freely between Member States, traceability can only be effective if they meet common requirements in all of them. It is vital that when national authorities or food supplements operators identify a risk, they can track it back to the source of the risk so as to be able to isolate the problem and prevent contaminated products endangering consumers.

A European Guide is available on the website of the European Commission[3], which requires food companies to document the names and addresses of suppliers and customers, as well as the nature of the product and the date of delivery. It also calls on companies to keep the information on the volume and quantity of a product, batch/lot number, and a detailed description of each product, whether it is raw or processed, etc.

All information on traceability must be kept for a relevant period, such as the shelf life of the extract and/or product plus one year. Information on traceability must be made available to the Competent Authority on demand. Food supplements placed on the market in the European Union (EU) must be adequately labelled and identified so as to facilitate traceability.

The Rapid Alert System for Food and Feed (RASFF) is a network start-up which has been operating since 1979, enhanced by the publication of Regulation (EC) 178/2002 *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*.

RASFF members are the Member States (MS) of the European Union, the European Commission (EC), the European Food Safety Authority (EFSA), Iceland, Liechtenstein and Norway. This alert system supports the traceability system allowing a rapid exchange of information at any time in which a dietary risk is identified. If a member of this network detects a potential health risk, it notifies the EC, immediately transmitting the information to the other members and carry out the subsequent corrective action.

3 - https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition-vitamins_minerals-guidance_tolerances_1212_en.pdf

Description	Responsibilities	Actions when a risk is identified
Food supplement companies	Identify and document information of products, one step backwards and one forward, into the food chain.	Immediately remove the products on the market and if necessary, recall them consumers. Destroy the lot, or food shipments that do not meet safety requirements. Inform the competent authorities of the risk and the action carried out.
Member State Authorities	Monitor the production, processing and distribution of food supplements to ensure that companies have traceability systems. Set and enforce penalties for companies that do not comply with European requirements for traceability.	Ensure that businesses are complying with their obligations. Take the necessary measures to ensure food safety. Locate the risks back and forth along the food chain. Notify the rapid alert system for food and feed (RASFF).
European Union	Establish specific legislation on traceability for those sectors that require it. The Food and Veterinary Office of the European Commission carries out regular inspections to ensure that food and feed companies comply with safety standards on food safety-including the implementation of traceability systems.	The European Commission warns Member States of risks via the Rapid Alert system for food and feed. They can ask for information from companies to enable traceability, and coordinate the actions of national authorities. The EU can impose restrictions on import/export.

14 - Complaints Procedure, Product Recall and Emergency Procedure

14.1 - GENERAL

It is a legal requirement under EU Regulation (EC) No. 178/2002 that if a food business operator considers, or has reason to believe, that a food which it has imported, produced, manufactured or distributed is not in compliance with food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market. The operator must also inform the competent authorities of the problem in the EU countries where the product(s) is marketed.

If the product has already reached the consumer, the operator must effectively and accurately inform the consumers of the reason for the withdrawal and, if necessary, effect a recall of the affected product.

The operator has a legal obligation to inform the competent authorities if he considers, or has reason to believe, that product on the market may be injurious to human health. The operator must also collaborate with the authorities on action taken to avoid or reduce risks posed by the food. The operator must ensure the traceability of the products as required by current legislation.

14.2 - COMPLAINTS

The full significance of a quality complaint may only be appreciated by certain responsible persons, and then possibly only with the knowledge of other related complaints. A procedure must therefore be provided for appropriate channelling of all quality complaint reports.

The system for dealing with complaints should follow written instructions which indicate the responsible person through whom the complaints must be channelled.

If the responsible person is not the Quality Control Manager, the latter should be fully informed and closely consulted. The responsible person should have the appropriate knowledge and experience, and the necessary authority, to decide the action to be taken.

All product quality complaints should be thoroughly investigated, where possible by the Quality Control Manager, with the co-operation of all relevant personnel, and a report prepared as a basis for action and for the records.

Action should include responding to the complainant and must include responding to any enforcement authority whenever involved. Where the complaint is justified, steps to remove or overcome the cause and thus prevent recurrence should be taken; and the defective material which the complaint sample might represent should be dealt with, including possibly a product withdrawal or recall.

Complaints reports should be regularly analysed, summarised, and reviewed for any trends or indication of a need for a product recall or of any specific problem requiring attention. It is strongly recommended that appropriate summaries include comparative data and that they are regularly distributed to directors and senior management.

14.3 - PRODUCT WITHDRAWAL AND RECALL

A product defect coming to the manufacturer's attention, whether through a complaint or otherwise, may lead to the need for a product recall. There should be a predetermined written plan, clearly understood by all concerned, for the recall of a product or a known lot or Lots of products known or suspected to be hazardous or otherwise unfit, or of wholesome but substandard products which the manufacturer wishes to recall. A crisis procedure and management team should be established.

A responsible person, with appropriate named deputies, should be nominated to initiate and coordinate all recall activities, and to be the point of any contact with the nominated competent authority on recall matters.

Out of hours contact details of key personnel and competent authorities should be kept in an accessible form.

The design of manufacturing records systems and distribution records systems, and the marking of outer cartons and of individual packs should be such as to facilitate effective withdrawal or recall if necessary. A good system of lot marking will pinpoint the suspect material and help avoid excessive recall. Lot marking of most food products is a requirement of EC Directive 89/396/EEC.

There should be written withdrawal and recall procedures, and these should be capable of being put into operation at short notice, at any time, inside or outside working hours.

The withdrawal and recall procedures should be shown to be practicable and operable within a reasonable time by carrying out suitable testing of the procedure.

The withdrawal and recall procedures should be reviewed regularly to check whether there is need for revision in the light of changes in circumstances or of the responsible person.

Product withdrawals or recalls may arise in a variety of circumstances which, usually, fall into three main categories:

a. Where the national or local authorities become aware of a hazard or suspected hazard, and information and co-operation from the manufacturer or importer is necessitated.

b. Where the manufacturer, importer, distributor, retailer or caterer becomes aware of a hazard or suspected hazard.

c. Where there is no hazard or suspected hazard involved, but there is some circumstance (e.g. substandard quality, mislabelling) which has come to light and which prompts the manufacturer, importer, or retailer to decide to withdraw or recall the affected product.

In case (c) above, the company will itself have to organise the withdrawal or recall operation. In cases (a) and (b), consideration may be given to issuing a public Food Hazard Warning. Generally, this would be done in consultation with the manufacturer or importer, the distributor or retailer, and any relevant enforcement authority interest. Normally, any arrangements for withdrawal would be discussed so that the most appropriate methods could be effected or endorsed by the authorities, and would also take into account any requirements for or arising from the information indicated below.

Although a defect or a suspected defect leading to withdrawal or recall may have come to light in respect of a particular lot or lots or a particular period of production, urgent consideration should be given to whether other lots or periods may also have been affected (e.g. through use of a faulty material or a plant or processing fault), and

whether these should also be included in the recall.

The withdrawal or recall system should lay down precise methods for notifying and implementing a recall from all distributive channels and retailers where the affected product might be, as well as affected goods in transit, and of halting any further distribution of affected goods. Procedures should also be laid down for recalling products from consumers.

Notification of withdrawal or recall should include the following information:

- Name, pack size and adequate description of the product
- Identifying marks of the lot(s) concerned
- The nature of the defect
- Action required, with an indication of the degree of urgency involved
- Name of contact and telephone number of contact who can supply further information.

Withdrawn or recalled material should be quarantined, pending a decision as to appropriate treatment or disposal. Quantities of the withdrawn or recalled batch/Lot of products, at their identified locations, should be reconciled with the total lot quantity in question.

14.4 - EMERGENCY PROCEDURE

Regrettably, the possibility of real or threatened hazard arising from the actions of second or third parties must be faced (e.g. deliberate contamination or poisoning of product or ingredient by extremists or otherwise misguided persons). Although some of the additional action that might be taken in such circumstances could be considered outside the scope of this Guide, it is included because those concerned in the manufacturing operation would very probably become involved.

The first intimation of a problem in this area could come from a whole variety of sources, e.g. consumer complaint, from a retailer, the media, the police, the enforcement authorities, employees, or by telephone, post or personal contact with any company location or any employee at any time.

It is therefore essential that any personnel engaged in manufacture should be aware of company action to be followed in dealing with such threats both within and outside of normal working hours, and that suitable arrangements exist for calling in key personnel out of hours in such an emergency. The extent to which any such emergency procedures may override normal lines of management should be explicitly stated, and these procedures should be formally documented.

Faced with an emergency, the withdrawal and recall procedures described above will apply, while the expertise of those involved in Quality Control and other relevant functions should be put at the disposal of the crisis management team responsible for handling the emergency.

The possibility of such sabotage and even site invasion may indicate a need for particular security precautions in vulnerable areas, e.g. locked rooms, use of seals, etc.

Cases of intentional or malicious contamination should be reported to the police for their involvement

Any emergency or recall situation is likely to involve retailers, wholesalers or caterers, and a smooth and effective interface with their procedures should be achieved as early as possible during the crisis.

15 - Internal Audits / Management Reviews

Internal Audits:
Internal audits must be conducted in order to monitor the implementation and compliance with best practice and to propose necessary corrective measures. These should cover:

- Personnel matters, premises, equipment, documentation (including the HACCP system), production, quality control, distribution of the products, arrangements for dealing with complaints and recalls.

Internal audits should be examined at intervals following a prearranged programme in order to verify their conformity with the principles of Quality Assurance.

Internal audits should be conducted in an independent and detailed way by designated competent person(s) from the company. Independent audits by external experts may also be useful.

All internal audits should be recorded and reviewed periodically by senior management. Reports should contain all the observations made during the inspections and, where applicable, proposals for corrective measures. Statements on the actions subsequently taken should also be recorded.

Management Reviews:
Management Review meetings should be held regularly. Minutes from the management review meetings, stating any action to be taken with designated responsibilities and timescales for completion, should be circulated promptly to the relevant personnel. A copy of the minutes should be retained as part of the organisation's quality records.

A checklist that manufacturers can use to measure their performance against the quality standards set out in this Guide, intended as a useful practical tool for companies, can be downloaded free from the EHPM website – www.ehpm.org.

16 - Laboratory Testing

A Quality Control laboratory should have appropriate premises, facilities, equipment and staff, and be so organised to enable it to fulfil Good Practice requirements and complement the scale of the manufacturing operations.

Both staffing and facilities will depend on the nature of the product range and the amount of testing required. It is essential that the facilities are appropriate to the needs of the tests.

Testing can be augmented by approved external laboratories accredited for the specific analysis required. Such accreditation should be recognised by official national or international authorities. The scope of the accredited analysis should cover the sample matrix. If not, sample-specific validation should be applied.

Staff should be appropriately trained and standards of work should be set at the highest level and maintained by rigid adherence to approved and agreed methods and method checks.

Quality Control laboratories should be designed and equipped to suit the operations required. Space should be made available for writing and the storage of documents and records and for any special provisions such as the storage of samples, etc. at the appropriate temperature.

All laboratory equipment and instrumentation should be appropriate to the approved test procedures, and should be regularly serviced and calibrated by assigned persons or organisations.

Records of each service and calibration must be maintained for each piece of equipment. These records should also identify when the next service or calibration is due.

Written operating procedures should be available for each instrument or piece of equipment, and all personnel operating the equipment should be familiar with the operating procedures.

Where necessary, analytical methods should include a control step to verify that the instrument or piece of equipment is functioning accurately. Defective instruments or equipment should be withdrawn from the possibility of use until the fault has been rectified.

All equipment should be maintained to a high standard of cleanliness in accordance with written procedures.

All personnel should wear clean protective clothing appropriate to the tasks being carried out, especially eye protection.

The disposal of laboratory waste material should be carefully and responsibly undertaken.

Samples should be analysed according to written procedures, which are validated for the required sample matrix. Validation can be minimal but consist of the following parameters: specificity / selectivity, recovery, precision, linearity and range, accuracy and LOD / LOQ. A validation report should be available and retained.

17 - Specific Requirements for Botanicals

17.1 - GENERAL REMARKS

This chapter refers to the specific requirements for the use of material, preparations or substances obtained from plants or other vegetative organisms ("botanicals") in Food Supplements. It should be read in conjunction with the "*EHPM Botanical Suppliers' Questionnaire*" (available on the EHPM website – www.ehpm.org – and as an attachment to this Guide). The Questionnaire provides a checklist, a useful and pragmatic overview 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. (Please note: the EU regulations, guidelines and normative references specified in Chapter 17 are correct at time of going to press, but should be checked against the relevant section of the accompanying document *Further Information/Regulatory links to the EHPM Botanical Suppliers' Questionnaire* for further detail/updates).

There is a rich history of use of botanicals in Europe. While many EU Member States have extremely well-developed regulatory systems in place covering the use of botanicals in food supplements, a common EU approach still needs to be developed. This section of the guide seeks to do this by outlining key quality requirements specific to botanicals that are based on existing best practice across EU Member States. These requirements are likely to be similar in non-EU European countries, but any relevant national rules should also be checked.

17.2 - BOTANICAL STARTING / RAW MATERIAL

The growth, development and chemical profile of botanical organisms are influenced by a number of external factors such as the quality of soil and water (mineral content, pH, etc.), temperature, sunlight, the season of cultivation and time of harvesting. All these factors influence and often determine the composition of botanicals that enters the supply chain.

As a consequence, the presence and concentration of physiologically active substances and contaminants in a botanical species can vary considerably depending on where, when and how the botanical was grown.

It is important that the batches/Lots of the botanical raw material undergo appropriate verification and testing before acceptance for further processing to ensure that the concentrations of substances with known physiological effects fall within predetermined limits and allow for the natural variability of the botanical material. In the same way, botanical raw material batch/lot testing must confirm an acceptable level of contamination. It is also particularly important that the sampling procedures used can guarantee the homogeneity and representativeness of the batch/lot tested.

Testing should include identification, purity tests and assay of physiologically active constituents or other, relative quality markers. This is particularly important when the sourcing of the botanical is first used or changed or when there are other considerations known to affect the quality of the source material, e.g. environmental or

climatic conditions, so that the risk analysis testing can, if necessary, be appropriately adapted. Thus, it is particularly important that suppliers commit themselves to providing manufacturers/food business operators with such information.

Full characterisation, including the identification of the botanical starting/raw material, is the compulsory initial step in the process of placing plant food supplements on the market. Safety assessments cannot be performed before quality parameters have been checked.

17.2.1 - IDENTIFICATION OF BOTANICAL RAW MATERIAL

Botanical identification at the harvesting stage is imperative, particularly with botanicals harvested in the wild. Particular care should be exercised with identification as there are many cases where botanicals have been renamed or reclassified. Care must also be taken with the use of common names as these can vary from region to region and in some instances can be used for a different species. Due to difficulties in translation, the common name given to some Chinese botanicals can relate to more than one species and identification must be made on the basis of the Scientific (Latin) classification.

The following scheme should be used for a detailed identification of a botanical.

- Scientific (Latin) name: full systematic species name incl. botanical family, genus, species, variety, subspecies, author's name, and chemotype if applicable.
- Synonyms: botanical name(s) that may be or have been used interchangeably with the preferred scientific name.
- Common names: vernacular name(s).
- Part used: e.g. root, leaf, seed, etc.

together with:

- Geographical origin: continent, country, region.
- Growth and harvesting conditions: wild or cultivated, cultivation practices, time of harvest in relation to both season and stage of the plant growth.

Additional information that should be available:

- Where applicable, information relating to *Regulation 338/97 on the protection of species of wild fauna and flora*, or to the *Convention on International Trades in Endangered Species of Wild Flora and Fauna* (CITES)
- Batch/lot/shipment ID number

Declaration signed by a responsible person

- Organic certification where applicable
- A statement on the irradiation status of the botanical source
- Allergen status
- GMO status.

As the accurate identification of some botanical sources can be complicated, it is recommended that authoritative sources be used, such as the "World Checklist of Selected Plant Families" (Royal Botanic Gardens, Kew, UK) https://wcsp.science.kew.org/advanced.do or "The International Plant Names Index", www.ipni.org. or the "World Flora Online (WFO)" (http://www.worldfloraonline.org). Where relevant, reference may also be made to the nomenclature of the European Pharmacopoeia.

17.2.2 - GACP

Botanical raw material sourcing should, where possible, follow the general principles of Good Agricultural and Collection Practices (GACP) to ensure identification and traceability. The supplier of the botanical raw material should provide written assurance that the botanical has been cultivated/collected, harvested, stored and, where relevant, processed in accordance with the requirements of applicable regional GACP.

Traceability is very important when assessing the quality of a botanical. If there are problems relating to a specific botanical or to a specific geographical zone, it is essential to be able to rapidly track back through the full supply chain so that adequate measures can be in place when necessary. While the level of detailed information available may vary, depending on whether the supplier is a manufacturer or distributor, every effort should be made to obtain as much information as possible. For instance, the origin of the plant and its conditions of cultivation will define the type of impurities that should be checked for in the plant preparation – and the less information on the plant that is available, the more analytical testing that may be required to demonstrate absence of or levels of impurities.

For both cultivated botanicals and those harvested in the wild, particular areas of concern at the harvesting/primary processing stage are cross contamination or adulteration, foreign matter contamination (from harvesting and from pest infestation), pesticide residues, contamination with mycotoxins (toxic excretory by-products of fungal/mould growth) and contamination with polycyclic aromatic hydrocarbons (PAHs).

As part of the risk management process, botanical material must be inspected and sorted prior to primary processing. This should include visual and organoleptic inspection of the physical characteristics for possible cross-contamination by other botanical species and/or plant parts, foreign matter and fungal/mould growth. However, the adequacy of such inspection depends on the form of the botanical material (cut size) and the level of expertise of the supervisor. This is why complementary testing is necessary to confirm the identity of the botanical material (see section 17.4). Any plant parts showing signs of fungal/mould growth should be discarded.

The use of the European Herb Growers Association (EUROPAM) *Batch Document*[1] (or an equivalent document) is recommended to support GACP compliance. Such collection of batch/lot information on cultivation and post harvesting processing provides a basis for identification and traceability of the botanical material and for the risk management process.

17.2.3 - CITES

All botanical species or preparations used in the production of botanical food supplements should comply with the requirements of the *Convention on International Trades in Endangered Species of Wild Flora and Fauna* (CITES), an international agreement between governments.

The objective of the CITES international agreement is to ensure that trade in wild plants does not threaten the survival of the species. The endangered species and the degree of protection assigned to them are given in three Appendices to the CITES agreement, depending on the level of protection required. CITES works by subjecting international trade in specimens of selected species to certain controls.

The CITES status of a botanical should be checked before it is sourced from the wild[2].

17.2.4 - ORGANIC GRADE

Organic production is an overall system of farm management and food production that combines best environmental and climate action practices, a high level of biodiversity, the preservation of natural resources and the application of high production standards, in line with the demand of a growing number of consumers for products produced using natural substances and processes and only approved organic chemicals and fertilisers.

Organic production thus plays a dual role where, on the one hand, it provides for a specific market responding to consumer demand for organic products and, on the other, delivers publicly available goods that contribute to the protection of the environment, as well as to rural development. The observance of high standards in the production of organic products is administered through external certification, and valid certification of organic status must be retained for all organic products.

17.3 - BOTANICAL PREPARATIONS

17.3.1 - DEFINITION

A botanical preparation is obtained from botanical material by various processes (e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying and fermentation). Botanical preparations include comminuted or powdered botanical material, extracts including tinctures and essential oils, expressed juices and processed exudates.

A botanical preparation is a complex product, the composition/substance profile of which is mainly determined by the quality/ natural variability of the raw material and the manufacturing process applied. In order to produce a finished product of consistent quality it is necessary to determine the specifications both of the production process and the final preparation.

If manufacturing processes such as comminution or pulverising do not alter the composition of the botanical raw material, extraction processes can subsequently be used to modify chemical profiles.

17.3.2 - BOTANICAL EXTRACTS

A botanical extract is a particular type of botanical preparation which, by using a solvent, results in a concentration or a dilution of the constituents of the botanical raw material.

The extraction process may be such as to select, or remove, particular components of the botanical material.

The solvent and the extraction conditions are the key parameters necessary to support the characterisation of an extract, as well as the ratio of the starting plant material to the final extract, which is considered as a range related to the natural variability of the plant material.

Reference should be made to Directive 2009/32 on extraction solvents used in the production of foodstuffs and food ingredients.

17.3.3 - BOTANICAL/EXTRACT RATIO

In practice, the extract ratio can be expressed either in relation to the native extract or the commercial extract. It is important that the reference is clearly indicated (either “native extract” or “commercial extract”)

A native botanical/extract ratio is the ratio of the dry mass of the botanical material entering the extraction process, to the mass of the resulting native extract. The ratio is normally given in the form:

- Botanical mass (dry material): native extract mass.

Due to the natural variability of botanical raw materials Botanical/Extract Ratios will

normally vary within an empirical range specific for the botanical/solvent combination. For example, a 3–5: 1 ratio means that 3–5 kg botanical material has to be extracted to give 1 kg of native extract.

In the case of liquid extracts a ratio of e.g. 1:6 means that from 1 kg of botanical material, a yield of 6 kg of liquid extract is obtained. Because of the fixed botanical/solvent ratio (s. below) botanical/extract ratios are fixed in liquid extracts. The term "native" extract is not applied in liquid extracts.

The extraction ratio should be expressed with the intention of providing the user with the number and quantity of the constituents of the extract on which the usage has been based. Thus, the extract must be characterised. If there is any variation or change in the extraction ratio, it must be supported by scientific data to show that the change does not impact on the overall composition of the extract.

17.3.3.1 - MANUFACTURING PROCESS

Each production step should be carefully described in order to check the compliance of the extract with EU Food Law, for instance Regulation (EU) 2015/2283 on novel foods.

The processes and extraction solvents considered as traditional are usually included in Pharmacopoeial monographs. These include, for example, maceration, infusion, lixiviation, percolation, decoction, and sometimes purification.

Suppliers should provide a Flow Chart that describes the main important production steps, together with In-Process controls and acceptance criteria.

The Flow Chart (or flow diagram) should contain all the agreed specification parameters and approved analytical methods for:

- Acceptance of raw materials including additives
- Verification of solvent concentration / ratios
- In-process controls
- Acceptance of native extract quality
- Acceptance criteria for final (commercial) extract.

For extracts containing additives or other food ingredients (like maltodextrin), the function and proportion of each must be indicated in order to permit calculation of the commercial ratio from the native one.

The process of standardisation and quantification should not include the addition of substances, whether synthetic or derived from botanical matter, other than permitted technological additives and carriers. All technological additives and carriers must conform to the requirements of EU food law. Only additives approved for the particular category of food (e.g. food supplements) can be used and the levels of use must comply with the relevant regulations.

17.3.3.2 - VERIFICATION OF PROCESS

Consistency of the production should be supported by appropriate use of master batch/lot records and change control procedures. In the framework of the HACCP system in place, manufacturers should take the necessary measures to ensure that all stages of the process will consistently achieve the expected results. Manufacturing and quality assurance should be conducted in accordance with defined procedures. At each step the results and conclusions should be documented.

New processes or formulae should be designed to meet consistently the defined parameters of quality. Any changes to the manufacturing process or to the raw material source, including any change in

equipment, should be addressed by necessary modifications to the quality system. The checklists for subcontractors, raw material suppliers and manufacturers which accompany this Guide and can be found at ehpm.org, specifically *designed to assist companies in carrying out this verification process*.

It is also recommended that companies conclude the detailed service level agreement with the raw material suppliers and subcontractors referred to in section 17.7 below.

17.3.3.3 QUALITY REQUIREMENTS

Extracts destined to be used in food supplements within the EU must fully comply with EU food law. This requires full traceability back to the source of the botanical for each batch/lot supplied.

All extracts must be in compliance with EU legislation including contaminants, GMO, irradiation, allergens, nano-ingredients or additives [Regulation (EU) 231/2012].

Regulation on contaminants strictly prohibits the mixing of contaminated extracts with non-contaminated extracts to reduce the contaminant levels.

For organic extracts, a valid certificate of organic status must be available.

For all forms of extracts, full specifications should be supplied to the purchaser.

17.3.4 - VERIFICATION OF NOVEL FOOD STATUS

Novel Food is defined as food that has not been consumed to a significant degree by humans in the EU prior to 1997. "Novel Food" can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU.

It is the responsibility of food business operators to verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation. For this purpose, Food business operators can refer to:

a. Regulations and Guidelines

- Regulation (EU) 2015/2283
- The novel food catalogue: (https://ec.europa.eu/food/safety/novel_food/catalogue_en)
- Union list of novel foods (https://ec.europa.eu/food/safety/novel_food/authorisations/union-list-novel-foods_en)
- The many additional Commission Implementing Regulations
- National guidelines.

b. Evidence of History of Use[4]:

- National Lists
- The BELFRIT List
- Official monographs (e.g. EP, EMA; WHO, Health Canada, Commission E)
- Other monographs and textbooks (e.g. American Botanical Council)
- Free sale certificates issued by Member States
- Evidence of commercialisation (e.g. invoices/catalogues/sales figures).

It should be noted that Novel Food evaluation is of particular importance for botanical food supplements because of the variety of botanical organisms used and the variety of parts thereof and also because research into the nutritional and physiological effects of these botanicals often involves modification of the botanical

from the original form in which it was consumed.

Accurate identification of the botanical and the parts used are essential to Novel Food Evaluation, as is the need to verify that the botanical preparation under review is substantially equivalent to any other botanical with which it is being compared. The following is a pragmatic approach to Novel Food evaluation:

1. Check the use of the botanical and part thereof in one of the above sources.

2. Check the solvent and production process comply with that acknowledged and documented.

3. Check possible similarities between the botanical preparation and other referenced botanical preparations.

4. Assess any differences in terms of safety (e.g. expert report).

5. Descriptions of the manufacturing process and flow charts can be invaluable when evaluating the Novel Food status of botanical preparations.

17.4 - CONTAMINANTS AND RESIDUES

17.4.1 - GENERAL REMARKS

This section reviews the management of contaminants and residues regulated by European Union food legislation and the food legislation of a number of economic areas/countries.

To ensure that food supplements placed on the market are safe and fit for purpose, food business operators must identify, assess and control contaminants and residues that may enter the supply chain or which arise in the course of the production process. Additionally, it should be noted that contaminants or pesticides may be concentrated during the extraction process and this must therefore be taken into consideration when agreeing the maximum levels in the botanical raw material with raw material suppliers.

Appropriate sampling and analysis of products for chemical contamination should be applied in conformity with the requirements laid down in EU legislation. However, many of the contaminants and residues that can potentially be found in botanicals can be the subject of national, not just EU, legal limits. Food operators should therefore be aware of the particular legislation applicable in the countries in which the bulk supplies are grown as well as those in which the final products are intended to be marketed, and introduce appropriate control measures.

It should also be noted that the legal obligation of food businesses to supply safe food is not limited to officially recognised contaminants. Any micro-organisms (their toxins or metabolites) that may pose a risk to foodstuffs should be guarded against via good hygiene practices and HACCP principles. Procedures should be adopted and validated to provide adequate control, including setting and managing limits in the specifications set for suppliers.

The frequency of testing for chemical contaminants is dependent on the potential risk of contamination. For botanicals, GACP provides important information as regards the risk assessment and Risk management of contaminants. Where no specific requirements have been laid down in legislation, other references can be used, e.g. sampling frequency applied or recommended by enforcement authorities or specified in the European Pharmacopoeia for botanicals. Where food law does not offer any provision as regards methodology and limits, those given by the European Pharmacopoeia may be used.

However, for all botanicals sold as food supplements it is important to remember that, for contaminants and residues, the requirements of food law take precedence over medicines law and pharmacopoeial monographs. This is particularly important in

the case of chemical contaminants where limits under food law are often more stringent than those in the Pharmacopoeias.

Under EU food legislation, any product in which the level of contaminants exceeds those permitted in the law cannot be traded in the EU for human consumption and cannot be exported. It is also illegal to mix batches/lots with high contaminant levels with ones of lower levels to bring the mixed batches/lots below the required limit.

The *EHPM Botanical Suppliers' Questionnaire* lists the parameters to be monitored under EU Food Law. However, some impurities may be outside the control of the supplier, as, for instance, when the plant preparation does not present any risk of contamination for a specific impurity: examples include Melamine, mycotoxins (plant, part of plant and climatic zones), and 3-MCPD.

Sometimes, existing analytical methods may not be adequate to show significant results, or it may be that no limits have been set for Food Supplements. It should also be noted that existing standards for impurities in Food are not always well adapted to botanical food supplements because the conditions of use for food supplements differ considerably from those for conventional foods. Pesticides are a particular case in point.

The document *Further Information/Regulatory links to the EHPM Botanical Suppliers' Questionnaire* lists the regulatory texts relevant to contaminants and residues. It also includes the methods and limits described in national and European Pharmacopoeias. In some cases, for reasons of practicality, microbiological levels may be instanced.

17.4.2 - MICROBIOLOGICAL CONTAMINATION

Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs lays down the microbiological criteria for certain micro-organisms and the rules to be complied with by food business operators when implementing general and specific hygiene measures.

Annex 1 of this regulation identifies the specific contaminants of certain classes of foods that must be monitored. Section 2.5 deals with botanical material, requiring the monitoring of E-Coli in pre-cut, fruit and vegetables and unpasteurised fruit and vegetable juices.

The specifications set out in the European Pharmacopoeia under 5.1.8. (Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation) serve as a guide to a broader understanding of the potential risks when working with the botanicals used in food supplements and the maximum acceptable levels.

In general, it is recommended that the following microbiological tests should be carried out on the botanical source, as identified by HACCP analysis:

- Total Plate Count (Total Viable Count)
- Escherichia coli
- Salmonella spp
- Moulds / Yeasts (total combined).

The frequency of testing is not only dependent on the form of cultivation and growing conditions, but also on the manufacturing process, which may itself lead to a reduction of microbial count.

In particular, microbiological contamination with potentially pathogenic organisms can be a serious risk in botanicals, especially in situations where animal waste (faeces) is used as a fertiliser during cultivation or where surface water is used for irrigation. In addition, during harvesting, post-harvesting, drying and subsequent processing stages, contamination with microbial pathogens relevant to human safety may occur. GACP and routine testing should therefore be

introduced to manage microbiological quality.

17.4.3 - IRRADIATION

(see also 17.5.4 – Mandatory Labelling)

Some botanicals can be treated with heat/steam which may reduce risk, and irradiation may be used to control microbiological contamination. Any herbal raw material with a very low microbiological count should be screened for irradiation. Foods and food ingredients authorised to be treated with ionising radiation must be declared on the label of the finished product.

17.4.4 - HEAVY METALS

Heavy metals are normally associated with the soil content in the area of cultivation.

Commission Regulation No. 1881/2006 sets maximum levels for the following Heavy Metals in Food supplements:

- Cadmium
- Lead
- Mercury

In general, the same limits are applied to botanical raw material. However, it is also important to check the requirements of individual Member States, as some may have specific requirements for certain heavy metals, such as arsenic.

17.4.5 - CHEMICAL RESIDUES

Some examples of chemical residues:

- Pesticide, herbicide and fungicide residues
- Ethylene oxide and other fumigants such as phosphine or methyl bromide are not permitted in botanicals - see also 17.4.5.1 re Ethylene oxide in Food Additives
- Solvent residues (see EU legislation on extraction solvents used in the preparation of food and foodstuffs – ref. maximum residue limits for methanol).

17.4.5.1 - ETHYLENE OXIDE CONTAMINATION IN FOOD ADDITIVES

In early 2022, the European Commission and Member States agreed on the following approach to Ethylene oxide ETO contamination in food additives:

- for the products that contain the additive E410 known to be contaminated with ethylene oxide no safe level of exposure for consumers can be defined and hence any level consumers may be exposed to, presents a potential risk to consumers;
- consequently, it is necessary, in order to ensure a high level of health protection, that the food or feed business operators who have placed such products on the EU market shall, under the control of the national competent authorities, withdraw those products from the EU market, and recall them from consumers.

Food product ingredients with residues of ETO above the Maximum Residue Levels (MRLs) must also be withdrawn from the market/recalled from consumers, as must composite/processed food products, in case they contain a contaminated ingredient, regardless of their ETO content.

In addition, for botanical/herbal substances, Implementing Regulation (EU) 2021/2246 of 15 December 2021 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries, requires that food supplements containing herbal substances from China, India and South Korea be tested for ethylene oxide (ETO) and 2-chloroethanol (2-CE), conducted with a control frequency of 20%. A test report and a health certificate should be issued by the Authorities of the exporting country.

It should be noted that whilst the above is the current agreed EU-wide approach, there may be differences in its implementation by Member States. Additionally, at time of writing (2022), EC discussions on the control of this contaminant continue. The Member State experts of the Novel Food and Toxicological Safety Committee have voted unanimously in favour of the draft Commission Regulation amending the Annex to Commission Regulation (EU) No 231/2012 on the presence of ethylene oxide (EtO) in food additives. The European Parliament and the Council can raise objections to the draft until 1 August 2022. Therefore, it is important that food business operators check the status of EC regulation and/or national rules/practices.

17.4.5.2 - PESTICIDE, HERBICIDE AND FUNGICIDE RESIDUES

A "pesticide" is something that prevents, destroys, or controls a harmful organism ("pest") or disease, or protects plants or plant products during production, storage and transport.

The most common use of pesticides is in the form of plant protection products. These products are "pesticides" that protect crops or desirable or useful plant products. The traces pesticides leave in treated products are called "residues".

A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly (e.g. under Good Agricultural Practice).

The European Commission fixes MRLs for all food and animal feed. The MRLs for all crops and all pesticides can be found in the MRL database on the Commission website: https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en

17.4.5.3 - MYCOTOXINS

Mycotoxins are toxic substances excreted by-products produced during the growth of certain fungi (moulds). They can be related to climatic conditions and more importantly to post-harvest storage.

EC Regulation specifies the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs, and include Aflatoxins, Ochratoxin A, Patulin, Deoxynivalenol, Zearalenone, Fumonisins, T-2 and HT-2 toxin, Citrinin, Ergot sclerotia and ergot alkaloids.

Certain species of botanicals are also specifically covered by EU legislation on mycotoxins.

17.4.5.4 - EXTRACTION SOLVENTS AND THEIR RESIDUES

"Extraction solvent" means a solvent which is used in an extraction procedure during the processing of raw materials, foodstuffs, or components or ingredients of these. The extraction solvent is removed, but may result in the unintentional, but technically unavoidable presence of residues or derivatives in the final foodstuff or food ingredient.

The EU Rules on extraction solvents for use in foodstuffs primarily take account of not only human health requirements but also the limits required for the protection of health, economic and technical needs. Directive 2009/32/EC on the approximation of the laws of the EU countries on extraction solvents used in the production of foodstuffs and food ingredients applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients either in the EU or imported into the EU. Annex I is a list of extraction solvents and their conditions of use which may be used during the processing of raw material, of foodstuffs, of food components or of food ingredients.

Extraction solvents used or intended for use in the production of food supplements should be defined together with the limits and conditions of use and the acceptable residue parameters5.

17.4.6 - ENVIRONMENTAL CONTAMINANTS

The other main organic contaminants found in the environment and which can therefore be found on botanical matter are:

17.4.6.1 - DIOXINS, FURANS AND DIOXIN-LIKE POLYCHLORINATED BIPHENYLS (PCBS)

Dioxins, furans and dioxin-like polychlorinated biphenyls (PCBs) are the abbreviated names for a family of chemicals that have similar toxicity and shared chemical characteristics. The dioxins and furans are not manufactured or produced intentionally but are created when other chemicals or products are made. People can be exposed to these chemicals by eating high-fat foods such as milk products, eggs, meat, and some fish or their derivatives. Maximum levels are set for different categories of foodstuff such as vegetable oils and fats.

17.4.6.2 - POLYCYCLIC AROMATIC HYDROCARBONS (PAHS)

Polycyclic aromatic hydrocarbons (PAHs) are a group of more than 100 chemicals that are also called polynuclear aromatic hydrocarbons. PAHs are released from burning coal, oil, gasoline, trash, tobacco, and wood. High-temperature cooking, such as grilling, will form PAHs in meat and other foods. PAHs can be released naturally from forest fires and volcanoes. Since 2015, maximum levels have been set for polycyclic aromatic hydrocarbons in cocoa fibres, banana chips, food supplements, and dried herbs and spices.

The potential formation of PAHs may be linked to the drying system used for the botanical raw material, particularly where direct drying is used and combustion fumes are in contact with the herb material.

17.4.6.3 - PERCHLORATE

Perchlorate occurs naturally in the environment, in deposits of nitrate and potash, and can be formed in the atmosphere and precipitate into soil and groundwater. It also occurs as an environmental contaminant arising from the use of nitrate fertilisers. Perchlorate can also be formed during the degradation of sodium hypochlorite used to disinfect water and can contaminate the water supply. Water, soil and fertilisers are considered to be potential sources of perchlorate contamination in food.

Perchlorate determination should be performed on Tea and Herbal infusions when used as ingredients in food supplements as per Commission Recommendation (EU) 2015/682.

17.4.6.4 - RADIOACTIVITY

Sourcing of botanical material from areas where cultivation / harvesting is in proximity to nuclear disasters (for example, Chernobyl and Fukushima) should be avoided.

17.4.7 - OTHER CONTAMINANTS

Food business operators must ensure that their products meet existing purity standards, and should also be aware of the possibility of other sources of contamination, impurities, undesirable elements that may be present in their products as a result of the various stages of production, packaging, transport or holding.

17.4.7.1 - PYRROLIZIDINE ALKALOIDS (PAS)

PAs are a large group of toxins produced by different plant species. EFSA has estimated that 6000 plant species worldwide may contain PAs including Boraginaceae,

Asteraceae and Fabaceae. To date, more than 350 different PAs, excluding the N-Oxides, have been described, with probably half of them being hepatotoxic. Composition and concentration of PAs may fluctuate and depend on various factors such as species, age and part of the plant, variety (genotype/chemotype), season, location, etc.

The toxins are commonly concentrated in the seeds and the flowering parts of the plant, with decreasing amounts in the leaves, stems and roots. Most plants produce mixtures of PAs in varying concentrations ranging from less than 0.001% to 5%. National limits are currently set in some countries. A new EU regulation [Regulation (EU) 2020/2040] enters into force in July 2022 which sets maximum levels of PAs in different categories of food including Teas, Herbal infusions, Bee products and Food supplements.

1.4.7.2 - 3-MCPD

3-monochloropropane diol (3-MCPD) and analogues called 3-MCPD esters are contaminants from food transformation and are present in certain processed food and vegetable oils, mainly palm oil. The main contributors of 3-MCPD to dietary intakes are soy sauce and soy-sauce-based products. Accordingly maximum levels are set for 3-MCPD in hydrolysed vegetable protein (HVP) and soy sauce, taking into account the risk related to the consumption of these foods.

17.4.7.3 - MELAMINE

Melamine is a chemical compound with a high nitrogen content which has been fraudulently used to boost the protein content of certain food and feed. Absence of melamine should be demonstrated. Where it is found to be present, Regulation EC 594/2012 which amends Regulation (EC) 1881/2006 as regards maximum levels for melamine in food products, and establishes a level of 2.5 ppm applies.

17.5 - MANDATORY LABELLING INFORMATION FOR FINISHED PRODUCTS

Regulation (EU) No 1169/2011 on the provision of food information to consumers is the main law relating to food labelling in the European Union.

17.5.1 - ALLERGENS

The main allergens relevant to botanicals, as an ingredient or processing aid are: celery; cereals containing gluten – including wheat (such as spelt and Khorasan), rye, barley and oats; lupin; mustard; tree nuts – including almonds, hazelnuts, walnuts, Brazil nuts, cashews, pecans, pistachios and macadamia nuts; peanuts; sesame seeds; soybeans sulphur dioxide and sulphites (if they are at a concentration of more than ten parts per million).

Regulation (EU) No 1169/2011 on the provision of food information to consumers requires that the presence of allergens is labelled on the finished product.

17.5.2 - NANOMATERIAL

"Engineered nanomaterial" (any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale), must be labelled on the finished product. See also Regulation EC 2015/2283 on Novel Foods.

Food additives and food enzymes whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, or which are used as processing aids, do not need to be declared on the product label.

17.5.3 - GENETICALLY MODIFIED ORGANISMS (GMOS)

Food business operators must ensure that for pre-packaged products consisting of, or containing GMOs, the following words appear on the product label:

- *"This product contains genetically modified organisms"*; or
- *"This product contains genetically modified [name of organism(s)]"*.

N.B. These labelling requirements do not apply to GM food/feed products in a proportion no higher than 0.9% of the food/feed ingredients considered individually and if this presence is adventitious or technically unavoidable. For further detail, see: Traceability and labelling (europa.eu)

17.5.4 - IRRADIATION

Foods which have been irradiated must have one of the following on the food labels:

- *"irradiated"*; or
- *"treated with ionising radiation"*.

Where an irradiated food is used as an ingredient in another food, these words must appear next to the ingredient in the list of ingredients. If irradiated food is not pre-packed, these words must appear on a display or notice above or besides the container in which the food is placed.

The list of Member States' authorisations of food and food ingredients which may be treated with ionising radiation is available here.

17.6 - PURITY OF FOOD ADDITIVES

Food additives, including colours and sweeteners, must comply with determined specifications that ensure purity levels. It is the responsibility of the Food Business Operator to ensure by supply chain management and scientific analysis that these standards are met. For further detail, see Reg.EC 231/2012,

17.7 - SPECIFICATIONS FOR BOTANICAL PREPARATIONS

All traded botanical preparations must have a comprehensive specification between the supplier and the food supplement manufacturer.

The specification should cover details of the botanical source, the manufacturing process and all relevant chemicals, microbiological and physical parameters. Where measurable parameters are given, they should include the target value and acceptable range. Physical, chemical and microbiological parameters should also be accompanied by the test methods from which the values were determined.

As a minimum, the following should be available in all specifications for botanical preparations:

- The accepted scientific name (Latin name) of the species used.
- The precise part(s) of the plant used in the process.
- Where available, detail of geographical origin (continent, country, region) and growth and harvesting conditions (wild or cultivated, cultivation practices, time of harvest in relation to both season and stage of the plant growth).
- A description of the post-harvesting process, the type of manufacturing process (e.g. pulverising, maceration, percolation), and, in the case of botanical extracts, the solvents must also be specified and any post-extraction processing to obtain the commercial extract.

- Details of the extract ratio (native and commercial extract).
- A full quantitative declaration of all additives (including carriers), other food ingredients and processing aids used in the commercial extract.
- Name and quantity (range) of the constituent(s) with known physiological activity in the case of standardised extracts OR name and quantity (minimum quantity or range) of the active markers in the case of quantified botanical extracts.
- Name and quantity (batch/lot specific control) of the analytical marker in other botanical extracts where appropriate.
- Details of relevant parameters, ranges and limits to confirm identification of the extract. This should include positive identification such as chromatography and/or quantification of a marker substance.
- Confirmation of compliance with all contaminants and residues controlled by legislation in the EU (including pesticide and solvent residues, where relevant).
- Specification of micro-biological criteria.
- Ranges of levels of relevant safety-related constituents.

17.8 - QUALITY CONTROL OF BOTANICAL PREPARATIONS

17.8.1 - GENERAL REQUIREMENTS

The production of botanicals follows the HACCP system. Product documentation should be produced and maintained. This documentation should cover in detail all aspects of the product, from the agreed specifications for the raw botanical material through to the release for sale of the extract. This documentation should include a specification sheet and a flow chart.

All raw material specifications and test procedures should be agreed with the suppliers of the materials. Details of the acceptance criteria for the commercial extract and details of the relevant analytical procedures should be made available to each customer. Information to support the analytical methods reliability should be provided. The documentation should be reviewed at periodic intervals and any amendments made should be recorded, with the date of the amendment.

1.8.2 - IDENTIFICATION

Identification of the botanical material used for its nutritional and physiological effects in food supplements should be confirmed by the following:

- Macroscopic examination;
- Microscopic examination; and, where necessary:
- Chromatographic/spectroscopic examination: e.g. thin layer chromatography (TLC); high-performance liquid chromatography (HPLC); high performance thin layer chromatography (HPTLC);
- Other characteristic assay.

Details of the identity specifications for most of the commonly used botanicals can be found in the scientific literature, international or national standards, or in-house specifications. In some cases other chemical and physical tests can support the identification and establish the quality standards for botanicals entering the production process. Where applicable, these are provided in the monographs relating to the botanical in the Pharmacopoeias. Examples of such tests are:

1. Total ash
2. Insoluble ash

3. Water soluble extractive

4. Foreign organic matter

5. Loss on drying

17.8.3 - SUBSTANCES TO BE MONITORED: MARKERS

As already stated, the identification and characterisation of the plant preparation is an essential first step, providing the parameters that guarantee its quality. An identification test of the raw material must be always carried out as it is essential to check that the species and the part of the plant to be used correspond to the specification. Generally, a plant shows characteristic analytical markers, and marker determination is another parameter used to confirm the quality of the botanical raw material as well as the corresponding preparation.

A marker is a chemically defined characteristic constituent, or group of constituents, present in a specified botanical material.

Markers can be used for control purposes, whether or not they have any physiological activity, as their function is to assist in the determination of the composition and quantification of the botanical raw material and preparation.

Markers can be classified into two categories. The first is termed the “active marker(s)”, which is a constituent or group of constituents that are generally accepted as contributing to a physiological effect in the body.

The second is known as “analytical marker(s)”, constituents or a group of constituents that are known to be characteristic of the botanical material and for which there are established analytical methods. Analytical markers are generally used to assure identity and consistency of a botanical preparation.

The ideal marker is a constituent(s) for which there is an established and validated assay method and for which the assay is not subject to interference from other constituents in the botanical source or from processing.

Analytical procedures and marker amounts can be found in the scientific literature, international or national standards (Ph. Eur, WHO monographs), or in-house specifications. Whenever possible published official methods should be used. Additionally, it is important to check that any methods used by raw material suppliers are readily available and have been validated: the results shown on the Certificate of Analysis must always be verifiable.

Compounds of concern should be monitored the same way. National regulatory texts such as positive lists usually specify relevant safety-related constituents with related maximum limits, as relevant. The EFSA Compendium of botanicals that are reported to contain naturally occurring substances of possible concern for human health is a key reference in this field (https://www.efsa.europa.eu/en/data/compendium-botanicals).

Each batch/Lot of commercial botanical preparation produced should be analysed to confirm that specified marker and/or restricted substance levels are within the required range and that the chemical composition/component spectrum (for example, chromatogram) conforms to acceptable limits.

Constituents responsible for physiological effects or other markers, as shown in Pharmacopoeial monographs or internal standards, should be monitored. In the absence of analytical determination, the supplier should be asked to provide the necessary justification.

The same process applies to substances used in specific preparations. However, if the constituent is only present in a specific type of plant preparation (i.e. an essential oil), it is not necessary to carry out similar

determination on other forms of preparation to demonstrate its absence.

17.8.4 - CERTIFICATE OF ANALYSIS

Each batch/Lot of commercial extract must be accompanied by a Certificate of Analysis (CoA) detailing the results of the tests carried out on that batch/lot. As a minimum, the CoA should cover the:

- Specific identification of the batch/lot, including date of manufacturing and retesting date.
- Confirmation of the identity of the botanical extract.
- Confirmation that the extract complies with the specification with regard to the physical and chemical composition of the extract.
- Confirmation that the extract complies with the legal and otherwise agreed requirements for contaminants.

Confirmation of the irradiation status of the commercial extract (including the botanical source) and other relevant compliance declarations can be reported on CoA or on separate statements.

For extracts intended for use in food supplements, it is essential that the CoA contains sufficient analytical data on extract composition and contaminant levels to allow the manufacturer of the supplement to ensure compliance of the final supplement product with all relevant food legislation.

The CoA should describe the parameter tested, the specification value and range, the test result and a reference to the analytical method. A trend analysis should be carried out by the extract manufacturer on all analytical results at periodic intervals to ensure consistency of production and facilitate risk management.

17.9 - SERVICE PROVIDERS AND THIRD PARTIES/OUTSOURCING

17.9.1 - INTRODUCTION

The supply chain for botanical food supplements can be highly complex and maintaining oversight of every activity undertaken throughout their lifecycle can be very challenging. Few organisations will undertake all the necessary activities themselves but instead will contract out certain activities to third parties. Such activities can include growing or sourcing botanical materials, processing and manufacture, analytical development and testing, or transport and logistics. Responsibility lies with all companies in the supply chain who supply the food material – thus, regardless of where these activities are undertaken, or by whom they are conducted, it is the responsibility of the food business operator (the company who places the product on the market – whether it be raw material or finished product and whether the market is Business to Business or Business to Consumer) to ensure the overall quality and compliance of the finished product.

17.9.2 - GENERAL

Often, and particularly for companies manufacturing botanical products, there will be a number of different suppliers or service providers, all of whom will require management. Although the services provided may be different in each case, vendor and service provider management programs generally consist of written agreements or contracts, supported by monitoring, verification or audit processes. The written agreements detail expectations for the services provided, and the verification and audit processes confirm that these expectations are being met.

17.9.3 - CONTRACTS AND AGREEMENTS

Outsourced activities need to be appropriately defined, detailed and controlled. This requires written agreements between the parties involved which clearly state their obligations and expectations. Ownership of materials, actions and responsibilities at all stages of the product lifecycle must be defined and there must be transparency of when and where all activities take place. Contracts and Service Level Agreements (SLAs) with raw material suppliers or subcontractors are a key element in assuring that quality requirements are met throughout the botanical supply chain.

17.9.4 - SUPPLIER ASSURANCE & PERFORMANCE

Supplier assurance is an important factor in ensuring the integrity of products. It can be demonstrated through the use of approved or certified suppliers, and through vendor management processes that target compliance activities towards the most vulnerable supply chain points.

For Botanical materials, supplier assurance is likely to involve demonstration of compliance with Good Agricultural, Collection and Manufacturing Practices, thus ensuring:

- Consistent controls at all single or multiple plantations/locations.
- Adequate testing protocols for plant materials pre-harvest
- Risk reduction measures to manage cross contamination from:
    - Type of harvesting e.g. mechanical or hand.
    - Post-Harvest activities such as storage and Transport.
    - Post-Harvest processing including activities such as:
    - Drying- especially if undertaken at a new location.
    - Mixing of plant batches/lots - Identification of plants to ensure that they are all the same species.

Supplier performance should also be continually monitored and evaluated through the company Quality Management System. For example, records should be kept ensuring that:

- Deliveries are made on time and are complete as ordered.
- Materials provided are within specification.
- Certificates of analysis and documentation are provided in good time.

This information should be trended and reviewed as part of the vendor management process. Where expectations are not being met, appropriate action should be taken with corrective and preventative measures put in place.

17.9.5 - AUDIT & INSPECTION

In addition to continually monitoring the performance of suppliers, a routine audit and inspection programme should be established. Prior to the engagement of services with any third party, it must first be established that the supplier can provide the services required. This can be assessed by a number of different means but primarily through the use of audits. Once audited and approved, the supplier can be granted “approved status”, permitting services to be engaged. It is recommended that organisations maintain a list of approved suppliers which is proactively managed through the Quality Management System.

In addition to the initial audit, suppliers and service providers should be subject to routine inspection and audit as part of the vendor management and assurance process. A risk-based audit schedule should be established which focusses audit activity on

those suppliers or parts of the supply chain that represent the most significant risks. For example, given the propensity for botanical material to be adulterated, misidentified or contaminated, audit activities should focus on those parts of the supply chain where such activities are most likely to occur – a raw material supplier would therefore have a higher risk rating than a tertiary packaging supplier and would subsequently be subject to more frequent and thorough audit.

The audit schedule itself should be managed proactively and updated with new information on suppliers as and when it becomes available. For example, new suppliers may need to be incorporated into the schedule, or "for cause" audits may need to be arranged due to a reported quality incident or poor performance recorded against the supplier as part of the vendor management process.

Desktop audits may be appropriate for some service providers, especially those with low associated risks or good performance records, and quality questionnaires can sometimes be used in place of on-site visits. However, in many instances physical audits of suppliers or third-party service providers will be required to ensure operations and services are of a suitable standard.

It is recommended that organisations who undertake third party audits themselves should develop appropriate SOP's to govern the organisation, scheduling, conduct and closure of audits. Consideration should also be given to developing bespoke audit checklists, tailored to the specific function or activity being audited. Such checklists are both useful tools for conducting audits, and also help to maintain a consistent company approach to auditing, across functions/ different activities and in conducting follow-up and repeat audits.

Examples of audit checklists can be found in the public domain or obtained through appropriate consultancies.

17.9.6 - RAW MATERIAL SUPPLIERS

The supply of botanical raw materials is perhaps the most critical and vulnerable element of the supply chain. Ensuring the identity and quality of botanical raw materials is paramount in determining the quality of the finished Botanical Food Supplement, so effective management of raw material suppliers is essential.

Robust contracts, Technical and Service Level Agreements help ensure that raw materials and end products are covered adequately by full specifications. Best practice requirements should be clearly emphasised, and quality control, record transfer, batch/lot coding, rejection, dispute and complaint procedures all clearly identified and agreed. Determining compliance with Good Agricultural and Collection Practices, as detailed in Section 4, can only be possible if there is transparency across the early stages of the product lifecycle. You must be able to determine which activities have happened, where, and by whom they were conducted. This can become increasingly complex if plants are sourced from multiple locations, and storage, primary processing, or blending activities are also undertaken.

17.9.6.1 - CHALLENGES WITH BOTANICALS

Sometimes, companies may work directly with small-scale growers or individuals who collect plants from the wild who may not be used to written contracts or agreements let alone the requirements of a Quality Management System - and in some parts of the world there may be additional language barriers to manage as well. Alternatively, raw materials may be sourced from a specialised botanical supplier, who in turn, sources materials from individual growers (both near and far).

Given the opportunities for botanical misidentification, substitution, adulteration and contamination during these stages of the product lifecycle, you must seek assurances that your supplier is managing their individual suppliers appropriately. With particularly complex supply chains, and especially those involving exotic plant species, full transparency and understanding all supply chain activities can be very challenging to achieve - and in some circumstances neither practical nor realistic.

It is not possible to eradicate all risks from supply chain activities, but a good risk management plan will highlight the potential risks so that mitigating actions can be taken against them, wherever possible, and business processes adapted accordingly. If no further risk mitigation steps are possible, then the detection methods employed need to be proportionate to the risks identified and must be sufficiently thorough to capture any quality incidents that may result.

17.9.7 - CONTRACT MANUFACTURERS

Organisations may choose to outsource all or part of the manufacturing process for Botanical Food Supplements. However, the critical elements of Good Manufacturing Practice must be taken into consideration when evaluating whether to outsource such activities. It must be established that the manufacturer operates to acceptable and appropriate quality standards and is suitably accredited or inspected to those standards. They must have an established risk management and reduction programme (HACCP for example) and a fully functioning Quality Management System.

It is highly recommended that they should have experience in handling and manufacturing products with botanical materials, and that regular audits are conducted to confirm operational quality standards are being maintained. Such audits should focus on the critical control points in the overall manufacturing process, which in the case of botanicals will include:

- Identification and testing of incoming materials
- Handling and Storage or materials and products
- Manufacturing Processes and Controls
- Cross contamination throughout the facility
- Finished product testing and release
- Out of Specification results and Deviations
- Rejections, Complaints and Recalls

Suitably detailed contracts and Technical Agreements must be established with contract manufacturers to ensure that each party is fully aware of their responsibilities and can meet each other's expectations. Such documents should also ensure transparency of all activities and specify, for example, if the contract manufacture subcontracts certain activities to a third party. This may be the case with analytical testing or transportation and logistics, and so assurances must be provided that these activities are appropriately managed and controlled.

17.9.8 - TESTING AND ANALYTICAL SERVICE PROVIDERS

Analytical testing is an activity which is quite frequently outsourced as it can involve highly specialised equipment and personnel which may not be available within every organisation. Some organisations may choose to outsource all testing as they have no laboratory facilities themselves, whereas others may perform some testing in house, but use external labs for more specialised

testing. Whatever the testing scenario, it must first be ensured that the testing facility in question is suitably accredited to perform the required testing and has adequate experience and expertise in conducting such tests on botanicals.

Analytical testing with botanical materials can be highly complex and organisations may choose to outsource testing for:

- Raw material identification
- Marker Analysis
- Microbial levels and contaminants
- Finished product specification compliance
- Stability time points

17.9.8.1 - CHALLENGES WITH BOTANICALS TESTING

There are multiple analytical techniques that can be applied to the testing of botanical materials and finished products. However, the test method utilised must be fully validated, both for the material being tested and the matrix being analysed. For example, there may be a published Pharmacopoeial test method available for the identification of a marker in botanical raw material, but the same test may not be valid once the raw material has been processed, incorporated into a tablet or extracted into a solvent. The laboratory must therefore be able to provide assurances that all test methods are suitably validated (for example, to demonstrate specificity, linearity, accuracy and precision) so as to produce replicable and reliable results. Thus, the integrity of the data – the maintenance and assurance of its accuracy and consistency is critical.

17.9.8.2 - TESTING LABORATORIES

Due to the complex nature of botanicals, and their natural variability, it is quite likely that testing laboratories will at some point encounter test results that are out of specification or out of trend. It is therefore essential that the testing laboratory has a robust out of specification procedure in place, is open and transparent about test (and re-test) results, and is able to provide expertise and advice in the interpretation of such results. It should also be ensured that updates or changes to testing methods are not implemented without notification, and that testing is not subcontracted out to third parties without prior approval.

17.9.9 - TRANSPORTATION AND LOGISTICS

Transportation of Botanical materials and finished products is a part of the supply chain and botanicals may be subject to movement and transport on multiple occasions. At some of these times the materials or products can be at their most vulnerable to contamination, tampering, adverse environmental conditions or even theft.

Good Distribution Practices should be applied to Botanical materials and finished products, and these elements in particular should be specified in contracts and Technical Agreements. For Botanicals with a particularly complex supply chain, or those sourced from overseas and exotic locations, ownership and responsibilities for materials must be clearly specified and all parties must understand who has responsibility for ensuring the quality of materials transported from one location to another. The more complex the supply chain and the more personnel or organisations involved in handling and transporting the materials, then the greater the risk that adulteration, contamination or tampering might occur and that the overall traceability of the material may be compromised.

ANNEX I: GENERAL GLOSSARY OF TERMS

General Terms

Terms	Explanation
Analytical Method	A detailed description of the procedure to be followed in performing tests for assessing conformity with the specification.
Audit System	Independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Audit Criteria	Set of policies, procedures or requirements.
Audit Evidence	Records, statements of fact or other information which are relevant to the audit criteria and are verifiable.
Auditor	Person with demonstrated personal attributes and competence to conduct and audit.
Batch/lot	See Lot/batch below.
Batch/lot Manufacturing Record	See Lot/batch Manufacturing Record below.
Batch/Lot number	See Lot/batch Number below.
Bulk Product	Any product that has completed all processing stages up to but not including, final packaging.
Characteristic	Distinguishing feature.
Competence	Demonstrated ability to apply knowledge and skills.
Conformity	Fulfilment of a requirement.
Contract	Binding agreement.
Contract Manufacture	An organisation (the contract acceptor) that manufactures or partially manufactures a product for another person or organisation (the contract giver).
Corrective Action	Action to eliminate the cause of a detected nonconformity or other undesirable situation.
Customer	A person or organisation that purchases another company's goods or services.

Terms	Explanation
Defect	Non-fulfilment of a requirement related to an intended or specified use.
Documentation	All written procedures, instructions and records, quality control procedures and recorded test results involved in the manufacture of a food supplement.
Effectiveness	Extent to which planned activities are realised and planned results achieved.
Finished Product	A food supplement which has undergone all the stages of manufacture.
Information	Meaningful data.
Ingredient	Any substance that is used in the manufacture of a food supplement and that is intended to be present in the finished product.
Inspection	Conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing, or gauging.
Intermediate Product	Any material or mixture of materials which have to undergo one or more stages of processing to become a bulk product or a finished product.
Lot/batch	A quantity of any food supplement produced during a given cycle of manufacture and from a specific formulation order, that is uniform in character and quality (the essence of a manufacturing lot is its homogeneity).
Lot/batch Manufacturing Record	A document stating the materials used and operations carried out during the manufacture of a given lot, including details of in-process controls and the results of any corrective action taken. It should be based on the Master Manufacturing Instructions and be compiled as the manufacturing operation proceeds.
Lot/batch Number	A designation [in numbers, letters or a combination of both] that identifies the lot and that permits the complete history of the lot, including all stages of production, control and distribution, to be traced and reviewed.
Management	Coordinated activities to direct and control an organisation.
Management System	System to establish policy and objectives and to achieve those objectives.
Manufacture	The complete cycle of production and quality control of a food supplement from the acquisition of all materials through all stages of subsequent processing, packaging and storage to the distribution or release of the finished product.

Terms	Explanation
Master Manufacturing Instructions	A document or documents identifying the raw materials, with their quantities, to be used in the manufacture of a food supplement, together with a description of the manufacturing operation and procedures including identification of the equipment and facilities to be used, processing conditions, in-process controls, packaging materials to be used and instructions for the removal of finished products to storage.
Measuring Equipment	Measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realise a measurement process.
Measurement Process	Set of operations to determine the value of a quantity.
Nonconformity	Non-fulfilment of a requirement.
Objective Evidence	Data supporting the existence or authenticity of something.
Organisation	Group of people and facilities with an arrangement of responsibilities, authorities and relationships.
Packaging	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product.
Packaging Materials	Any material, including printed material, employed in the packaging of a food supplement, such as containers, closures, bags, packing, label materials (labels, inserts, etc.), seal, binding materials, adhesives and tapes.
Preventive Action	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
Process	Set of interrelated or interacting activities which transform one or more of the properties (physical, chemical, microbiological, sensory) of the raw materials.
Procedure	Specified way to carry out an activity or a process.
Product	Result of a process.
Quality	Degree to which a set of inherent characteristics fulfils requirements.
Quality Assurance	Part of quality management focussed on providing confidence that quality requirements will be fulfilled. Mainly focussed on intended product.
Quality Control	Part of quality management focussed on fulfilling quality requirements. Includes all measures undertaken during manufacture designed to ensure the uniform output of food supplements that conform to established specifications of identity, purity, strength and other characteristics.

Terms	Explanation
Quality Management	Coordinated activities to direct and control an organisation with regard to quality.
Quality Manual	Document specifying the quality management system of an organisation.
Quality Plan	Document specifying which procedures and associated resources shall be applied by whom and when to a specific product, process or contract.
Quarantine	The status of any materials or product set aside (physically or by a system) while awaiting a decision on their suitability for processing, packaging or distribution.
Raw Materials	All materials whether active or inactive ingredients that are employed in the processing of food supplements.
Record	Document stating results achieved or providing evidence of activities performed.
Released	The status of starting materials, intermediate, bulk or finished products which are allowed to be used for processing, packaging or distribution.
Rejected	The status of starting materials, intermediate, bulk or finished products which are not permitted to be used for processing, packaging, or distribution and which should be discarded in a safe manner.
Reprocessing	Using, in the manufacture of a food supplement, clean, uncontaminated materials or products that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a food supplement.
Requirement	Need or expectation that is stated, generally implied or obligatory.
Review	Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives
Rework	Action on a nonconforming product to make it conform to the requirements.
Specification	A document giving the description of a starting material, intermediate, bulk or finished product in terms of its chemical, physical and (if any) biological characteristics. A specification describes in detail the requirements with which the products or materials used or obtained during manufacture have to conform and normally includes descriptive clauses and numerical clauses, stating standards and permitted tolerances. It serves as a basis for quality evaluation.
Starting Materials	Any substance or mixture of substances (premix) used in the production of a food supplement excluding packaging material.

Terms	Explanation
Supplier	Organisation or person that provides a product.
System	Set of interrelated or interacting elements.
Test	Determination of one or more characteristics according to a procedure.
Traceability	Ability to trace the history, application or location of raw materials or product.
Validation	Confirmation through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Botanical Specific Terms

Terms	Explanation
Botanical	Plant material, including whole, fragmented or cut plants, plant parts, plant products (such as exudates), algae, fungi and lichens.
Botanical Preparation	All preparations obtained from botanicals by various processes (e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation). These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.
Botanical Extract	Is the complex, multi-component mixture obtained after extracting a botanical raw material (consisting of one or more botanicals) with a solvent. The extraction process may be such as to select for, or remove, components of the botanical material. Extracts may be in dry, liquid or semi-solid form.
Native Extract	Is the material consisting only of extracted components present in the original botanical or formed during the extraction process and excludes any technological additives or any other added substances. This term may refer to liquid extracts or semi-solid extracts from which the added solvent has been removed or to a dry extract or that portion of a finished extract that is comprised solely of botanical components. Note: when determining whether two extracts are comparable, the native extracts should be used for comparison.

Terms	Explanation
Commercial Extract	Is a native extract to which one or more technological additives (for example, inert carriers, anti-caking agents) or other food ingredients (for example maltodextrin, dextrose, and vegetable oil) may have been added to facilitate inclusion in the final supplement product. It should be noted that the added substances can, in some cases, comprise a very large proportion of the commercial extract.
Marker	Is a chemically defined characteristic constituent, or group of constituents, present in a specified botanical material.
Active marker(s)	Which is a constituent or group of constituents that are generally accepted as contributing to a physiological effect in the body.
Analytical marker(s)	Which are constituents or a group of constituents that are known to be characteristic of the botanical material and for which there are established analytical methods. Analytical markers are generally used to assure identity and consistency of a botanical preparation.
Ratio	Is the relation between the dry mass of the botanical material entering the extraction process, and the mass of the resulting native extract.
Standardised botanical extracts	Are adjusted within an acceptable tolerance to a given content of specific and relevant physiologically active constituents. Standardisation is achieved by adding additives or other food ingredients (such as maltodextrin) for adjustment to the botanical extract or by blending batches/Lots of the botanical extract. For standardised botanical extracts the name and content of the constituent(s) with known physiological activity, together with details and quantities of all additives (including carriers) and other food ingredients (such as maltodextrin) should be given in documents accompanying the batch/Lot of standardised extract.

Terms	Explanation
Quantified botanical extracts	Are adjusted to a defined range of those constituents considered to contribute to the physiological activity. Adjustments are made by blending batches/lots with differing constituent levels to achieve the desired range. Additives (including carriers) and other food ingredients can be used but in fixed quantities. For quantified extracts the names of the active markers on which the adjustments are made should be given, together with their quantity or range. The details, together with information on the types and quantities of any additives should be given in documents accompanying the batch/Lot of quantified extract.
Other Botanical Extracts	For botanical extracts where there are no known constituents with defined physiological activity or active markers, the extracts can only be defined by their production process and by appropriate specifications. Such extracts can be produced from one or mixtures of botanicals. For such extracts the quantity of the native (genuine) botanical extract and details and quantities of any additives (including carriers) and other food ingredients should be given in documents accompanying the batch/Lot of extract. Additives (including carriers) and other food ingredients can be used but in fixed quantities.

ANNEX II: GLOSSARY OF TERMS ASSOCIATED WITH HACCP

Terms	Explanation
Control Point	Any point, step or procedure at which microbiological, physical or chemical factors can be controlled.
Critical Control Point (CCP)	A step in a process or a procedure which, if controlled will eliminate or reduce a hazard to an acceptable level.
Critical Limit	A criterion which separates acceptability from unacceptability.
CCP Decision Tree	A sequence of questions to determine whether a control point is or is not a CCP.
Deviation	Failure to meet a critical limit.
Flow Chart/Diagram	The detailed sequence of operations involved with a particular product or process, usually from the raw material through to the end user.
HACCP	Hazard Analysis Critical Control Point. A systematic and documented approach to hazard identification, assessment and control.

HACCP Plan	The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.
Hazard	An intrinsic property of a system, operation, material or situation that could in certain circumstances cause harm to the consumer; can be microbiological, chemical or physical.
Hazard Analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the plan.
Monitoring	The planned observations and measurements of targets and tolerances of control points to confirm that the process is under control.
Preventative Measure	Any factor that can be used to control an identified hazard.
Tolerance	The specified degree of latitude for a control measure which, if exceeded, would render the process or product unsafe.
Validation	Obtaining evidence that the elements of the HACCP plan are effective.
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Annexes I and II are adapted from:

"Current Good Manufacturing Practices in Manufacturing, Packaging, Labelling, or Holding Operations for Dietary Supplements" (2007) Department of Health and Human Services, Food and Drug Administration, USA. Reference No. 21 CFR Part 111.

'Food and Drink Good Manufacturing Practice, 7th edition (2018) Institute of Food Science and Technology (UK) London.

"Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements" 1st edition (2008) ASEAN Working Party, Malaysia.

"International Standard ISO 9000 3rd edition: Quality management systems – Fundamentals and vocabulary" (2005) Reference No. ISO 9000 2015.

ANNEX III: EXAMPLE OF PRACTICAL APPLICATION OF HACCP

Adapted from the Belgian Auto-control Guide developed by BE-SUP — the Belgian Federation for Food Supplements, Dietary and Organic products, re-named Be-Sup from 19/02/2020.

A) Steps to follow for carrying out an HACCP study

Define the field of study	Specify clearly what product and manufacturing process you are going to study; make clear where your responsibility starts and finishes.
Put together the HACCP team	For your HACCP study to be effective and relevant, bring a multidisciplinary team of colleagues around the table.
Describe the product	When you are seeking to guarantee the safety of your products, the first question which obviously arises is "What are the risks that could contaminate my product?"
Ascertain its expected use	The risks depend closely on the product itself, its composition and its characteristics, and also on the method of manufacture and on your work environment in the widest sense (premises, equipment, and operators). Before beginning it is therefore necessary to collect maximum information about the food supplement under study and its manufacturing process, including the raw materials used. Once this information is assembled, you are equipped to begin analysis of the risks.
Construct a diagram of the manufacturing	
Check the diagram of the manufacturing	
Principle 1 Analyse the risks	First of all, you will identify all the hazards likely to be present in the finished product. You will then try to determine the measures that can be carried out to overcome each hazard. Finally, you will categorise the risks by evaluating each of them on the basis of the gravity of its effects and the probability of its presence in the food supplement. This evaluation of the risks will enable you to identify the hazards, prior to their thorough monitoring and management within your establishment to avoid the risk of a consumer incident.

Principle 2 Determine the critical control points (CCP)	It then remains to define, for each risk judged unacceptable, how and at what stage of production you will ensure that this risk is in fact well under control, i.e. that it will be anticipated, eliminated or brought down to an acceptable level. Let us take the case of the production of ampoules with algae (or seaweed) extract as the main ingredient. Algae are naturally contaminated by various micro-organisms certain of which are potentially pathogenic. If you do not take specific measures, there is a risk that the ampoules may contain those micro-organisms likely to cause toxic food poisoning. To avoid this, you need to carry out a systematic and adequate heat treatment of the ampoules. Therefore this risk will be controlled at the moment of the heat treatment of the ampoules. The stages or steps at which you can and must monitor efficient control of a risk are called the critical control points for risks. They are in fact critical in the sense that bad management at this stage has a strong chance of leading to the manufacture of a food supplement not fit for consumption.
Principle 3 Define the critical limits for each CCP	To understand this, imagine the development of bacteria in ampoules which, for one reason or another, have not been properly sterilised. As a matter of course, the risk would be if you did not realise the sterilisation problem, and you commercialised the ampoules in this condition.
Principle 4 Establish a plan for monitoring the CCPs	Good management of the problem thus assumes that you monitor the proper sequence of operations at the points which are critical in the manufacture of food supplements. Good monitoring of the sterilisation scales will enable you to verify that all is well. This obviously presumes that you have defined in advance what you call the proper sequence of operations for sterilisation: What length of time, what temperature? These are the critical limits which must be observed to avoid losing control of the risks.
Principle 5 Anticipate the corrections and corrective measures to be put into place in case of exceeding critical limits	Should these limits not be observed, a fact which will be brought to light in good time as a result of your monitoring of the critical point, you must act quickly to enable a return if possible to the usual standards of the product (the correction). In this situation you will consider a new cycle of sterilisation. If needed, you will also consider what must be done to avoid a repetition of the problem which has arisen, by treating the cause at the origin of the problem (the corrective action).

A) Steps to follow for carrying out an HACCP study

Principle 6 Verify the effectiveness of the HACCP system	It then remains for you to verify in an organised way that your self-monitoring gives the anticipated results, notably by checking the safety of your products by means of analysis.
Revised the HACCP Plan	Review your HACCP plan at every modification of the company's organisation which could have repercussions on the safety of the food supplements.
Principle 7 Document the implementation of the preceding principles	Keep a written record of your observations at the time of the HACCP study. Document very clearly the instructions on monitoring to be carried out at the different critical points. Keep registers related to the CCP controls.

Adapted from the Belgian Auto-control Guide by BE-SUP — the Belgian Federation for Food Supplements, Dietary and Organic products, re-named Be-sup from19/02/2020.

B) Example of a HACCP document that may be used for the processing of each food supplement batch

MANUFACTURING OF				Edition:		
INTERNAL PRODUCT PROCESS				Date:		
Phase	Risk (Physical/ Chemical/Biological)	Preventative Actions	Critical Control Point (CCP)	Target Levels and Tolerances	Control (Vigilance)	Corrective Measures

ANNEX IV: LEGISLATION ON MICROBIOLOGICAL CRITERIA

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Commission Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Other pertinent references to address microbiological aspects:

European Pharmacopoeia – Chapter 5.1.8: Microbiological Quality of herbal medicinal products for oral use and extracts used in their preparation

European Pharmacopoeia – Chapter 2.6.12: Microbiological examination of non-sterile products – microbial enumeration tests

European Pharmacopoeia – Chapter 2.6.13: Microbiological examination of non-sterile products – test for specified micro-organisms

European Pharmacopoeia – Chapter 2.6.31: Microbiological examination of herbal medicinal products for oral use and extracts used in their preparation

ANNEX V: LEGISLATION ON CONTAMINANTS AND RESIDUES

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs

Commission Regulation (EC) No 629/2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs

Commission Regulation (EU) No 105/2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards ochratoxin A

Commission Regulation (EU) No 165/2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins

Commission Regulation (EU) No 420/2011 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs

Commission Regulation (EU) No 835/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs

Commission Regulation (EU) No 1258/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for nitrates in foodstuffs

Commission Regulation (EU) No 1259/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs

Commission Regulation (EU) No 252/2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006

Commission Regulation (EU) No 594/2012 amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non-dioxin-like PCBs and melamine in foodstuffs

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance

Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Commission Regulation (EU) No 488/2014 of 12 May 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in foodstuffs

Commission Regulation (EU) 2015/1005 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs

Commission Regulation (EU) 2015/1933 of 27 October 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in cocoa fibre, banana chips, food supplements, dried herbs and dried spices

Commission Regulation (EU) No 696/2014 of 24 June 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of erucic acid in vegetable oils and fats and foods containing vegetable oils and fats

Commission Regulation (EU) No 1327/2014 of 12 December 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of polycyclic aromatic hydrocarbons (PAHs) in traditionally smoked meat and meat products and traditionally smoked fish and fishery products

Commission Regulation (EU) 2015/704 of 30 April 2015 amending Regulation (EC) No 1881/2006 as regards the maximum level of non-dioxin-like PCBs in wild caught spiny dogfish (Squalus acanthias)

Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs

Commission Regulation (EU) 2015/1125 of 10 July 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in Katsuobushi (dried bonito) and certain smoked Baltic herring

Commission Regulation (EU) 2015/1137 of 13 July 2015 amending Regulation (EC) No 1881/2006 as regards the maximum level of Ochratoxin A in Capsicum spp. spices

Commission Regulation (EU) 2015/1933 of 27 October 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in cocoa fibre, banana chips, food supplements, dried herbs and dried spices

Commission Regulation (EU) 2015/1940 of 28 October 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting

Commission Regulation (EU) 2016/239 of 19 February 2016 amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children

Commission Regulation (EU) 2017/1237 of 7 July 2017 amending Regulation (EC) No 1881/2006 as regards a maximum level of hydrocyanic acid in unprocessed whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer

Commission Regulation (EU) 2018/290 of 26 February 2018 amending Regulation (EC) No 1881/2006 as regards maximum levels of glycidyl fatty acid esters in vegetable oils and fats, infant formula, follow-on formula and foods for special medical purposes intended for infants and young children

Commission Regulation (EU) 2019/1870 of 7 November 2019 amending and correcting Regulation (EC) No 1881/2006 as regards maximum levels of erucic acid and hydrocyanic acid in certain foodstuffs

Commission Regulation (EU) 2019/1901 of 7 November 2019 amending Regulation (EC) No 1881/2006 as regards maximum levels of citrinin in food supplements based on rice fermented with red yeast Monascus purpureus

Commission Regulation (EU) 2020/685 of 20 May 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of perchlorate in certain foods

Commission Regulation (EU) 2020/1255 of 7 September 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of polycyclic aromatic hydrocarbons (PAHs) in traditionally smoked meat and smoked meat products and traditionally smoked fish and smoked fishery products and establishing a maximum level of PAHs in powders of food of plant origin used for the preparation of beverages

Commission Regulation (EU) 2020/1322 of 23 September 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain food

Commission Regulation (EU) 2020/2040 of 11 December 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain foodstuffs

ANNEX VI: LEGISLATION ON ADDITIVES

Regulation (EC) No 1333/2008 on food additives

Commission Regulation (EU) No 238/2010 amending Annex V to Regulation (EC) No 1333/2008 with regard to the labelling requirement for beverages with more than 1,2% by volume of alcohol and containing certain food colours

Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008 by establishing a Union list of food additives

Commission Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

Commission Regulation (EU) No 1131/2011 amending Annex II to Regulation (EC) No 1333/2008 with regard to steviol glycosides

Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008

Commission Regulation (EU) No 232/2012 amending Annex II to Regulation (EC) No 1333/2008 as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124)

Commission Regulation (EU) No 380/2012 amending Annex II to Regulation (EC) No 1333/2008 as regards the conditions of use and the use levels for aluminium-containing food additives

Commission Regulation (EU) No 472/2012 amending Annex II to Regulation (EC) No 1333/2008 as regards the use of glycerol esters of wood rosins (E 445) for printing on hard-coated confectionery products

Commission Regulation (EU) No 1057/2012 of 12 November 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of dimethyl polysiloxane (E 900) as an anti-foaming agent in food supplements

Commission Regulation (EU) No 816/2013 of 28 August 2013 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Neutral methacrylate copolymer and Anionic methacrylate copolymer in solid food supplements and the Annex to Commission Regulation (EU) No 231/2012 as regards the specifications for Basic methacrylate copolymer (E 1205), Neutral methacrylate copolymer and Anionic methacrylate copolymer

Commission Regulation (EU) No 264/2014 of 14 March 2014 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyvinylpyrrolidone-vinyl acetate copolymer in solid food supplements and the Annex to Commission Regulation (EU) No 231/2012 as regards its specifications

Commission Regulation (EU) No 497/2014 of 14 May 2014 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Advantame as a sweetener

Commission Regulation (EU) No 923/2014 of 25 August 2014 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of aluminium lakes of riboflavins (E 101) and cochineal, carminic acid, carmines (E 120) in certain food categories and Annex to Regulation (EU) No 231/2012 as regards the specifications for riboflavins (E 101)

Commission Regulation (EU) 2015/647 of 24 April 2015 amending and correcting Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain food additives

Commission Regulation (EU) 2016/324 of 7 March 2016 amending and correcting Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain food additives permitted in all categories of foods

Commission Regulation (EU) 2017/1399 of 28 July 2017 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards potassium polyaspartate

Commission Regulation (EU) 2017/874 of 22 May 2017 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations

Commission Regulation (EU) 2017/1271 of 14 July 2017 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of use of silicon dioxide (E 551) in potassium nitrate (E 252)

Commission Regulation (EU) 2018/98 of 22 January 2018 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards calcium sorbate (E 203)

Commission Regulation (EU) 2018/1461 of 28 September 2018 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Low-substituted hydroxypropyl cellulose (L-HPC) in food supplements

Commission Regulation (EU) 2018/1481 of 4 October 2018 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards octyl gallate (E 311) and dodecyl gallate (E 312)

Commission Regulation (EU) 2018/1497 of 8 October 2018 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards food category 17 and the use of food additives in food supplements

Commission Regulation (EU) 2020/279 of 27 February 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of soybean hemicellulose (E 426)

ANNEX VII – GENERAL LABELLING REQUIREMENTS

The following are key pieces of EU legislation relevant to the labelling of food supplements.

- Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements
- Regulation 1829/2003 on genetically modified food and feed
- Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
- Regulation (EC) No 1924/2006 on nutrition and health claims
- Regulation 1333/2008 on food additives
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods
- Regulation (EC) No 1169/2011 on food information to consumers
- Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health
- Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food
- Regulation (EU) 2015/2283 on novel foods
- Regulation (EU) 2017/2470 establishing the Union list of novel foods

- Commission Implementing Regulation (EU) 2018/775 laying down rules for the application of Article 26(3) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards the rules for indicating the country of origin or place of provenance of the primary ingredient of a food
- Regulation (EC) No 834/2007 on organic production and labelling of organic products
- Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

The table below provides a list of 44 factors/ information that may need to be taken into account when labelling food supplements, based on requirements in EU legislation. The column in the table for mandatory particulars indicates the information to be provided on the labelling. The explanatory information column provides explanations. Not all the 44 items listed will be applicable to every food supplement product. Rows 1, 6 and 12 in the table are mandatory particulars that must be provided in the same field of vision on labelling.

Number	Mandatory Particulars	Explanatory Information
1	Name of the food "FOOD SUPPLEMENT"	
2	The names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances	
3	List of ingredients	Preceded with the word "ingredients" in descending order of weight, as recorded at the time of their use in the manufacture of the food (ingredients constituting less than 2% of the finished product may be listed in a different order after the other ingredients).
4	All ingredients present in the form of engineered nanomaterials	Shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets[4].

4 - See Regulation (EU) 1169/2005

Number	Mandatory Particulars	Explanatory Information
5	Certain substances or products causing allergies or intolerances (listed in the Regulation)	Shall be indicated in the list of ingredients and emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour.
6	Net quantity	
7	Date of minimum durability or “use by” date	Case of individual portions: should be indicated on each portion.
8	Any special storage conditions and/or conditions of use.	Indicate, if applicable, conditions and/or deadline for consumption once the packaging is opened.
9	The name or business name and address of the food business operator (responsible for the labelling information)	
10	The country of origin or place of provenance	If its omission can mislead the consumer.
11	Instructions for use	Where it would be difficult to make appropriate use of the food in the absence of such instructions.
12	Beverages containing more than 1,2% by volume of alcohol, must specify his actual alcoholic strength by volume	
13	The portion of the product recommended for daily consumption	
14	A warning not to exceed the stated recommended daily intake	
15	A statement to the effect that food supplements should not be used as a substitute for a varied diet	
16	A statement to the effect that the products should be stored out of the reach of young children	

Batch

Number	Mandatory Particulars	Explanatory Information
17	Indication of the batch/lot number.	Mandatory information established by 2011/91 Directive.

Nutritional Information (Only for Active Substances)

Number	Mandatory Particulars	Explanatory Information
18	The amount of the nutrients or substances with a nutritional or physiological effect present in the product	• Shall be declared on the labelling in numerical form. • The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling. • Information on vitamins and minerals shall also be expressed as a percentage of the nutrient reference intake (NRV).

Other Compulsory Information

Number	Mandatory Particulars	Explanatory Information
19	Foods treated with ionising radiation	Shall bear one of the following indications: "irradiated" or "treated with ionising radiation".
20	Indicate the presence of genetically modified organisms (GMO)	
21	Foods whose durability has been extended by means of packaging gases authorised pursuant to Regulation (EC) No 1333/2008	"Packaged in a protective atmosphere".
22	Foods containing a sweetener or sweeteners authorised pursuant to Regulation (EC) Nº 1333/2008	"With sweetener(s)" this statement shall accompany the name of the food.
23	Foods containing both an added sugar or sugars and a sweetener or sweeteners authorised pursuant to Regulation (EC) No 1333/2008	"With sugar(s) and sweetener(s)" this statement shall accompany the name of the food.

Number	Mandatory Particulars	Explanatory Information
24	Foods containing aspartame/aspartame-acesulfame salt authorised pursuant to Regulation (EC) Nº 1333/2008	• "Contains aspartame (a source of phenylalanine)" shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients only by reference to the E number. • "Contains a source of phenylalanine" shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients by its specific name.
25	Foods containing more than 10% added polyols authorised pursuant to Regulation (EC) Nº 1333/2008	"Excessive consumption may produce laxative effects".
26	Containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant Glycyrrhiza glabra, at concentration of 100 mg/kg or 10 mg/l or above	"Contains liquorice" shall be added immediately after the list of ingredients, unless the term "liquorice" is already included in the list of ingredients or in the name of the food. In the absence of a list of ingredients, the statement shall accompany the name of the food.
27	Confectionery containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant Glycyrrhiza glabra at concentrations of 4 g/kg or above	"Contains liquorice – people suffering from hypertension should avoid excessive consumption" shall be added immediately after the list of ingredients. In the absence of a list of ingredients, the statement shall accompany the name of the food.
28	Beverages containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant Glycyrrhiza glabra at concentrations of 50 mg/l or above, or of 300 mg/l or above in the case of beverages containing more than 1,2% by volume of alcohol	"Contains liquorice – people suffering from hypertension should avoid excessive consumption" shall be added immediately after the list of ingredients. In the absence of a list of ingredients, the statement shall accompany the name of the food. The level shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

Number	Mandatory Particulars	Explanatory Information
29	Beverages, with the exception of those based on coffee, tea or coffee or tea extract where the name of the food includes the term "coffee" or "tea", which: • are intended for consumption without modification and contain caffeine, from whatever source, in a proportion in excess of 150 mg/l; or • are in concentrated or dried form and after reconstitution contain caffeine, from whatever source, in a proportion in excess of 150 mg/l	"High caffeine content. Not recommended for children or pregnant or breast-feeding women" in the same field of vision as the name of the beverage, followed by a reference in brackets to the caffeine content expressed in mg per 100 ml.
30	Foods other than beverages, where caffeine is added with a physiological purpose	"Contains caffeine. Not recommended for children or pregnant women" in the same field of vision as the name of the food, followed by a reference in brackets to the caffeine content expressed in mg per 100 g/ml. In the case of food supplements, the caffeine content shall be expressed per portion as recommended for daily consumption on the labelling.
31	Foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters	"With added plant sterols" or "with added plant stanols" in the same field of vision as the name of the food and mentions established in annex III of Regulation (EC) No 1169/2011.
32	Voluntary statement: "gluten free"	May only be made where the food as sold to the final consumer contains no more than 20 mg/kg of gluten

Number	Mandatory Particulars	Explanatory Information
33	Foods with this food colours may include additional information on labelling: Sunset yellow (E 110), Quinoline yellow (E 104), Carmoisine (E 122), Allura red (E 129), Tartrazine (E 102), Ponceau 4R (E 124) Food and food supplements containing novel food ingredients. Food and food supplements declared as 'organic;.	"name or E number of the colour(s): may have an adverse effect on activity and attention in children". Specific label requirements as per the Union List. The organic ingredients must be made explicit (with *, for example that refers to the bottom of the ingredient list * = organic). The term "organic" can be used both at the bottom of the ingredients list and sales denomination. The label must include the community logo and reference to the origin of agricultural raw materials (optional for imported products). The Control Body authorised by MiPAAF must be indicated as IT BIO YYY. The label must include the number of the controlled operator. If the amount of biological ingredient is less than 95%, the term "organic" can be associated only with the specific ingredient at the bottom of the ingredients list. The Organic logo cannot be used.
34		
35		

General Aspects

Number	Mandatory Particulars	Explanatory Information
36	Mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible.	
37	Mandatory particulars (1, 3, 5, 6, 7, 8, 9, 10, 11, 18) shall be printed on the package or on the label in such a way as to ensure clear legibility, in characters using a font size where the x-height, is equal to or greater than 1,2 mm. In case of packaging or containers the largest surface of which has an area of less than 80 cm2, the x-height of the font size shall be equal to or greater than 0,9 mm.	In the case of packaging or containers the largest surface of which has an area of less than 10 cm2 only the particulars listed in points 1, 5, 6, 7 shall be mandatory on the package or on the label. The particulars referred to in point 3 shall be provided through other means or shall be made available at the request of the consumer.

Number	Mandatory Particulars	Explanatory Information
38	Food additives and food enzymes must be designated (on the list of ingredients) by the category appropriate to the principal function followed by their specific name or E-number.	
39	Flavourings shall be designated either by the term “flavouring(s)” or by a more specific name or description of the flavouring if the flavouring component contains flavourings as defined in points (b), (c), (d), (e), (f), (g) and (h) of Article 3(2) of Regulation (EC) No 1334/2008.	The term “natural” for the description of flavourings shall be used in accordance with Article 16 of Regulation (EC) No 1334/2008.
40	Vegetal or animal origin of oils should be specified.	

Health Claims

Number	Mandatory Particulars	Explanatory Information
41	Conditions of use of health claims: food quantity + consumption required (ex: the beneficial effect is achieved through the consumption of 250 mg of DHA).	
42	A statement indicating the importance of a varied and balanced diet and a healthy lifestyle (could be combined with the mandatory particular n°15).	
43	A statement targeted to people who should avoid consuming the product.	
44	A warning if the product is likely to represent a risk in case of excessive consumption.	

ANNEX VIII – EHPM BOTANICAL SUPPLIERS' QUESTIONNAIRE

The EHPM Botanical Suppliers' Questionnaire is a reference checklist intended to assist botanical ingredient suppliers and manufacturers fulfil the requirements of Chapter 17, *"Specific Requirements Botanicals"*, of the EHPM Quality Guide. It is a control document that identifies the quality of the product as it enters or passes along the supply chain. The questions briefly address all the aspects of quality that need to be confirmed when working with botanicals. Where detailed specifications are required, they are supplied as Annexes.

It is the responsibility of the supplier of the botanical to provide the information. It is the responsibility of the purchaser to validate the accuracy of the information and decide whether the product complies with their requirements. Based on this assessment the purchaser may accept the product, subject it to further analysis, or reject it. It is a fundamental requirement of botanical quality assurance that an analytical process of this nature is carried out and recorded every time t a botanical preparation passes along the supply chain.

Food Supplement manufacturers should use this Questionnaire to evaluate the quality level of the ingredients offered by their suppliers in order to assess the level of risk, and in order to make appropriate risk management decisions.

Further information on the information requested in Sections 1–5 below and links to the relevant regulatory texts will be found in the accompanying document *"Further Information/Regulatory Links to the EHPM Botanical Suppliers"* Questionnaire.

Please note: the Questionnaire applies only to ingredients – it does not cover the quality requirements for finished products. Not all the fields in the Questionnaire are mandatory but the document should be completed as fully as possible and signed by the responsible person.

IDENTIFICATION: DETAILS OF SUPPLIER AND BOTANICAL PREPARATION

Supplier
Company Name

Supplier status

- Grower/Harvester _____
- Manufacturer _____
- Distributor/Broker _____
- Sales representative _____

1 - INFORMATION RELATING TO THE PLANT

1.1 - Plant name

1.1.1 - Scientific name (Latin name, family, genus).
Variety and chemotype, where necessary:

Common (vernacular) name:

1.1.2 - Risk of adulteration

☐ No ☐ Yes

Specify if a risk of adulteration with other species of the same genus or other genus of the same family or other plants containing, for instance, similar active constituents or other plant parts (for instance use of the leaf, partially or completely, instead of the root

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1.1.3 - Cultivated or wild variety

☐ Cultivated ☐ Wild

1.2 - Place of harvesting / collection

1.2.1 - Country / Region: *Specify country and, if possible, region*

1.2.2 - Specific authorisations (e.g. licences, official authorisations, etc)

1.2.3 - Where applicable, specific information relating Regulation 338/97 on the protection of species of wild fauna and flora (or to the Convention on International Trades in Endangered Species of Wild Flora and Fauna (CITES)

☐ Not applicable ☐ Applicable

1.3 - Method of harvesting / collection

☐ Manual ☐ Mechanical

1.4 - Period of harvesting / collection
Specify the month or months during which harvesting /collection took place

---

1.5 - Stage of harvesting / collection
Indicate the stage of plant growth at the time of harvesting / collection

---

1.6 - Process used for drying
Specify: (e.g. external, internal, open air, drying with gas, fuel, wood, etc.)

1.7 - Treatments (e.g. phytosanitary) applied

Before harvesting / collection

☐ No ☐ Yes *(Specify)*

After harvesting / collection

☐ No ☐ Yes *(Specify)*

1.8 - GACP form (Good Agricultural and Collection Practice)
For example: EUROPAM Batch Document

☐ Not available ☐ Available **(Attach the document)**

2 - PLANT PART OR PRODUCT USED

☐ Aerial part ☐ Fruit ☐ Flower ☐ Seed

☐ Leaf ☐ Bark ☐ Exudate

☐ Other *(Specify)*

☐ Complete plant (including both aerial and underground parts)
Specify if relevant

---

3 - BOTANICAL PREPARATION

3.1 - Preparation type

☐ Comminuted or dried herb ☐ Powder ☐ Liquid extract

☐ Tincture ☐ Macerate ☐ Soft extract ☐ Oleoresin

☐ Essential Oil ☐ Dry extract ☐ Other *(Specify)*

3.2 - Manufacturing process

☐ Cutting / Comminuting / Grinding

☐ Pressing

☐ Distillation

☐ Extraction

Process
Specify the extraction process: dry/liquid, maceration, percolation, etc

Solvents used *(Specify)*

☐ Purification

Process
Specify process of purification: liquid/liquid, chromatographic, etc

Solvents used *(Specify)*

☐ Other process(es)
Specify the process used (e.g. biotechnological, culture cellular, etc...)

3.3 - Ratios

Ratio dried plant / native extract *(Specify)*

Ratio dried plant / final extract *(Specify)*

Attach a flow chart describing the ingredient's manufacturing process, including In Process Controls (IPC)

3.4 - Country / Region

Specify the country, region or manufacturing plant where the manufacturing or extraction took place (and not the location where the product was repacked, diluted or labelled). Where relevant, attach a certificate of origin

_____

3.5 - Full composition of the preparation (including additives and other food ingredients)

Ingredient	**Theoretical %**	**Type and function**

3.6 - Contaminants and residues of the preparation

Contaminants and Residues		**Control**					
		Plant		**Preparation**		**Level / Limit**	**Reference, method of analysis, Accreditation (external/internal)**
		Lot	Plan	Lot	Plan		
Residual Solvent	_____	☐	☐	☐	☐	____	_____
	_____	☐	☐	☐	☐	____	_____
	_____	☐	☐	☐	☐	____	_____
Heavy Metals	Pb	☐	☐	☐	☐	____	_____
	Cd	☐	☐	☐	☐	____	_____
	Hg	☐	☐	☐	☐	____	_____
	Others (e.g As)	☐	☐	☐	☐	____	_____
Microbiology	Total plate count	☐	☐	☐	☐	____	_____
	Yeasts and moulds	☐	☐	☐	☐	____	_____
	Enterobacteriaceae *(Bile-tolerant gram-negative bacteria)*	☐	☐	☐	☐	____	_____

Contaminants and Residues		Control					
		Plant		Preparation		Level / Limit	Reference, method of analysis, Accreditation (external/internal)
		Lot	Plan	Lot	Plan		
Microbiology	Escherichia coli	☐	☐	☐	☐	____	_____
	Salmonella spp	☐	☐	☐	☐	____	_____
	Others *(e.g. Staphylococccus aureus, Pseudomonas aeruginosa, ...)*	☐	☐	☐	☐	____	_____
	Pesticides	☐	☐	☐	☐	____	_____
	Ethylene Oxide	☐	☐	☐	☐	____	_____
	Mycotoxins *(e.g. Aflatoxins B1, B2, G1, G2, Ochratoxin A)*	☐	☐	☐	☐	____	_____
	Polycyclic Aromatic Hydrocarbons (PAHs)	☐	☐	☐	☐	____	_____
	3-MCPD (3-monochloro-propanol-1,2-diol)	☐	☐	☐	☐	____	_____
	Nitrate	☐	☐	☐	☐	____	_____
	Dioxins and PCBs (Polychlorobiphenyls)	☐	☐	☐	☐	____	_____
	Melamine and other structural analogues	☐	☐	☐	☐	____	_____
	Radioactivity (if relevant)	☐	☐	☐	☐	____	_____
	Perchlorate	☐	☐	☐	☐	____	_____
	Pyrrolizidine alkaloids	☐	☐	☐	☐	____	_____

Attach the control plan where appropriate

3.7 - Genetic modification

Specific labelling on the presence of GMO derived ingredients

☐ No ☐ Yes *(Specify the specific components. Where relevant, attach a certificate)*

3.8 - Treatment of raw materials

One or more components have been treated by irradiation

☐ No ☐ Yes *(Specify)*

One or more components have undergone another treatment

☐ No ☐ Yes *(Specify)*

3.9 - Presence of allergens (from raw materials or processing aids)

☐ Allergens absent ☐ Allergens present *(Specify bellow)*

Allergen	**Present**	
Cereals containing gluten namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except wheat-based glucose syrups including dextrose *****, wheat based maltodextrins *, glucose syrups based on barley, and cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin. * And the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by EFSA for the relevant product from which they originated	☐ Yes	☐ No
Crustaceans and products thereof	☐ Yes	☐ No
Eggs and products thereof	☐ Yes	☐ No
Fish and products thereof except fish gelatine used as carrier for vitamin or carotenoid preparations, and fish gelatine or Isinglass used as fining agent in beer and wine	☐ Yes	☐ No
Peanuts and products thereof	☐ Yes	☐ No

Allergen	Present	
Soybeans and products thereof except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources, vegetable oils derived phytosterols and phytosterol esters from soybean sources, and plant stanol ester produced from vegetable oil sterols from soybean sources	☐ Yes	☐ No
Milk and products thereof (including lactose), except whey used for making alcoholic distillates including ethyl alcohol of agricultural origin and lactitol	☐ Yes	☐ No
Nuts and products thereof namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), except nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin	☐ Yes	☐ No
Celery and products thereof	☐ Yes	☐ No
Mustard and products thereof	☐ Yes	☐ No
Sesame seeds and products thereof	☐ Yes	☐ No
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO2	☐ Yes	☐ No
Lupin and products thereof	☐ Yes	☐ No
Molluscs and products thereof	☐ Yes	☐ No

3.10 - Nanomaterials

One or more components are present in the form of engineered nanomaterials

☐ No ☐ Yes *(Specify)*

Are the component(s) to be labelled according to Reg. (UE) 1169/2011 (Article 20)?

☐ No ☐ Yes *(Specify)*

3.11 - Purity criteria of the additives (including carriers)

Additive	Covered by Regulation 231/2012		Conformity with Regulation 231/2012	
_____	☐ Yes	☐ No	☐ Yes	☐ No
_____	☐ Yes	☐ No	☐ Yes	☐ No
_____	☐ Yes	☐ No	☐ Yes	☐ No

4 - ANALYTICAL DATA OF THE BOTANICAL PREPARATION

Attach the product specifications file (PSF)

Monograph

☐ Internal *(Specify)*

_____

☐ Official *(Specify)*

_____

4.1 - Physico-chemical characterisation: data from the PSF

4.1.1 - Organoleptic properties (appearance, odour, colour, ...)
Specify the analyses performed

_____

4.1.2 - Identity (TLC, HPLC, ...)
Specify the analyses performed

_____

4.1.3 - Tests (e.g. ash, viscosity, ...)
Specify the analyses performed

_____

4.1.4 - Dosages (substances to be monitored, Ethanol content. ...)
Specify the analyses performed

4.1.5 - Purity tests (residues, relative density, microbiological results, etc.)
Specify the analyses performed

4.2 - Substances to be monitored

4.2.1 - Markers

Type	**Content limit**	**Method** *(HPLC, UV-VIS, GC, ...)*	**Reference, official method / internal method**	**Validated**

4.2.2 - Compounds that are subject to restrictions of use

Type	**Content limit**	**Method** *(HPLC, UV-VIS, GC, ...)*	**Comments**

5 - STORAGE, PACKAGING, TREATMENT, TRANSPORT OF THE BOTANICAL PREPARATION

5.1 - Storage conditions

5.2 - Retest period

Stability data

☐ No ☐ Yes *(Specify)*

5.3 - Homogenicity *(sampling, use)*

Required before sampling

☐ No ☐ Yes *(Specify)*

Required before use

☐ No ☐ Yes *(Specify)*

5.4 - Labelling / Conditions for transport and storage *(Specify)*

5.5 - Packaging

Type *(Describe the container)*

5.6 - Other information

Linked to packaging (e.g. desiccant, nitrogen)

Indicated?

☐ No ☐ Yes *(Specify)*

Further treatment

Attach the Material Safety Data Sheet (MSDS) of the preparation
Attach the certificate of conformity with food contact of the primary packaging

RISK ANALYSIS AND QUALITY CONTROL

It is a fundamental principle of food regulation that safety should be assured through systematic risk assessment and management procedures. Both the quality and level of information supplied by the supplier and the evaluation of this information by the buyer should therefore reflect appropriate risk assessment and management procedures.

Risk management measures should be decided on a case-by-case basis as the nature of risks may vary from one botanical to another:

- Identification tests to address potential adulteration (e.g.: Ginseng leaf instead of root, Cimicifuga foetida instead of C. racemosa, etc.)
- Analysis of certain raw materials for potential contaminants (e.g.: pesticides on Ginseng, Pyrrolizidine alkaloids in dandelion leaf...)
- Process related analyses (e.g. for solvent residues);
- Analyses of added substances: (e.g. Vitamins, beta-sitosterols, etc.).
- Levels of markers to reflect dilutions with additives or bulking substances.

The buyer may:

- Systematically analyse each lot received from a new supplier until sufficient experience has been gathered to proceed to periodic controls;
- Evaluate whether the price of the raw material, of the ratio plant/extract and the declared solvents and level of markers is consistent with the price quoted;
- Require a number of specific analytical parameters are met to address the requirements of the food supplements they are placing on the market.

If the buyer is not satisfied with the data provided, the buyer may reject the botanical on offer or subject it to additional quality assurance measures before deciding whether or not to purchase.

ANNEXES INCLUDED WITH THE COMPLETED QUESTIONNAIRE

- Product Specifications File
- Material Safety Data Sheet
- Process Flow Chart
- GACP, where available
- Control Plan, where applicable
- Example of a Certificate of Analysis
- Stability data, if available
- Any other relevant document

DECLARATION:

The information given above is to the best of my knowledge correct as at *(insert date)*

_____

Signed *(Signature)*

_____

Name in capital letters

_____

Status of person signing Questionnaire

_____

Date

_____

ANNEX IX – FURTHER INFORMATION / REGULATORY LINKS TO THE EHPM BOTANICAL SUPPLIERS' QUESTIONNAIRE

The headings below provide you with further information/links to the regulations relevant to the corresponding section of the EHPM Botanical Suppliers' Questionnaire.

1 - INFORMATION RELATING TO THE PLANT

1.1 - Plant name

For additional information, please refer to the risk analysis and control plan at the end of the document EHPM Botanical Suppliers Questionnaire

1.2 - Place of Harvesting/Collection

1.2.1 - Specify whether the plant comes under Regulation (EC) 338/97 on the protection of species of wild flora or fauna (or to the Convention on International Trade in Endangered Species Flora and Fauna – CITES)

1.3 - GACP

Specify if a GACP (Good Agricultural and Collection Practice) form is available and if so, attach the EUROPAM Batch Document

2 - PLANT PART OR PRODUCT USED

Tick the corresponding check boxes. Use the "Other" box for more precise descriptors: flowering tops, pressed fruits, buds, etc.

3 - BOTANICAL PREPARATIONS

3.1 - Preparation type:

All preparations obtained from botanical raw materials (e.g. pressing, squeezing, extraction, fractionation, distillation, purification, concentration, drying up and fermentation, biotechnological processes, cells cultures, liposomes. These include comminuted or powdered herbal substances (note that in some EU Member States comminuted herbs for herbal teas are not considered as a plant preparation), tinctures, extracts essential oils expressed juices and processed exudates. (This information, together with Section 3.2: Manufacturing Process, is relevant to the Risk Analysis and Control Plan at the end of the Questionnaire, and is important to help determine whether or not the plant preparation is a Novel Food, defined as food that has not been consumed to a significant degree by humans in the EU prior to 1997. "Novel Food" can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU. For further information on Novel Foods, see section 17.3.3, *Verification of Novel Food Status*, of the EHPM Quality Guide.)

3.2 - Manufacturing Process

Specify the:

- Extraction process (solid/liquid, maceration, percolation, etc..).
- Solvents used.
- The relative proportion of solvents (e.g. Ethanol 30% / Water 70% = Ethanol 30% v/v).
- The quality of the solvent: e.g. recycled, denatured, purity with the references for the norms applied.

Specify if applicable:

- Purification process (liquid/liquid, chromatography, etc.)
- Solvents used.
- The relative proportion of solvents (e.g. Ethanol 30% / Water 70% = Ethanol 30% v/v).

- The quality of the solvent: (e.g. recycled, denatured, purity with the references for the norms applied.

Other processes: Specify the process used (ex. biotechnological process, cells culture, liposomes, etc.).

Attach a flow chart:

A flow Chart or Diagram must enable:

- Visual tracing of the raw materials used during the process (plant, solvents, additives, or other substances...), the main manufacturing steps, and the In Process Controls used to check that there is no deviation from the production protocol.

- Verification of the conformity of the solvents used (Directive 2009/32/EC) or Eur. Ph. 2.4.24 (Method) and 5.4 (Limits)

- Verification of the conformity of the processes described (presence of purification steps, or elimination of constituents at risk, or use of non-traditional techniques). Processes and solvents considered as traditional are usually listed in Pharmacopoeial monographs, including: maceration, infusion, digestion, elution, lixiviation, percolation, decoction, etc.

Plant extract manufacturers are not always willing to divulge detailed information about their manufacturing processes. In such cases, it may be possible to negotiate a written agreement to the effect that the extract manufacturer holds the full documentation and will provide it to the Authorities, should it be required

3.3 - Ratios

The Plant/Extract ratio, native and final, must be indicated. The native extract ratio corresponds to the ratio between the quantity of the plant and the extract yield from the extraction / transformation (before addition of any compounds, such as technological additives, carriers or dilution matrix).

The final extract ratio corresponds to the ratio between the plant and the extract as commercialised (with technological additives and other food ingredients added).

3.4 - Country/Region

Country, region where the plant preparation is produced (this is not necessarily the same place as where the plant preparation is repacked, diluted or labelled). A certificate of Origin may be provided.

3.5 - Full composition of the preparation, including additives and other food ingredients

Specify the full composition: quantity of native extract, additives including carriers, bulking agents, etc.– together with the levels in the product and their function. The product specification file must indicate the composition.

3.6 - Contaminants and Residues of the preparation

It is not essential to fully complete all the questions in the table before a raw material can be approved, but the more information available, the better the level of risk can be determined. Where necessary, the supplier should be asked to justify any missing analysis.

Specify. where applicable:

- if control is performed on the plant or on the preparation, and if control is applied on a lot basis, or according to a control plan.

Where applicable, as a result of analysis of the botanical raw material used for production and the nature of the production process, tests for microbiological quality, contaminants and residues in the botanical preparation may / may not/ be necessary.

When certain residues or contaminants are subject to periodic monitoring, the control plan must be attached

Solvent residues: (except for aqueous extracts) in accordance with Directive 2009/32/EC and, where appropriate, European Pharmacopeia 2.4.24 (Methods) – 5.4 (limits).

Heavy metals: Reference texts: Regulation (EC) 1881/2006 and Regulation (EC) 629/2008 and European Pharmacopeia: 2. 4. 27 (methods) + monograph 1433 "herbal drugs" (limits). In addition to Lead, Cadmium and Mercury, other compounds usually tested (iodine, arsenic, ...) can also be indicated, where relevant or legally required.

Bacteriological results: Reference texts: European Pharmacopeia 5.1.8 B and C (limits) – European Pharmacopeia 2.6.12 and 2.6.31 (methods).

Indicate the specifications and the methods of analysis. If internal methods are used, specify whether the methods are validated.

Pesticide residues: Reference texts: European Commission database (https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en) + Regulation (EC) 396/2005 modified + Regulation (EC) 149/2008 + Regulation (EU) 2020/1085 for Maximum Residue Limits (MRL) or where relevant: European Pharmacopeia 2.8.13.

Specify Under "Type" the reference applied (Regulation 396/2005, Ph. Eur., etc.) and under "accreditation" if the laboratory performing the analysis is accredited.

Ethylene oxide

- In early 2022, the European Commission and Member States agreed on the following approach to Ethylene oxide ETO contamination: for the products that contain the additive E410 known to be contaminated with ethylene oxide no safe level of exposure for consumers can be defined and hence any level consumers may be exposed to, presents a potential risk to consumers;
- consequently, it is necessary, in order to ensure a high level of health protection, that the food or feed business operators who have placed such products on the EU market shall, under the control of the national competent authorities, withdraw those products from the EU market, and recall them from consumers.

Food product ingredients with residues of ETO above the Maximum Residue Levels (MRLs) must also be withdrawn from the market/recalled from consumers, as must composite/processed food products, in case they contain a contaminated ingredient, regardless of their ETO content.

In addition, for botanical/herbal substances, Implementing Regulation (EU) 2021/2246 of 15 December 2021 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries, requires that food supplements containing herbal substances from China, India and South Korea are tested for ethylene oxide (ETO) and 2-chloroethanol (2-CE), conducted with a control frequency of 20%. A test report and a health certificate should be issued by the Authorities of the exporting country.

Mycotoxins: Reference texts: Regulation (EC) 1881/2006 and Regulation (EC) 1259/2011, specifying maximum limits for aflatoxin B1, total aflatoxins, ochratoxin A, patulin, zearalenone, fumonisins and toxins for a number of food. These limits take into consideration the level of contamination generally observed.

European Pharmacopeia 2.8.18 (aflatoxin B1) and 2.8.22 (ochratoxin A).

PAH determination: according to Regulation (EC) 1881/2006 modified

Dioxins and PCBs: according to Regulation (EC) 1881/2006 modified

Melamine and analogues: according to Regulation (EC) 1881/2006 modified

Perchlorate determination: according to Regulation (EU) 2020/685 (restriction on ingredients which may be used in food supplements). No limits are set for finished products. Analysis to be performed on tea and herbal Teas for infusions when used in a food supplement.

Pyrrolizidine alkaloids (PAs) determination: see Regulation (EC) 1881/2006 on the maximum level of PAs in specific foods:

- plant-based food supplements: 400 µg/kg,
- food supplements containing pollen 500 µg/kg).

(This regulation came into force on April 1st 2021. Food products not in conformity with the above limits but present on the market before July 1st 2022, can be sold until December 2023.)

3.7 - Genetic Modification

GMO Certificate: concerns the specific labelling requirements relating to the presence of GMO material. Reference texts: Regulations (EC) 1829/2003 and (EC) 1830/2003

The information can be reported directly into the questionnaire if signed by an authorised person, meaning a separate certificate is not necessary.

3.8. Treatment by irradiation

Reference texts: Directive 1999/2/EC modified by Regulation (EC) 1883/2003 + Directive 1999/3/EC: ingredients treated with ionising radiation shall be indicated in the list of ingredients accompanied by the words “irradiated” or “treated with ionising radiation”.

The information can be included directly in the questionnaire and an additional certificate is not necessary if compliance is signed for by an authorised person.

3.9 - Presence of allergens

Allergens certificate: Reference text Regulation (EU) 1169/2011 relates to Labelling.

The information can be included directly in the questionnaire and an additional certificate is not necessary if compliance is signed for by an authorised person. The information can be completed by, for example specifying the total absence in the substance/plant.

It is noted that it is obligatory to mention the presence of any ingredient or processing aid containing or derived from a substance or product listed in Annex II of Regulation (EU) 1169/2011 used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form. The name of the substance or product as listed in Annex II must be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour.

3.10 - Nanomaterials

Commission recommendation of 18 October 2011 (2011/696/EU) defines nanomaterial as a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. (It is advisable to check the date of the most recent legislation on nanomaterial as the 2011 regulation is subject to revision.)

In some Member States such as France, a declaration is mandatory when at least 100 g of nanomaterial has been produced, distributed or imported in French territory.

Thus the French Authorities do not apply the 50% threshold but consider that any ingredient containing nanoparticles must be labelled. They consider that an ingredient to be "nano" when 10% of the particle dispersion shows nanometric size (10% correspond to method uncertainty).

Omission of constituents of food from the list of ingredients – Regulation (EU) 1169/2011: Article 20 gives the list of exemptions. This is the case of food additives and food enzymes whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, provided that they serve no technological function in the finished product.

3.11 - Purity criteria of the additives (including carriers)

As set out in Regulation (EU) 231/2012

4 - ANALYTICAL DATA OF THE BOTANICAL PREPARATION

The product specification must include at least the following information:

- Name of the preparation
- Scientific name of the plant and plant part or product used.
- Description: extraction solvent and strength (with specification of the extraction method), ratio plant/native extract, composition (types and levels of additives present)
- Organoleptic characterisation: appearance, odour, colour identification (TLC, HPLC, ...)*
- Tests *
- Loss on drying, total ash, dry residue, viscosity, turbidity, etc.
- Assay: markers * / Reference document: Members States national lists such as France or Belgium (Substances requiring monitoring, restrictions...)
- Assay: substances subject to restrictions of use *

* The reference of the methods of analysis applied needs to be specified (Pharmacopeia, internal methods, etc.). If the botanical preparation (or where appropriate the plant) is not in a Pharmacopeia (Eur, Ph., French, DAB, USP...), the methods for identification and dosage must be included in the submission, as well as their validation (Refer to the ICH Guidelines).

Reference documents: Members States national lists such as those of France, Belgium or Italy. (substances requiring monitoring, restrictions...). Where relevant, consult the *EFSA Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements.* https://www.efsa.europa.eu/en/efsajournal/pub/2663

The absence of quantification of a substance must be justified. Technical arguments or arguments based on bibliographic references can be sufficient. Analytical results must confirm the values of the specifications files and be available for each of the lots supplied.

It must be specified if the preparation has been subject of an official or internal monograph and the reference must be provided.

4.1 - Physico-chemical characterisation

List the determinations in general. Details given in [4.2]

4.2 - Substances to be monitored

4.2.1 - Markers / tracers / active compounds in the preparation.

Specify for each of the markers the identity, nature, minimum and/or maximum levels and method of assay (UV, HPLC, UPLC, GC, GC-MS, quantitative TLC, etc.). Specify the standard used and a brief description (e.g. C18 - 210 nm, HPLC as cyaniding, etc.).

Specify whether the method is internal/in house (when an official method does not exist), or official.

Analytical results must confirm the values of the specification files and be available for each batch supplied.

4.2.2 - Compounds that are subject to restrictions of use.

Where applicable, as with markers and tracers, specify the substances that are subject to restrictions of use, level and method of analysis, etc. Where not applicable, justify the reason under the heading “Comments”.

5. STORAGE, PACKAGING, TREATMENT, TRANSPORT OF THE BOTANICAL PREPARATION

5.1 - Retest period

The dates of the reanalysis are usually determined on the basis of the results of the stability

studies available. The supplier needs to justify the date of recontrol of the preparation.

The ICH requirement (the pharmaceutical standard) specifies that shelf-life testing must apply to 3 batches under the following conditions:

- Accelerated conditions: (40 °C/ 75% HR): T0, T3, T6
- Intermediate conditions: (30 °C/ 65% HR): T0, T3, T6, T9, T12
- Long-term conditions: (25 °C/ 60% HR): T0, T3, T6, T9, T12, T18, T24, T36

The parameters are likely to vary over time: physical, chemical, biological and microbiological properties must be retested regularly. These conditions may be adapted to specific climatic zones.

5.2 - Homogeneity (sampling, use): specify whether the plant preparation needs to be homogenised before use.

5.3 - Labelling/Conditions for transport and storage: give details of the label content as well as the conditions for transport and storage.

5.4 - Packaging: describe the nature of the packaging (primary and secondary packaging). Specify whether a Food contact material safety certificate for the primary packaging is available.

5.5 - Other information, add as necessary, and specify whether it appears in the specifications sheet and/or Certificate of Analysis.

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