HEALTH FOOD MANUFACTURERS' ASSOCIATION

CODE OF PRACTICE FOR MAINTAINING QUALITY THROUGHOUT THE SUPPLY CHAIN FOR BOTANICAL FOOD SUPPLEMENTS

Updated June 2019

Buckinghamshire&Surrey trading standards

PRIMARY AUTHORITY ADVICE

Code of Practice for Maintaining Quality throughout the Supply Chain for Botanical Food Supplements – November 2018 (Updated June 2019)

As part of our 'Primary Authority' partnership with the Health Food Manufacturer's Association (HFMA), Surrey County Council (Buckinghamshire and Surrey Trading Standards) are issuing ' Primary Authority Advice' with respects to the:
HFMA 'Code of Practice for Maintaining Quality throughout the Supply Chain for Botanical Food Supplements'.

This Primary Authority Advice has been developed for HFMA members by the HFMA in partnership with Surrey County Council as part of a dedicated Primary Authority scheme. If HFMA members follow this Primary Authority Advice, we [the Primary Authority] are of the opinion that their quality systems in relation to Botanical Food Supplements would be appropriate for maintaining quality throughout the supply chain and therefore should be respected by local authority officers including environmental health and trading standards.

Buckinghamshire and Surrey Trading Standards will not support enforcement authorities within England & Wales who pursue enforcement action relating to the aspects of the Code of Practice for Maintaining Quality throughout the Supply Chain for Botanical Food Supplements that we have approved.

ABOUT THE HFMA

The Health Food Manufacturers' Association, (HFMA), founded in 1965, is the authoritative and responsible voice for the UK natural products industry and promotes, protects and defends the general interests of members of the industry and promotes high standards of product manufacture and presentation to ensure consumer safety, responsible and informative communications and compliance with applicable legislation. We represent around 120 manufacturers and suppliers of specialist health products, notably food supplements, herbal and botanical products, natural remedies, sports nutrition products, natural cosmetics and health foods.

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HFMA CODE OF PRACTICE FOR MAINTAINING QUALITY THROUGHOUT THE SUPPLY CHAIN FOR BOTANICAL FOOD SUPPLEMENTS

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1. EXECUTIVE SUMMARY

There is a well-developed regulatory system in the EU for the use of botanicals in food supplements, particularly in relation to safety. However, in the UK, a common approach to the essential quality requirements for botanical food supplements is currently lacking. The HFMA Code of Practice for Maintaining Quality throughout the Supply Chain for Botanical Food Supplements sets out to remedy this, by outlining the key safety and quality requirements and considerations for this category of supplements, from raw materials through to finished product. Thus, its content encompasses Quality and Risk Management approaches, Good Agricultural and Collection Practice, Identification and Verification systems for raw materials, manufacturing and processing systems, Good Distribution practice, and requirements for Service providers and Third Parties. The practices and protocols set out in this Code will help to ensure maintenance of the highest quality standards throughout the lifecycle of botanical food supplements and provides useful tools and guidance wherever you may operate within the botanical supply chain.[1] In particular, the Code requires companies to seek assurance of the provenance of the botanical ingredients they source – to be aware that if the price quoted seems too good to be true, then it probably is.

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.

Whilst the primary goal of the Code is to assist HFMA members to achieve and maintain high quality standards for their botanical products, it should also be noted that Section 21 of the Food Safety Act 1990 provides for a defence of due diligence for many matters related to compliance in the food law field. In general terms, it is a defence for the person charged to prove that he/she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by him/herself or by a person under his/her control. Thus, adherence to the principles of this industry Code of 'best practice' can form part of such a defence - that reasonable precautions and the exercise of all due diligence to avoid the commission of the offence were taken.[2]

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[1] This code of Practice focusses specifically on the quality and safety-related quality issues relevant to the supply chain for botanical food supplements. It is not intended to cover the various methodologies for the safety assessment of botanical ingredients per se, where work is ongoing. EFSA's current approach to this aspect of the safety of botanical ingredients is detailed in the following links:

[2] Case law relating to the concept of "due diligence" offers the following principles:

- Doing nothing is unlikely to protect you
- Positive action is necessary to satisfy the defence; but the nature of that action will depend on the relevant circumstances.
- If a reasonable precaution is not taken, any defence is likely to fail
- Documented systems in larger companies would be expected.
- Due diligence means ensuring that your system of checks work and that you can prove it
- Any programme of checks, must work, must be followed and must be monitored with appropriate frequency.
- The system must consider all aspects of the activity, throughout the life cycle of the product (service in this case) from end-to-end.
- The system must identify the risks, adopt appropriate controls and safeguards, record actions and keep them under review.
- What is reasonable will depend upon particular circumstances but publications and professional advice on risk assessment, hazard analysis and quality assurance will assist.
- Support for "due diligence and reasonable precautions" must come from the top ensuring it is appropriately resourced in the company
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2. BACKGROUND

2.1 Introduction

Botanicals used in foods and food supplements have a long history of safe and effective use in the UK. However, many factors can negatively impact the quality of botanical material and it is therefore essential that adequate measures and controls be applied throughout the entire lifecycle of botanical food supplements, from sowing the seed through to finished product manufacture. Such a lifecycle incorporates planting, cultivation, harvesting and primary processing of plant materials, not simply the manufacturing controls and testing applied to finished products.

Contamination and adulteration of botanical raw materials, whether accidental or intentional, is an ever-present threat, which poses a number of challenges to the industry. Supply chains are often complex, spanning multiple countries, continents, and/or climatic zones, making oversight and traceability more difficult. In addition, the market place for botanicals is fast paced and dynamic, with demand often exceeding supply for some plant species, which can apply further pressures to both suppliers and manufacturers. To be assured of maintaining quality throughout the supply chain, appropriate measures must therefore be taken.

2.2 General: Understanding Vulnerabilities in the Supply Chain

Knowing your supply chain is a key factor in understanding vulnerabilities and mitigating against them, and is an on-going process. Potential vulnerabilities at each stage of the supply chain should be taken fully into account when assessing the quality compliance of the supply chain as a whole. In addition, it should be noted that the time lag from events that may impact supply availability to the botanical reaching the market can be as long as 12 – 18 months for some crops, meaning a considerable period of time may have passed before a food fraud issue is noticed/identified.

2.2.2 Potential areas of vulnerability

Areas of potential vulnerability that should be taken into account can include:

- The number of countries/regions/places and intermediaries through which the original ingredient has been processed or transited: is the chain visible, transparent?
- Whether there a history of fraud for a particular ingredient/category of ingredients
- Whether the ingredient is subject to seasonality/limitations on availability of supply
- Whether there have been weather events/natural disasters (i.e. drought, flood, earthquakes) that may impact supply availability
- Whether there are cultural or geo-political events (i.e. food security, terrorism, political instability) which may impact on the global supply chain for the material
- Whether economic factors make fraud more attractive for the particular ingredient(s)

Further factors to consider are:

- The prevalence of corruption or any other cultural influences on business ethics.
- Advances in technology which can mask food fraud.

3. QUALITY MANAGEMENT AND RISK ASSESSMENT

3.1 Introduction

A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. Thus, to meet customer requirements fully, a Quality Management System relevant to botanical products must, by definition, encompass the entire supply chain – from seed to finished product.

The depth and breadth of the QMS employed will be dependent on the operations being undertaken, either by a given company or individual, and roles being performed and their position in the overall supply chain. A small-scale producer of organic plants would therefore not be expected to have as complex a QMS as a multinational company supplying finished products to the global market. However, regardless of the role you are fulfilling, the Quality Management tools you employ must be appropriate and fully justifiable for the tasks being undertaken or performed.

3.2 General

Although the individual approaches taken to Quality Management will differ from organisation to organisation, they will all share similarities and are ultimately designed to deliver the same outcomes. They will usually begin with the development of a Quality Policy and the setting of appropriate Quality Objectives. The procedures and practices employed can be detailed and summarised in a Quality Manual and monitored through regular management review.

Whilst not specific to botanicals, or even the food sector in particular, many companies in the industry have adopted ISO management principles and incorporated them into their structure and ways of working. With regard to foods in particular, BRC[3] Global standards have been widely adopted, and whilst they share similarities with ISO[4] principles, they are more closely aligned with controls to ensure food safety and hygiene.

3.3 Essential elements of a QMS system

Whatever standards you choose to adopt or follow, the essential elements of a QMS to manage the risks associated with Botanical food supplements can include, but are not limited to, the following:

- Personnel, Premises and Equipment
- Documentation, data and change management
- Processes and Procedures
- Manufacturing Processes and Controls
- Quality Control and Quality Assurance
- Storage and Transportation
- Complaints, Recalls and Post-Market Surveillance
- Self-inspection, Continuous Improvement, Corrective and Preventative Actions
- Third Party Management and Assurance

These elements should be described and detailed in the Quality Manual.

3.4 Risk Management: HACCP

Hazard Analysis Critical Control Point (HACCP) is a practical technique which food businesses (including manufacturers of Botanical supplements) must use to ensure their products are safe. In essence, a HACCP system identifies the main risk areas in an operation, adopts appropriate controls and applies them at the point in the process where they matter the most, ensuring proper operation of the overall system.

[3] https://brcglobalstandards.com/

[4] https://www.iso.org

The seven essential steps of the HACCP process are:

1. Conduct a hazard analysis
2. Identify critical control points
3. Establish critical limits for each critical control point
4. Establish critical control point monitoring requirements
5. Establish corrective actions
6. Establish procedures for ensuring the HACCP system is working as intended
7. Establish record keeping procedures

(See **Annex 1** for more detail of each step of the HACCP process)

4. GOOD AGRICULTURAL AND COLLECTION PRACTICES (GACP) – THE HANDLING OF BOTANICAL MATERIALS

4.1 Introduction

The lifecycle of a botanical food supplement incorporates planting, cultivation, harvesting and primary processing of plant materials, not simply the manufacturing controls and testing applied to finished products. Good Agricultural and Collection Practices (GACP) should therefore be applied to ensure the appropriate and consistent quality of botanical starting materials that are to be used in the manufacture of botanical food supplements, whilst consideration should also be given to environmental impacts, biodiversity and the Convention in Internal Trade in Endangered Species (CITES).[5]

4.2 General

Plant growth and quality is strongly influenced by environmental factors, such as light, temperature, water availability and the level of nutrients in the soil, all of which influence the chemical composition of the plant material itself, and ultimately, the final composition of the botanical food supplement. Similarly, how the plant material is harvested, handled, processed and stored also impacts upon its quality. Whilst environmental factors cannot always be controlled, they can, and should, be recorded and documented. Human activities however, such as collection, harvesting, processing and storage can be more precisely controlled. All reasonable steps must be taken to ensure botanical materials are grown under suitable conditions, are harvested appropriately and hygienically, handled and processed carefully, and stored with sufficient protection to maintain their quality.

Careful consideration should also be given to the opportunity for misidentification of plant materials as well as contamination (microbial, heavy metals or other contaminants) and adulteration, either accidental or intentional, which can often occur during the stages of cultivation, harvesting, processing and storage of materials. Adherence to the principles of GACP are essential to ensure the appropriate and consistent quality of botanical raw materials, and the key elements as they relate to starting materials for botanical food supplements are outlined below.

4.3 Personnel & Training

All personnel involved in the handling and processing of botanical materials must have received adequate training in food hygiene and understand their responsibilities with regard to hygiene standards within the human food chain. Should crop protection products, such as herbicides, pesticides, or chemical fertilizers be used during cultivation, personnel must be adequately trained in their use.

Personnel involved in the identification and collection of botanical materials must have sufficient training in plant identification techniques and be able to differentiate between the target species and botanically related species. Such personnel shall also have sufficient knowledge and training on optimal harvest conditions and harvesting techniques for the botanical material being collected.

4.4 Buildings & Facilities

All buildings and facilities should be sufficiently secure to prevent unauthorised access. Buildings and facilities used for the storage and processing of botanical materials must be clean, suitably ventilated, and must never be used for any activities involving livestock. Such facilities must provide adequate protection for the botanical material from environmental factors, such as wind, rain and direct sunlight, as well as protection from pests.

Storage buildings must be of sufficient size to enable safe, easily accessible storage. Where more than one crop is stored in the same building, there should be sufficient space for materials to be

[5] All botanical species used for the production of botanical food supplements must comply with the requirements of the Convention on International Trades in Endangered Species of Wild Flora and Fauna (CITES). The objective of the CITES international agreement is to ensure that trade in wild plants does not threaten the survival of the species. Endangered species and the degree of protection assigned to them are given in three Appendices to the CITES agreement. The status of a botanical species should be checked before it is sourced from the wild.

adequately segregated so as to reduce the likelihood of cross-contamination. In facilities where processing of botanicals is undertaken, changing and washing facilities should be provided to minimise contamination risks from personnel and clothing. Facilities for handwashing should be provided, separate from those used for washing botanical material or washing/cleaning equipment.

4.5 Equipment

Different types of machinery and equipment can be used during the cultivation, harvest and processing of botanical materials. All such equipment should be made from suitable materials so as to minimise wear and the possibility of contamination from soil, chemicals and cross contamination from other plant materials or crops.

All equipment should be well maintained, regularly serviced (where appropriate) and in good working order before operation. Calibration, where necessary, should be repeated at suitable time intervals and documented. All machinery and equipment should be thoroughly cleaned after use, to help prevent cross contamination, especially if it comes into direct contact with the botanical material or has been exposed to chemical protection products or fertilizers.

4.6 Documentation

The geographical location of the crop must be specified. If plant material has been sourced from multiple sites, these must be detailed as accurately as possible. If plant material has been collected from the wild, descriptions of the collection site locations must be provided. Unusual or extreme weather patterns that have occurred during the cultivation of the crop, such as drought or flood, should be detailed as they can directly impact the quality of the plant material. The use of any chemical crop protection products or fertilizers must also be detailed.

Records must be kept for the harvest date and time, and weather conditions. Where possible, plant materials should not be collected during wet/excessively hot conditions, or under circumstances which may increase the likelihood of cross contamination with other plant materials or foreign bodies. Any processing steps which can impact the quality of the botanical material, which can include washing, drying cutting or grinding, must be fully documented.

The botanical material must be fully traceable, designated with a unique identifier (batch number) and clearly labelled. If plant material from different locations is mixed, the process must be fully documented and traceability maintained. All agreements between growers, collectors and purchasers should be written and not verbal, and should detail the expectations of both/all parties.

4.7 Seeds and growing practices

To ensure the correct plants are cultivated, seeds should be acquired from reliable sources and must be identified according to genus, species, variety/cultivar/chemotype.

All agricultural land must be free from sources of contamination, such as heavy metals, industrial waste or crop protection products. Good crop husbandry principles must be followed and any necessary steps taken to avoid negative impacts on the environment. If irrigation is applied to the crop, water must be of suitable quality and must not introduce contaminants which could impact the quality of the botanical material.

The application of crop protection products, such as herbicides and pesticides, must be kept to an absolute minimum. Use must be used in accordance with local regulations and the manufacturer's instructions for use.

4.8 Collection and Harvest

Plant materials must be fully identified by suitably trained and qualified personnel before harvesting, and the harvesting methods employed must be suitable for the crop in question, minimising the possibility of damage to the plant material and the potential for cross contamination during the process. Harvesting should take place during suitable weather conditions, when the crop is at optimum health and the plant material is of the highest quality. Plants should not be harvested if they are suffering from disease, pest damage or are otherwise unhealthy. Containers and storage vessels used during harvest must be clean, dry and free from contamination with foreign bodies or material from previous harvests.

Throughout harvesting, all practical steps should be taken to avoid cross contamination of the botanical material with weeds and any other plant material. Cross contamination with weeds during harvesting can significantly impact the quality of the final botanical food supplement. As an example, Pyrrolizidine alkaloids (PAs) are common cross-contaminants, toxins found naturally in a wide variety of plants. Approximately 6,000 species are known to contain PAs, which are produced by plants as a defence against herbivores. They most usually occur as weeds in cereal or legume crops and the seeds are accidentally mixed with the main crop at harvest. The plants most commonly associated with PA food poisoning in humans are Heliotropium (in the family Boraginaceae) and Crotalaria • The European Food Safety Authority (EFSA) has recently updated its opinion on the safety of PAs in foods[6] and is considering setting maximum limits.

Harvested crops must be stored in an environment which provides adequate protection, minimising degradation of the material or the possible risk of damage from pests. To avoid degradation of Botanical materials, they should be processed or delivered for processing as quickly as possible after harvesting

4.9 Primary Processing, Packing & Storage

Botanical materials can be subject to a number of different processes and treatments. These can include washing, drying, cutting, or even freezing. The processing employed must always be suitable for the botanical material in question and its intended end use.

The opportunity for adulteration of botanical materials can increase with the amount of processing undertaken. For example, it is more difficult to visually identify highly processed or finely chopped plant material, or to detect potential contaminants or adulterants. Therefore, and all processing steps should be fully documented and verified.

Many botanical materials will be dried following harvest, often in the open air, and this must be undertaken during suitable weather conditions and using appropriate equipment, such as drying frames. Botanical material dried in the open must be protected from environmental contamination, including pests. Whatever processing is performed, all steps must be taken to ensure uniform results are obtained across the harvested crop, using reliable and reproducible methods that result in a consistent material being produced.

Harvested or processed crop materials should be packaged as soon as possible, reducing the possibility of cross contamination or adulteration of the plant material. Packaging materials must be stored under clean, dry, well-ventilated conditions, and protected from pests or livestock so as to ensure they do not introduce any contaminants to harvested botanical material.

Packaging materials themselves must comply with the Materials and Articles in contact with Food Regulations[7] be compatible with the plant material being packed, and must be clean, dry and free from potential contaminants. Packaging materials must not cause the botanical material itself to become contaminated by, for example, shedding fibres. If re-useable packaging is used, cleaning processes should be verified and the potential for contamination with previously packed components must be minimised.

Packaged botanical components must be clearly labelled and full traceability maintained. Once packaged, materials should be stored in secure premises, under clean, dry, well-ventilated conditions, protected from pests or livestock.

4.10 Challenges with Botanicals

Botanical food supplements can be made either from specific plant parts, or in some cases from the whole plant itself. Flowers, fruits, seeds, aerial parts and roots can require different harvesting or collection techniques and will likely require different storage conditions and packaging materials. To ensure botanical materials are of the highest quality, it is important to establish that the

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6 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4908

7 The Materials and Articles in Contact with Food Regulations 2012

correct techniques, equipment and storage conditions have been utilised and applied for your material.

A single harvest of a given plant material may be destined for multiple applications and be sold to several different customers. Some customers may require different parts of the crop to others, and the material may be processed in different ways for different end uses. It is also possible, and in some cases likely, that multiple crops and different species will be grown, processed, stored and packaged at a single facility, or may enter into shared facilities at any given time. All these factors have the potential to result in cross contamination, misidentification and mislabelling of botanical materials, as well as introducing opportunities for intentional adulteration.

The early stages of the product Lifecyle for botanical food supplements therefore contain a number of critical control points which need to be risk assessed and actively managed. Quality cannot be applied retrospectively, so it is vitally important to ensure adequate quality controls and measures are in place during cultivation, harvesting and initial processing, otherwise the raw materials may not meet the required quality standards and cannot be used to manufacture finished products.

Different parts of a plant can also have different commercial values, or may require longer periods of time and investment to cultivate. Flowers, for example, can be collected annually from some species and may provide multiple crops for several years from a single plant. However, if the whole plants is collected, or just the root, then it may take several years to grow a crop which will only yield a single harvest. Such factors can play a role in the potential for adulteration of some species and should be considered in risk management planning. Especially if the material being purchased has been highly processed (for example, finely chopped or powdered) as this can make adulteration easier, and identification of such adulterants or contaminants more difficult.

5. BOTANICAL RAW MATERIALS: IDENTIFICATION & VERIFICATION

5.1 Introduction

It is critical that there is accurate identification of all botanical source material selected for further processing. As the accurate identification of some botanical sources can be complicated, the nomenclature of the European Pharmacopoeia should be followed where appropriate. Other authoritative sources include the 'World checklist of Selected plant Families'[8] or 'The International Plant Names Index'[9] .

5.2 General

The growth, development and chemical profile of a botanical is influenced by external factors such as soil quality, water (mineral content, pH, etc.), temperature, sunlight, the season of cultivation and time of harvesting. Thus, the presence and concentration of nutrients, physiologically active substances and contaminants can vary considerably, depending on where, when and how the botanical was grown. It is important that all batches of botanical raw material undergo appropriate testing before acceptance for further processing to ensure that the right compounds are present in the plant material, at acceptable concentrations, and any other substances or contaminants are within predetermined limits.

The natural variability of Botanical materials can present several challenges with regards to such testing, and robust specifications are essential to determine and maintain the quality of starting materials and finished products. Adulteration (both accidental and intentional) and substitution are serious issues that can impact botanical food supplements and therefore need to be fully taken into consideration when developing a testing strategy for incoming materials. The most critical tests conducted on Botanical raw materials are therefore those concerning identification.

Due to the complex nature of botanicals, a combination of different testing techniques is required in order to confirm the precise identity of the starting material in question. Physical identification of the plant is essential and begins in the field with personnel trained in plant identification. Other plants may appear very similar to the target species, and grow in similar habitats to locations, which can lead to mis-identification and collection of the wrong species.

Once harvested, botanical materials are often processed, which can make physical identification more difficult or impossible. Whole plant is easier to identify than chopped or powdered material, from which it may not be possible to identify which plant species the material may have come from, let alone which parts of the plant may be present. Physical identification must therefore be complimented with additional chemical testing to confirm identity, which can include various wet chemistry tests, Chromatographic techniques, or where appropriate, DNA testing.

Different botanical materials will have different levels of risk associated with their identification and testing. Some species will be at greater risk of adulteration and contamination than others, and some species will present greater challenges in correctly confirming their identity. The testing regime and testing frequency of a botanical material therefore needs correlate to the potential risks associated with it. The higher the potential risks, then the more thorough the testing regime will need to be, either in terms of the number of tests conducted, the frequency of such testing, or both. The following sections detail the critical testing required to develop robust specifications that guarantee the homogeneity and representativeness of each batch of material being tested for use in the manufacture of botanical food supplements.

5.3 Identification

Accurate identification of all botanical source material selected for further processing should be carried out at the harvesting stage, particularly with botanicals harvested in the wild. As a minimum, the following information should be available:

- Scientific (Latin) name[10]

[8] https://wcsp.science.kew.org/prepareChecklist.do;jsessionid=7FF8802FCCC859C475588243FAC6EBFD.kppapp06-wcsp?checklist=selected_families%40%40285121020181113416

[9] www.ipni.org

[10] Care should be exercised with the identification, as there are many cases where botanicals have been renamed or reclassified.

  - full systematic species[11] 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 name (vernacular name)
- Whether cultivated and/or collected from the wild
- Cultivation practices
- Plant part or plant product used e.g. root, leaf, seed…
- Geographical origin (where relevant continent, region, country and province/state)
- Period of harvest (season)
- Stage of the plant growth (on harvesting)
- Declaration signed by a suitably qualified, experienced or designated responsible person
- Organic certification where applicable
- A declaration stating whether or not the botanical has been genetically modified.
- Statement on the irradiation status of the botanical material
- Provisions for traceability (e.g. batch/lot/shipment ID number)

5.3.1 Novel Food Legislation

Given the global nature of the habitats of the numerous botanicals used in botanical food supplements, food business operators must ensure that the botanicals selected for use in their botanical food supplements have a history of use in significant degree in the European Union prior to May 1997. If they do not, they will require safety clearance according to the terms of EU Novel Foods legislation. For further detail, see footnote [12]

5.3.2 Traceability

European food legislation requires each operator in the supply chain in the EU to be responsible for maintaining an appropriate traceability system, including supplier and customer records for each batch of product or material, whether from EU or non-EU origin. As example, by definition the quality of botanical raw material starts in the field, but information on the origin of natural compounds can be lost in complex trading channels: 'Siberian ginseng' (Eleutherococcus senticosus) can often originate in China or Korea, and the South African plant Hoodia gordonii has been substituted for the species Opuntia ficus-indica, originating from Mexico. As defined in EU Directive 178/2002/EC, producers of food- and hence of botanical food supplements – are obliged to make the origin of herbal raw materials traceable. **Therefore, all operators involved in the food chain must identify and document information on products 'one step forward and one step back' - and, for quality to be assured throughout the supply chain, this information should be readily available on request from the competent authorities.**

5.4 Incoming materials – confirmation of identity

The complex nature of botanical material and the vagaries of the botanical supply chain mean that it is essential that all batches of incoming material are sampled and tested as appropriate to positively confirm the identity of the material. Appropriate reference standards must be used in order to confirm the identity of botanical materials, and pre-delivery samples or material taken from the supplied batch of plant material should not be used. Reference standards can usually be sourced commercially from independent or specialist suppliers, but there may occasions when no standards are available, especially for more exotic plant species. Under such circumstances, alternative approaches will need to be considered. For example, it may be possible to acquire botanical material from two additional sources and to compare analytical samples from each. If materials from multiple suppliers across different batches are found to match, then the identity of the material can be verified.

5.4.1 Sampling and Testing

Identification of the selected botanical material should be confirmed by:

[11] Botanical species - a key indicator which allows differentiation between two similar products and should be documented with as much specificity as appropriate, which may include examination by an expert (e.g., botanist, pharmacognosist, or other person with appropriate training) of the plant's morphologic characteristics.

[12] https://ec.europa.eu/food/safety/novel_food_en

- Macroscopic examination of a sample of the botanical material
- Microscopic examination of a sample of the botanical material - and where necessary:
  - Chromatographic/Spectroscopic examination: e.g. Thin layer chromatography (TLC); high performance liquid chromatography (HPLC); high performance thin layer chromatography (HPTLC); Fourier-transform infrared spectroscopy (FTIR)
  - Other characteristic assay

Other chemical and physical tests can sometimes support the identification. Where applicable, these are shown in the relevant Pharmacopoeial monograph. Identification testing optimally should be able to discriminate between related species and/or potential adulterants/substitutes, which are likely to be present. Identification tests should be specific for the herbal substance and are usually a combination of three or more of the following:

- Macroscopic characters, Microscopical characters, Chromatographic procedures, Chemical reactions.
  Tests:
- Foreign matter.
- Total ash.
- Ash insoluble in hydrochloric acid.
- Water-soluble extractive.
- Extractable matter.
- Particle size: For some herbal substances intended for use in herbal teas or solid herbal medicinal products, particle size can have a significant effect on dissolution rates, bioavailability, and/or stability. In such instances, testing for particle size distribution should be carried out using an appropriate procedure, and acceptance criteria should be provided. Particle size can also affect the disintegration time of solid dosage forms.
- Water content: This test is important when the herbal substances are known to be hygroscopic. For non-pharmacopoeial herbal substances, acceptance criteria should be justified by data on the effects of moisture absorption. A Loss on drying procedure may be adequate; however, in some cases (essential oil containing plants); a detection procedure that is specific for water is required.

A range of new analytical methods/technologies are being developed and applied which can be used to complement the findings which are generated using established methods. These include:

- DNA-based technologies (e.g. DNA-fingerprinting and DNA-sequencing) • Nuclear magnetic resonance spectroscopy (NMR) • Ultraviolet (UV), mid-infra-red (MIR) and near infra-red (NIR) spectroscopy combined with computational analysis
- Hyphenated techniques (HPLC-MS, LC-NMR, etc.) • Chemometric approaches (including Multivariate analysis (MVA) and Principal component analysis (PCA)
- Biosensors

5.5 Raw Material Specifications and Markers

Specifications should describe in detail the requirements with which the material should conform, and includes descriptive and numerical clauses and permitted tolerances. Specifications serve as the bases for quality evaluation. Marker determination is a further parameter used to confirm the quality of the botanical raw material.

5.5.1 Specifications

Details of the identity specifications for most commonly used botanicals will be found in scientific literature, international or national standards (such as Codex Alimentarius or European or national Pharmacopoeias) or in-house specifications.

See Annexe 2 for examples of in-house specifications.

5.5.2 Markers

A marker is a chemically defined characteristic constituent or group of constituents present in a specified botanical material, and marker determination is a further parameter used to confirm the quality of the botanical raw material and the corresponding preparation irrespective of whether they have any physiological activity: their function is to assist in the determination of the composition and quantification of the botanical raw material and preparation. The two main categories of marker are:

- 'Active Marker(s)' – a constituent/group of constituents generally accepted as contributing to a physiological effect in the body
- 'Analytical Marker(s)' – generally used to assure identity and consistency of a botanical preparation, analytical markers are constituents or a group of constituents known to be characteristic of the botanical material and for which there are established analytical methods.

The 'ideal' marker is a constituent(s) with an established, validated assay method where the assay is not subject to interference from other constituents in the botanical source material or from processing. Analytical procedures and marker amount can be found in the scientific literature, international or national standards (Ph.Eur, WHO monographs) or in-house specifications.

5.6 Contaminants/Residues

It should be noted that as regards contaminants and residues, the requirements of food law take precedence over medicines law/pharmacopoeial monographs, and are often more stringent, particularly for chemical contaminants.[13] However, where food law does not offer any provision as regards methodology and limits, those given by the European Pharmacopoeia may be used.

5.6.1 Microbial Contamination

The specifications set out in the European Pharmacopoeia section 5.1.8 (Microbiological quality of herbal medicinal products for oral use) is a guide to maximum acceptable levels. The following microbiological tests should be carried out on the botanical source, as identified by HACCP:

- Total plate count (Total viable count)
- Escherichia coli
- Salmonella spp.
- Enterobacteriaceae
- Moulds/Yeasts (total combined)

The frequency of testing should be identified/included in the HACCP plan together with details of any treatment that is applied, such as heat/steam/irradiation. The frequency of testing is generally the result of a case by case assessment, not only dependent on the form of cultivation and growing conditions, but also on the manufacturing process, which may in itself lead to a reduction of microbial count.

Microbiological contamination with potentially pathogenic organisms can be a serious risk in botanicals particularly 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. Routine testing should therefore be established, based on risk, e.g, a powdered herb may present a bigger risk than an extract. e.g. a powdered herb presents a much higher risk than an extract; water-based extraction presents a higher risk than, say, a 70% ethanolic extraction.

Some herbals can be treated with heat/steam that may reduce risk, and irradiation may be used to control microbiological contamination. However, this must be declared on the label of the finished product – and any herbal raw material with a very low count should be screened for irradiation.

Many of the contaminants and residues that can potentially be found in botanicals have legal limits. Food operators should be aware of the particular legislation applicable in the countries where the bulk supplies are grown and those where the final products are marketed. Where there are no legal limits, a safety-based approach should be applied, including the use of specific limits.

5.6.2 Heavy Metals

EU legislation (adopted into UK law) [14] sets maximum levels for:

[13] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance) and all subsequent amendments

[14] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance)

- Cadmium[15]
- Lead[16]
- Mercury[17]

In general, these EU/UK limits apply to botanical raw material, but national positions should always be checked, as different countries may have specific requirements – for instance for arsenic.

Limits for food supplements in legislation for the finished product need to control/monitor levels in materials to ensure the finished product will comply, based on risk assessment: high risk may mean that every batch should be tested - a lower risk control plan may require that only one batch a year is tested. See **Annex 3** for an example of a Raw Materoa; Risk and Vulnerability Assessment form.

5.6.3 Chemical Residues

- Pesticide, herbicide and fungicide residues.
- Ethylene oxide, not permitted under EU food law
- Other fumigants (e.g. phosphine or methyl bromide)
- Solvent residues[18] (see EU legislation on extraction solvents used in the preparation of food and foodstuffs – ref. maximum residue limits for methanol)

Contaminants or pesticides may be concentrated during the extraction process and this must be taken into consideration when adopting and agreeing with the raw material supplier the maximum levels in the botanical raw material. Where applicable concentration factors may be taken into consideration as described in EU legislation.

Any product for human consumption in which the level of contaminants exceeds those legally permitted cannot be traded in the EU or exported. The mixing of batches with high contaminant levels with those with lower levels in an attempt to meet legal requirements is extremely poor practice and seriously compromises the level of quality of the product.

Appropriate sampling and analysis of product for chemical contamination should be applied according to the requirements of the relevant EU legislation. Where there are no specific requirements, other references such as the sampling frequency applied/recommended by enforcement authorities or specified in botanical pharmacopoeias may be relevant.

Frequency of testing depends on the potential risk of contamination: heavy metals are usually associated with the soil content in the area of cultivation; mycotoxins may be related to climatic conditions and often to post-harvest storage conditions. Dioxins and PAHs are usually the result of combustion processes (industrial combustion, vehicle emissions, fires) and in some regions a high frequency of testing may be needed as a risk management measure.

5.6.4 Polycyclic aromatic hydrocarbons (PAHs)

Polycyclic aromatic hydrocarbons (PAHs) are hydrocarbons - organic compounds containing only carbon and hydrogen – that are composed of multiple aromatic rings. Exposure to PAHs has been linked with cardiovascular disease and poor foetal development.

High levels of PAHs have been found in food supplements which contain or are derived from botanical ingredients – often linked to bad drying practices. High levels have also been found in dried herbs and spices – again related to poor drying practice. Similarly, traditional smoking/processing methods for smoked paprika and cardamom result in high PAH levels. For legislation on PAHs, see footnote[19]

[15] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0488
[16] https://ec.europa.eu/food/safety/chemical_safety/contaminants/catalogue/lead_enc
[17] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l21290
[18] Directive 2009/32/EC
[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1933

5.6.5 Mycotoxins

Mycotoxins are excreted by-products produced during the growth of certain fungi/moulds. Mycotoxins already limited by EU legislation include the aflatoxins and ochratoxin A. Aflatoxins are carcinogens that are produced by particular moulds. *Aspergillus flavus* and *Aspergillus parasiticus*, which grow in soil, decaying vegetation, hay, and grains. They are regularly found in improperly stored nuts, seeds, rice and vegetable material. Aflatoxins or ochratoxin A (OTA) have been found in botanicals such as ginseng, ginger, liquorice, turmeric, and kava-kava in the USA, Spain, Argentina and India. Certain species of botanical are specifically covered by EU mycotoxin legislation[20]. Guidance on reducing/controlling Mycotoxin levels can be found in the FSA[21] and the WHO Guidelines on Good Harvest and Collection Practice[22]

5.6.6 Environmental Contaminants

Organic contaminants found in the environment which can be found on botanical material. Examples include:

- Dioxins, furans and dioxin-like Polychlorinated biphenyls (PCBs), found in botanical oils and fats
- Polycyclic aromatic hydrocarbons (PAHs), currently only regulated in the EU for botanical oils and food supplements/botanical food supplements.
- Radioactivity: where cultivation/harvesting is in proximity to nuclear disasters (e.g. Chernobyl, Fukishima).

5.6.6 Limit tests

A limit test is a quantitative measure aimed at identifying control of small quantities which seeks to establish if there are any impurities in the substance. When a new product is submitted for Microbial Limits Testing the method of choice must first be verified to ensure it is fit for purpose for the new product and the new product does not contain any antimicrobial properties that will prevent the recovery of the organism of choice from growing if present in the product.

5.7 Validation & Verification

Validation and verification are independent procedures that are used together for checking that a product, service, or system meets requirements and specifications and that it fulfils its intended purpose. They are critical components of a quality management system such as ISO 9000.

Validation is intended to ensure a product or system results in a product or system that meets the operational needs of the user.

Verification is intended to check that a product or system meets a set of specifications and verification procedures. It involves carrying out tests to model or simulate a portion, or the entirety, of a product or system, and then reviewing/analysing the results. Verification procedures also involve regularly repeating tests devised specifically to ensure that the product or system continues to meet the initial design requirements, specifications, and regulations as time progresses.

For further detail of validation and verification processes and testing see 6.6 below.

[20] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1881:20100701:EN:PDF
[21] ;FSA Guidance on Mycotoxins: https://www.food.gov.uk/business-guidance/mycotoxins
[22] WHO Guidance on Good Harvest and Collection Practice: apps.who.int/medicinedocs/en/d/Js4928e/10.11.html

6 BOTANICAL PREPARATIONS, MANUFACTURING AND PROCESSING – MAKING FINISHED PRODUCTS

6.1 Introduction

A botanical preparation is obtained from botanical material by various processes (e.g. pressing, squeezing, extraction, fractionation distillation, concentration, maceration, drying and fermentation). Botanical preparations include comminuted or powdered botanical material, extracts including tinctures and essential oils, expressed juices and 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. To produce a finished product of consistent quality, the specifications of both the production process and the final preparation must be determined.

A botanical extract is a particular type of botanical preparation which, by using a solvent, results in a concentration of a dilution of the constituents of the botanical raw material. The extraction process may select or remove particular components of the botanical material. Thus, the solvent and extraction conditions are key parameters necessary to support the characterization of an extract, as well as the ratio of starting plant material to the final extract, which is considered as a range related to the natural variability of the plant material.

6.2 General

The essential tools required to produce a high quality finished product so as to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate to their use are Quality Assurance (QA) and Quality Control (QC) and Good Manufacturing Practice(GMP).

6.3 Quality Assurance (QA)

To produce a quality product, quality assured standards must be applied and met throughout the entire production process. Quality Assurance (QA) is a programme for systematic monitoring and evaluation to ensure that these standards of quality are being met.

6.3.1 QA for botanical preparations

For botanicals food supplements quality assurance must encompass:

- Personnel and education; Buildings and facilities; Equipment; Documentation
- Seeds and propagation material; Cultivation; Collection; Harvesting
- Primary processing, Packaging, Storage and Distribution.

6.4 Quality Control (QC)

Quality control (QC) is a procedure or set of procedures intended to ensure that a manufactured product or adheres to a defined set of quality criteria. 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.

6.4.1 QC for botanical preparations

Product documentation, which covers in detail all aspects of the product, from the agreed specification for the raw botanical material through to the release for sale of the extract, should be produced and maintained. All raw material specification 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, together with documentation supporting the reliability of the analytical methods. The documentation should be reviewed at periodic intervals and any amendments made should be recorded, as should the date of the amendment.

6.5 Good Manufacturing Practice

Good manufacturing practice guidelines provide guidance for manufacturing, testing, and quality assurance in order to ensure that a manufactured product is safe for human consumption or use. Many countries have legislated that manufacturers follow GMP procedures and create their own GMP guidelines that correspond with their legislation. GMP guidelines are not prescriptive instructions on how to manufacture products. They are a series of general principles that must be observed during manufacturing. When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfil GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process that both meets business and regulatory needs.[1][2]

All guidelines follow a few basic principles:

- Manufacturing facilities must maintain a clean and hygienic manufacturing area
- Manufacturing facilities must maintain controlled environmental conditions in order to prevent any physical, chemical and micro contamination including cross-contamination from adulterants and allergens that may render the product unsafe for human consumption or use.
- Manufacturing processes must be clearly defined and controlled. All critical processes must be validated to ensure consistency and compliance with specifications
- Manufacturing processes must be controlled, and any changes to the process must be evaluated. Changes that affect the quality of the product are validated as necessary.
- Instructions and procedures must be written in clear and unambiguous language using good documentation practices, and include instruction/procedures relevant to pest control, portable water supply, waste control, personal hygiene.
- Operators must be trained to carry out and document procedures.
- Records must be made, manually or electronically, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations must be investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced must be retained in a comprehensible and accessible form
- Any distribution of products must minimize any risk to their quality.
- A system must be in place for recalling any batch from sale or supply
- Complaints about marketed products must be recorded and examined, the causes of quality defects must be investigated, and appropriate measures must be taken with respect to the defective products and to prevent recurrence.

6.6 Finished Product Specifications, Sampling and Testing

6.6.1 Botanical Preparations

All traded botanical preparations must have a comprehensive specification between the supplier and the manufacturer which should cover the botanical source, the manufacturing process and all relevant chemical, microbiological and physical parameters, which should also be accompanied by the test methods from which the values were determined. Where measurable parameters are given, they should include the target value and acceptable range.

6.6.2 Commercial Extracts

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

- Specific identification of the batch, including date of manufacturing and re-testing 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 (with sufficient data to allow the manufacturer of the supplement in which the extract is used to ensure compliance of the final product with all relevant food legislation.)
- Where relevant, confirmation of the irradiation status of the extract and the botanical source

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. Out of Specification (OOS) results should be investigated through the Quality Management System, and appropriate corrective and preventative measures put in place, where applicable, to prevent re-occurrence. Out of Trend (OOT) results should also be investigated, as they may be indicative of a change or incident having taken place at some point in the supply chain, during manufacturing or processing, which has the potential to negatively impact the quality of the product.

6.6.3 Identity (ID) testing of incoming commercial extracts

Identity testing of the raw material on receipt, using techniques such as FTIR, TLC, HPTLC is essential, and the choice of reference standard is critical: a pre-delivery sample or the first batch should not be used. Instead, an independent reference standard, ideally primary or secondary, should be used. Many such standards are commercially available – however, if no commercially available material is available it may be acceptable to purchase the same material from two other separate sources and, if all three match this then verifies the ID standard. Consideration should also be given to whether the test method technique used is appropriate for the specific circumstance e.g if maltodextrin is used in the extract, FTIR may not be capable of differentiating the herbal and therefore another technique such as TLC or HPTLC may be required.

6.7 Markers, Assays & limit tests

6.7.1 Markers

See Section 5.5.2 for further detail.

6.7.2 Assays

For herbal substances with constituents of known therapeutic activity or with active markers, assays of their content are required with details of the analytical procedure. Where possible, a specific, stability-indicating procedure should be included to determine the content of the herbal substance. In cases where use of a non-specific assay is justified, other supporting analytical procedures may be used to achieve overall specificity if required. For herbal substances where the constituents responsible for the therapeutic activity are unknown, assays of analytical markers or other justified determinations are required. The appropriateness of the choice of markers should be justified. For example, reference to the assay of a marker in the relevant monograph of the European Pharmacopoeia is an appropriate justification.

Some botanical species may also contain potentially toxic or damaging compounds. Suitable assays testing should therefore be conducted to determine the content of any substances of toxicological interest and appropriate limits should be incorporated into the corresponding product specification.

6.7.3 Limit tests/Confirmation of active content

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

6.8 Validation & Verification (Processes and testing)

Consistency of the production should be supported by appropriate use of master batch records and change control procedures. Any changes to the manufacturing process or to the

raw material source, including any change in equipment, should be addressed by necessary modifications to manage risks to authenticity. In the framework of the HACCP system used, 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 and results and conclusions 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 materials source including any change in equipment, should be addressed by necessary modifications to the quality system.

6.9 Stability Testing and Shelf Life

It is a legal requirement that botanical food supplements 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 product on the market has to determine the length of time during which, after being packed for sale, it will comply with its label claim.

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
- Where appropriate, use of previous data from other stability studies made on similar products
- Extrapolation of results from relevant bibliographical data.

If stability studies are necessary to estimate the life of a botanical product (for example, if there no accumulated data as above), tests should be carried out on the final product as sold to the ultimate consumer. As the product's stability is dependent on the barrier properties and seal integrity of the packaging, stability studies should be carried out in the selected pack. Any change in packaging can require a re-evaluation of stability.

Stability studies on the extract should be designed so 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:

- Organoleptic properties (taste, smell, presentation/appearance, colour) and in particular, colour and flavour stability.
- Chemico-physical and microbiological properties, and in particular, that the final product does not permit microbiological growth
- Fat stability (oxidation/rancidity in vegetable oils)
- Physical changes on storage (appearance, caking, hardness, agglomeration)
- That there are no interactions between ingredients (confirming 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 the declared ingredients.

7. STORAGE & DISTRIBUTION: GOOD DISTRIBUTION PRACTICE (GDP)

7.1 Introduction

Storage and distribution of Botanical raw materials and finished products are fundamental activities in the overall supply chain, must be subject to appropriate Quality Management processes, and measures. Often, the focus of quality activities and controls can be on those actions undertaken at specific locations by specific individuals, and how materials are stored or transported from one location to another can be overlooked. In reality, and with botanical materials in particular, how they are stored, handled, packaged and transported can have a significant impact on their quality.

7.2 General

A botanical material can be subject to storage and distribution at several different points in the supply chain. Once harvested botanical materials will start to decay, so the initial actions taken immediately after harvest can be of critical importance and how a material is packed, transported and delivered can have a significant impact on its quality. Some plant materials may be required fresh, some might be transported frozen, others may be transported from (or through) climatic zones with extreme weather conditions, so the type of transport and storage systems required could be very different.

Even within a basic supply chain, transportation and storage activities should be incorporated into the Quality Management System to ensure that when a material is transported from one location to another, it is of suitable quality when it arrives, that it has been kept securely, and that full traceability has been maintained throughout.

7.3 Quality Management Systems

Throughout the lifecycle of Botanical Raw Materials and Botanical Food Supplements, the party responsible for ensuring and maintaining quality must be specified. Storage and distribution activities must be incorporated into the organisations Quality Management System, and importantly, when this responsibility is transferred from one party to another in the supply chain, this transition must be clearly defined, agreed and documented. For example, a raw material supplier may transport a botanical ingredient to a manufacturer using a third party courier company. The quality of the material must be maintained throughout this process, and however responsibilities may be divided, all parties must understand their quality commitments and be able to provide assurances that these commitments have been met.

7.4 Personnel and Training

Roles and responsibilities throughout the supply chain must be defined and tasks designated to specific personnel. This includes staff and personnel involved in the storage, handling and distribution of botanical materials.

Such personnel should receive both initial and ongoing training specific to their tasks, including training in basic food hygiene and handling practices.

7.5 Premises and Equipment

All premises and equipment must be suitable for their intended use and made of material in a condition that can be cleaned easily and effectively, and must be adequate to ensure proper protection of the materials being either stored or transported.

Storage facilities must be clean, secure and adequately protected from pests such as rodents, birds and insects. Premises should be designed to reduce the likelihood of contamination occurring between stored materials, and there should be suitable space to allow access to, and segregation of, different materials.

Vehicles and containers should be suitably clean, secure and designed for their intended purpose. They should also be free from traces of previously stored materials or potential contaminants, especially if re-useable containers are being utilised.

In facilities where transportation and deliveries take place, suitable loading and unloading areas must be designated, which are adequately protected from the environment and minimise potential contamination, damage or degradation during loading or unloading.

7.6 Operations and Procedures

Distribution and storage activities should be subject to written procedures which are incorporated into and controlled via the Quality Management System.

Specific procedures should be in place for the inspection of transport vehicles prior to loading, and for the inspection and receipt of incoming delivery materials. This should include inspection of goods for any damage that may have occurred as a result of, or during, transport.

With Botanical materials especially, there is increased likelihood of damage, degradation or infestation with pests during transport. Suitable quarantine procedures should be established for rejecting or handling such materials, as well as those which show signs of tampering.

7.7 Documentation

In addition to documenting procedures and processes, all activities undertaken with regard to transportation and storage of botanical materials must be recorded and detailed to maintain quality and traceability.

Transportation and storage are activities that are often contracted to third parties, and if so, suitable technical and quality agreements must be in place, which detail the expectations and commitments of each party, including, where relevant, appropriate arrangements for temperature control. Couriers and third party transport companies must be adequately trained or informed on the nature of their cargo and any particular transport conditions that may be required for the botanical material.

Detailed records should be kept to document receipt and inspection of incoming materials, including the identity of the supplier or manufacturer, the identity of the material, receipt and purchase information, batch details and any documentation accompanying the delivery, such as certificates of Analysis or testing results.

Packaging material compatibility
Not only must suitable consideration be given to the storage facilities and conditions under which botanical materials are stored, the packaging materials themselves must also be fit for purpose.

Packaging materials used for short-term transport and storage must be suitably clean, free from contaminants, and themselves should not introduce contamination such a fibres to the materials being stored. If reusable packaging is employed, then it must be made from material that can be cleaned easily and effectively.

When longer term storage of botanicals, intermediates and finished botanical food supplements is being undertaken, then further consideration should be given to compatibility of the botanical with the packaging materials being used. For example, an ethanolic botanical extract stored in a plastic container may leach substances from the packaging material into the product. Consideration should therefore be given to conducting packaging compatibility and stability studies to ensure botanical materials are suitably protected by, and not contaminated from, the packaging materials they are stored in.

7.8 Challenges for Botanicals

The particular nature of botanical material in terms of natural habitat and climatic zones means that they are vulnerable to a number of specific challenges.

7.8.1 Sourcing from the developing world

A number of botanical materials are sourced from exotic locations, many in the developing world, from co-operatives, individual growers and some may be collected from the wild. Even with the best of intentions, it is difficult for a Quality Management System to extend so far afield and still maintain full oversight of all operations. Under such circumstances, it

is important to conduct a full risk analysis, highlighting the areas of greatest risk to your plant material or product, and then developing strategies to mitigate them as much as possible. Under such circumstances, there may only be limited mitigation options available and strategies may have to focus more on detecting quality issues rather than trying to prevent them. Whatever approach is adopted, it must be fully justified and adequate to guarantee the overall quality of the botanical material or finished product.

7.8.2 Climatic Zones

Not only are a number of botanical materials sourced from the tropics or countries with extreme weather conditions, but others may also be transported through such regions at some point during the supply chain, whereas some may be sold there as finished products. When Botanical materials are being sourced from such climates, consideration should be given as to how they will be transported, processed or stored after harvest, as the material will likely degrade more quickly if exposed to high temperatures or humidity.

When materials are being transported through regions with different climatic zones, it must be ensured that the material is packaged and transported under conditions that will protect it from environmental extremes. It must also be ensured that the material is handled correctly so, for example, it is not unloaded at dockside and left in direct sunlight.

Contrarily, the entire supply chain for other botanicals may be contained solely within the European Climatic zone, but the finished product itself could be exported for sale in a totally different climate. Under such circumstances, consideration should be given to confirming the shelf life for the finished product by testing under comparable environmental conditions as would be found in the destination market.

8 SERVICE PROVIDERS & THIRD PARTIES/OUTSOURCING

8.1 Introduction

Because the supply chain for botanical food supplements can be highly complex, so maintaining oversight of every activity undertaken throughout their lifecycle can be very challenging. Most organisations are not likely to undertake all of these activities themselves but instead 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.

8.2 General

In the majority of cases, companies are likely to have 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 process confirm that these expectations are being met. When considering Botanical supply chains, there are a number of areas which require particular attention.

8.3 Contracts and Agreements

Outsourced activities need to be appropriately defined, detailed and controlled. This requires written agreements between the parties involved which clearly state the obligations and expectations on all sides. Ownership of materials, actions and responsibilities at all stages of the product lifecycle need to 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.

8 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, they may seek to demonstrate 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 - 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 in full
- 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.

8.5 Audit & Inspection

In addition to continually monitoring the performance of suppliers, a routine audit and inspection program 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 initial audit, suppliers and services 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 focuses 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, mis-identified or contaminated, audit activities should therefore focus on 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. In many instances however, physical audits of supplier 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 not only useful tools for conducting audits themselves, but they can also help maintain a consistent company approach to auditing, both 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.

8.6 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 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.

8.6.1 Challenges with Botanicals

In some instances, companies may work directly with small-scale growers, or individuals who collect plants from the wild. Such individuals 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 are liable to 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 mis-identification, 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 perhaps those involving exotic plant species especially, 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.

8.7 Contract Manufacturers

Organisations may choose to outsource all or part of the manufacturing process for Botanical Food Supplements. The information in Section 6 of this guide, which details the most critical elements of Good Manufacturing Practice, should therefore be taken into considering 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 program (HACCP for example) and a fully functioning Quality Management System.

It is highly recommended that they should have prior 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 manufactures 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 sub-contracts certain activities to third party. This may be the case with analytical testing or transportation and logistics, under which circumstances assurances must be provided that these activities are appropriately managed and controlled.

8.8 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, as detailed in Section 5 and 6 of this guide, and organisations may choose to outsource testing for:

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

- Stability timepoints

8.8.1 Challenges with Botanicals Testing

As detailed in Section 5, 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.

8.8.2. 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 should therefore be ensured that the laboratory employed in testing 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.

8.9 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.

Section 7 details the Good Distribution Practices that should be applied to Botanical materials and finished products, and these elements in particular should be specified in contracts and Technical Agreements. With Botanicals that have a particularly complex supply chain, or those sourced from overseas and exotic locations, ownership and responsibilities for materials need to 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 1

The 7 steps of the HACCP process:

Conduct a hazard analysis: plan to determine the food safety hazards and identify the preventive measures the plan can apply to control these hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Identify critical control points: a critical control point (CCP) is a point, step, or procedure in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

Establish critical limits for each critical control point: a critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce that hazard to an acceptable level.

Establish critical control point monitoring requirements: monitoring activities are necessary to ensure that the process is under control at each critical control point.

Establish corrective actions: actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product is injurious to health or otherwise adulterated as a result if the deviation enters commerce.

Establish procedures for ensuring the HACCP system is working as intended: *Validation* is the process of finding evidence for the accuracy of the HACCP system – it ensures that the HACCP process is doing what is has been designed to do: to ensure the production of safe product. *Verification* ensures the HACCP plan is adequate, that is, working as intended. Verification procedures may include such activities as review of HACCP plans, CCP records, critical limits and microbial sampling and analysis.

Establish record keeping procedures: the HACCP regulation[23] requires that all food businesses maintain certain documents, including the hazard analysis and written HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations. Implementation involves monitoring, verifying, and validating of the daily work that is compliant with regulatory requirements in all stages all the time.

[23] Article 5, Regulation EC 852/2004

ANNEX 2

Examples of in-house specifications

RAW MATERIAL SPECIFICATION / REPORT

			KF289	**NO. OF SAMPLES TAKEN:**
OTHER NAMES:		**BATCH NO:**		**QUANTITY DELIVERED:**
		RS BOX:		**NO. OF CONTAINERS:**
APPROVED SUPPLIER		**SHELF LIFE**		**ORDER NO:**
		DATE:		**GRN:**
		MICRO SAMPLE	NO	**BBD:**
C OF A RECEIVED:	**YES/NO/NR** **SAMPLE SIZE 20g**	**PLAN : A**		

APPEARANCE	(0001)	BROWN POWDER		
FTIR-ID	(1115)	CONFORMS		
PSL COUNT	(1132)	< 700/ MINUTE		
BAP/PAH4	(sub contracted)	<10ppb/<50ppb TEST EVERY BATCH		
LEAD	(COA)	< 3.0 mg/kg		
CADMIUM	(COA)	< 1.0 mg/kg		
MERCURY	(COA)	< 0.1 mg/kg		

DISPOSITION

PASS

CONCESSION
(STATE QUANTITY & DEFECT)

HOLD (STATE REASON)

FAIL (STATE QUANTITY & REASON)

.

QCM / LAB MANAGER DATE TESTED:

DATE CREATED: 23 JAN 2018

……
APPROVED BY QC MANAGER

REASON FOR ISSUE: CHANGE TO SAMPLE PLAN	ISSUE NO : 8
ISSUED BY……	ISSUED BY:

RAW MATERIAL SPECIFICATION / REPORT

PRODUCT:	SAGE EXTRACT 5:1		**CODE**	KF86	**NO. OF SAMPLES TAKEN:**
			BATCH NO:		**QUANTITY DELIVERED:**
OTHER NAMES:	SPECIES: SALVIA OFFICINALUS		**RS BOX:**		**NO. OF CONTAINERS:**
			SHELF LIFE	2 YEARS	**ORDER NO:**
SUPPLIER			**DATE:**		**GRN:**
			MICRO:	YES	**BBD:**
C OF A RECEIVED:	**YES/NO/NR**	**SAMPLE SIZE 20g**	**PLAN : A**		

APPEARANCE	(0001)	LIGHT BROWN FINE POWDER	
FTIR-ID	(1115)	CONFORMS	
PSL COUNT	(1132)	< 700 / MINUTE	
LEAD	(COA)	< 3.0 mg/kg	
CADMIUM	(COA)	< 1.0 mg/kg	
MERCURY	(COA)	< 0.1 mg/kg	
MICRO 5.1.8B	(TESTED EXTERNALLY)		

DISPOSITION

PASS

CONCESSION (STATE QUANTITY & DEFECT)

HOLD (STATE REASON)

FAIL (STATE QUANTITY & REASON)

QCM / LAB MANAGER DATE TESTED:

DATE CREATED: 29 NOV 2017

…….

APPROVED BY QC MANAGER PAGE 1 OF 1

REASON FOR ISSUE: PLAN CHANGED TO A	ISSUE NO: 12		
ISSUED BY……	ISSUED BY:		

PRODUCT:	VALERIAN EXTRACT (4:1)		**CODE**	KF60	**NO. OF SAMPLES TAKEN:**
			BATCH NO:		**QUANTITY DELIVERED:**
OTHER NAMES:	EXTR.VALERIANAE OFF.		**RS BOX:**		**NO. OF CONTAINERS:**
			SHELF LIFE		**ORDER NO:**
SUPPLIER			**DATE:**		**GRN:**
			MICRO:	NO	**BBD:**
C OF A RECEIVED:	**YES/NO/NR**	**SAMPLE SIZE 5g**	**PLAN : A**		

APPEARANCE	(0001)	BEIGE TO BROWN POWDER	
FTIR-ID	(1115)	CONFORMS	
PSL COUNT	(1132)	< 700 / MINUTE	
PAH		TESTED EXTERNALLY BAP <10ppb 4PAH <50ppb	
LEAD	(COA)	< 3.0 mg/kg	
CADMIUM	(COA)	< 1.0 mg/kg	
MERCURY	(COA)	< 0.1 mg/kg	

DISPOSITION

PASS

CONCESSION
(STATE QUANTITY & DEFECT)

HOLD (STATE REASON)

FAIL (STATE QUANTITY & REASON)

QCM / LAB MANAGER DATE TESTED:

DATE CREATED: 8 NOV 2017

……...
APPROVED BY QC MANAGER

PAGE 1 OF 1

REASON FOR ISSUE: CHANGE TO SAMPLE PLAN. BAP REPLACED PAH. ISSUED BY…….	ISSUE NO: 13 ISSUED BY:		

ANNEX 3

Example of a Raw Material Risk & Vulnerability Assessment Form

Raw Material Risk & Vulnerability Assessment Form

Raw Material:		**Code:**		**SE No.:**	

Supplier(s):			**Manufacturer(s):**		
Manufacturing site(s):			**Major Processing Steps:**		
BRC Accredited?		**Material Source:**		**% Usage:**	

Risk rating: Materials from outside the EU particularly from Asian countries will be high risk. Materials from USA may not comply with EU food regs e.g high risk for GMO and irradiation. Pharma grade materials may not comply with food regs e.g. Heavy Metals/pesticides.
Risk Analysis: The risk factor is calculated as per QCP29F. Please provide details of decision making process e.g. MSDS, questionnaires, previous NCMR, Type of material, etc.

Hazard Source	Risk Factor AxB=C	Sig Hazard Y/N	Decision process	Control Measure	Action	Risk Acceptable? Y/N
Microbiological (Use EP as guideline limits)						
Heavy metals *						
Contaminants e.g. PAH *, solvent residues (If natural source (not mineral) add to PAH RA)						
Pesticides/aflatoxins						
GMO						
Irradiation						
TSE/BSE (animal origin questionnaire required)						
Odour/Colour						
Particulate contamination						
Hazardous (refer to MSDS)						
Other ** (please state)						
ALLERGENS #						

* If levels cannot be reduced consider using NCMR (QCP22) and/or add to the separate Risk Assessment spreadsheets for Heavy Metals & PAH

If allergens are a risk factor, complete the separate allergen spreadsheet RAPR016

** Includes any sampling requirements to be added to RMS such as full cleandown after sampling porcine materials

Other Risks Identified as a result of control measures:			
Sampling Plan A-C allocated (refer to SOP 67, appendix 1):			
Completed By:	**Date:**	**Approved By:**	**Date:**

GOSSARY OF TERMS

General Terms

Analytical Method	A detailed description of the procedure to be followed in performing tests for 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.
Bulk Product	Any product that has competed 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 Manufacturer	Manufacture or partial manufacture ordered by one person/organisation (the contract giver) and carried out by a separate person/organisation (the contract acceptor).
Corrective Action	Action to eliminate the cause of a detected nonconformity or other undesirable situation.
Customer	Organisation or person that receives a product
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 product.
Finished product	A product which has undergone all the stages of manufacture.
Ingredient	Any substance that is used in the manufacture of a product and that is intended to be present in the finished product,
Intermediate product	Any material or mixture of materials which must undergo one or more stage of processing to become a bulk product or a finished product.
Lot	A quantity of product produced during a given cycle of manufacture and from a specific formulation order that is uniform in character and quality.
Lot 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. The Record should be based on the Master Manufacturing instructions and be compiled as the manufacturing operation proceeds.
Management System	A system to establish policy and objective and to achieve those objectives.
Manufacture	The complete cycle of production and quality control of a product from the acquisition of all materials through all stages of subsequent processing, packaging and storage, to the distribution or release of the finished product.
Master Manufacturing Instructions	A document or documents identifying the raw materials, with their quantities, to be used in the manufacture of a product, 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 instruction for the removal of finished product to storage.
Non-conformity	Non-fulfilment of a requirement
Objective evidence	Data supporting the existence or authenticity of something.
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, used in the packaging of a product, such as containers, closures, bags, packing label materials (labels, inserts, etc), seals, binding materials, adhesives and tapes.
Preventative Action	Action to eliminate the cause of a potential non-conformity or other potentially undesirable situation.
Process	A set of inter-related or interacting activities which transform one or more of the properties (physical, chemical, microbiological sensory) of the raw materials.
Product	The result of a process
Quality	The degree to which a set of inherent characteristics fulfils requirements.
Quality Assurance	That part of quality management focussed on providing confidence that quality requirement will be fulfilled. Primarily focussed on the intended product.
Quality Control	Part of quality management focussed on fulfilling quality requirements. Includes al measures undertaken during manufacture designed to ensure the uniform output of products that conform to established specifications of identity, purity, strength and other characteristics.
Quality Management	Co-ordinated activities to direct and control and organisation with regard to quality.
Quality Manual	A document specifying the quality management system of an organisation.
Quality plan	A document specifying which procedures and associated resource shall be applied to a specific product, process or contract, by whom and when.
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 products.
Released	The status of starting materials, intermediate, bulk or finished products which are permitted 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.
Re-processing	Using, in the manufacture of a product, clean, uncontaminated materials or product hat has been previously removed from manufacturing and that has been made suitable for use in the manufacture of a product.
Re-Work	Action on a non-conforming product to make it conform to requirements.
Starting Materials	Any substance or mixture of substances (pre-mix) used in the production of a product, excluding packaging material.
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

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 and fermentation). These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.
Botanical Extract	A 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 or remove components of the botanica material. Extracts may be in dry, liquid or semi-solid form.
Native Extract	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. The term can 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. When determining whether two extracts are comparable, the native extracts should be used for comparison purposes.
Commercial Extract	A native extract to which one or more technological additives (inert carriers, anti-caking agents, etc.) or other food ingredients (maltodextrin, dextrose, vegetable oil, etc.) may have been added to facilitate including the final supplement product. In some cases added substances may form a substantial proportion of the commercial extract.
Marker	A chemically defined characteristic constituent or group of constituents present in a specified botanical material.
Active Marker(s)	A constituent or group of constituents that are generally accepted as contributing to a physiological effect in the body.
Analytical Marker(s)	Constituents or groups of constituents 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	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	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 of other food ingredients (such as maltodextrin) for adjustment to the botanical extract, or by blending batches of the botanical extract. 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, should be given in the documents accompanying the batch of standardised extract.
Quantified botanical extracts	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 with differing constituent levels to achieve the desired range. Additives, including carriers and other food ingredients, may be used, but in fixed quantities. 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 the documents accompanying the batch of quantified extract.
Other 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 botanical or from mixtures of botanicals. The quantity of the native botanical extract and details and quantities of any additives, including carriers and other food ingredients, should begiven in the documents accompanying the batch of extract. Additives, including carriers, and other food ingredients can be used, but in fixed quantities.

HFMA Code of Practice for Maintaining Quality throughout the Supply Chain for botanical Food Supplements

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