Food Supplements Europe

Self-Assessment Questionnaire on Good Manufacturing Practice

food supplements europe

Self-Assessment Questionnaire on Good Manufacturing Practices

The following questionnaire has been designed to accompany the Food Supplements Europe (FSE) publication 'Guide to Good Manufacturing Practice for Manufacturers of Food Supplements'. Its aim is to assist a company with assessing their current GMP status and to highlight any areas where further efforts to raise the GMP standard may be required.

If any or all manufacturing is contracted out, it is recommended that a copy of the questionnaire be sent to each external contractor to seek confirmation that they are in full compliance with the following requirements.

If no external GMP assessment is undertaken, annual self-assessment of GMP is recommended, as a minimum.

Please bear in mind that under European Union law, it is the company whose name is on the label that will be held responsible for any concerns that may arise with the quality of a product. In addition, the EU legal requirements on food hygiene apply also to food supplements that are manufactured in a EU Member State for direct export to countries outside of the EU.

Section 1: Company Information

1.1. Name of Company: .....

1.2. Address of Company: .....
.....
.....
.....

1.3. Telephone No: .....

1.4. Contact Name: .....

1.5. Email: .....

1.6. Position within Company: .....

1.7. Type of Business:

- Manufacturing / Packaging ☐
- Packaging only ☐
- Contract manufacturer / Packer ☐
- Marketing ☐

1.8. Does your company manufacture and / or pack supplements:

- On site ☐
- At another site within group ☐
- Contract out manufacturing ☐
- Contract out packing ☐

1.9. No. of full-time employees: .....

1.10. No. of part-time / seasonal employees: .....

1.11. Does your company hold a current manufacturing authorisation under EU Medicines legislation?

Yes ☐ No ☐

– If Yes, please provide details and date of expiry:

.....

1.12. Are your company's premises registered for the manufacture and sale of food (Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, Article 6(2))?

Yes ☐ No ☐

Section 2: Quality Management

2.1. Is your company registered / registering for an accredited quality system, e.g. ISO?

Yes ☐ No ☐

– If Yes, which?

.....

2.2. Does the company have personnel specifically responsible for quality (e.g. Quality Control / Quality Assurance Manager)?

Yes ☐ No ☐

If Yes, are the authority and responsibilities of these personnel clearly defined?

Yes ☐ No ☐

2.3. Do these personnel have the authority to make independent decisions on product quality?

Yes ☐ No ☐

2.4. Is there documented evidence for all lots (batches) of product that demonstrates that all steps during manufacture are being carried out as per the defined procedures and that the quantity and quality produced are as expected?

Yes ☐ No ☐

2.5. Are reference samples retained of:

– Starting materials? Yes ☐ No ☐

– Finished products in the final pack? Yes ☐ No ☐

2.6. Are there procedures in place to ensure the traceability of all raw material, intermediate and finished product?

Yes ☐ No ☐

2.7. Do the traceability records allow for rapid identification of:

– the suppliers of the raw materials Yes ☐ No ☐

– the complete manufacturing history of a lot of finished product
Yes ☐ No ☐

– the businesses to which finished products have been supplied?
Yes ☐ No ☐

2.8. Is the information on traceability in a form that can be made available to the authorities on demand?
Yes ☐ No ☐

2.9. Is there a Supplier Quality Assurance procedure in place, laying down the criteria for selection, approval, review and ongoing approval, to ensure that the supplied products and services meet the expected requirements?
Yes ☐ No ☐

2.10. Are the Quality Assurance procedures of suppliers of raw and packaging materials monitored?
Yes ☐ No ☐

2.11. Is there a system in place allowing rapid feedback to the purchasing department if concerns are raised on the quality of purchased materials?
Yes ☐ No ☐

2.12. Is there a system in place allowing rapid feedback to the manufacturing department regarding modifications or corrective actions to be taken, if required?
Yes ☐ No ☐

2.13. Are summaries of quality performance data and advice (where relevant) regularly given to manufacturing personnel?
Yes ☐ No ☐

2.14. Is there a system in place to ensure changes to relevant legislation are promptly noted and applied where applicable?
Yes ☐ No ☐

Section 3: Personnel and Training

Training

3.1. Is 'on the job' training given to personnel?

Yes ☐ No ☐

3.2. Are new employees given an induction course?

Yes ☐ No ☐

If Yes, does the course include hygiene training?

Yes ☐ No ☐

3.3. Is additional appropriate regular training offered to personnel?

Yes ☐ No ☐

3.4. For full time personnel, is their training subjected to formal review and assessment?

Yes ☐ No ☐

3.5. Are individual training records kept and maintained?

Yes ☐ No ☐

3.6. Have all relevant personnel who come into contact with raw materials / products, had training in basic food hygiene and hold the associated certification, where relevant?

Yes ☐ No ☐

3.7. Do office, maintenance and cleaning staff and any contractors who enter the production or storage areas receive food hygiene instructions?

Yes ☐ No ☐

3.8. Are all employees issued with a Company handbook which includes hygiene rules?

Yes ☐ No ☐

Hygiene

3.9. Is appropriate protective clothing provided to employees?

Yes ☐ No ☐

3.10. Is there a requirement for protective outerwear to be removed when leaving the manufacturingareas?

Yes ☐ No ☐

3.11. Are pre-employment medical checks carried out?

Yes ☐ No ☐

3.12. Are all visitors made aware of the Company's hygiene policy?

Yes ☐ No ☐

3.13. Is there a policy in place to ask visitors or contractors, before they enter any manufacturing areas, whether they have suffered or been in contact with any recent illness that may be a potential contamination risk to products?

Yes ☐ No ☐

3.14. Is there a reporting procedure for staff suffering from, or who are in close contact with people suffering from, specific medical conditions?

Yes ☐ No ☐

3.15. Is there a Personal Medication procedure in place?

Yes ☐ No ☐

3.16. Is there a Return to Work procedure in place following illness or holidays abroad?

Yes ☐ No ☐

3.17. Are there clear written policies in place:

– on the wearing of wristwatches and jewellery in the manufacturing areas?

Yes ☐ No ☐

– on items of clothing or jewellery that may be allowed in the manufacturing areas for medical, ethnic or religious reasons?

Yes ☐ No ☐

– on the wearing of make-up, associated items and perfumed products in the manufacturing areas?

Yes ☐ No ☐

– on the carrying of loose items (pens, mobile phones etc.) in the manufacturing areas?

Yes ☐ No ☐

3.18. Are procedures in place for hand washing?

Yes ☐ No ☐

3.19. Is antibacterial cream, foam or gel available for applying after hand washing for personnel working in areas of high microbiological sensitivity?

Yes ☐ No ☐

3.20. Is there a procedure in place to control glove issue, where relevant?

Yes ☐ No ☐ N/A ☐

Section 4: Premises and Equipment

Premises

4.1. Is there a Maintenance Plan that ensures the condition of buildings (both internal and external) and equipment is regularly reviewed and action taken when necessary?

Yes ☐ No ☐

4.2. Is there an Environmental Monitoring programme?

Yes ☐ No ☐

Ventilation and lighting

4.3. Are manufacturing areas ventilated with a constant supply of appropriately filtered air?

Yes ☐ No ☐

4.4. Are manufacturing areas ventilated with a constant supply of appropriately filtered air?

Yes ☐ No ☐

4.5. Are there shatterproof covers on lights in the following areas:

– raw material storage area? Yes ☐ No ☐

– manufacturing areas? Yes ☐ No ☐

– finished products storage area? Yes ☐ No ☐

4.6. Is there a formal glass and plastic breakage control (Brittle Materials) procedure?

Yes ☐ No ☐

Floors, walls and ceilings

4.7. Are the floors in the manufacturing areas made of an impervious and non-absorbent material?

Yes ☐ No ☐

4.8. Are they free from cracks and joints in areas where product is exposed?

Yes ☐ No ☐

4.9. Do drains have trapped gullies and proper ventilation?

Yes ☐ No ☐

4.10. Are any open drainage channels shallow and easy to clean?

Yes ☐ No ☐

4.11. Are walls intact and free of faults and finished with a smooth impervious and easily cleaned material?

Yes ☐ No ☐

4.12. Are windows made of toughened glass or plastic?

Yes ☐ No ☐

4.13. Are there fly screens on windows that open?

Yes ☐ No ☐

4.14. Do window ledges slope away from the glass at an angle to prevent items being placed on them?

Yes ☐ No ☐

4.15. Do doors have smooth, non-absorbent, easy to clean and disinfect surfaces?

Yes ☐ No ☐

4.16. Does the ceiling construction in manufacturing areas prevent the accumulation of dirt / growth of mould / shedding of particles?

Yes ☐ No ☐

Floors, walls and ceilings

4.17. Is there a Site Hygiene Plan?

Yes ☐ No ☐

– If Yes, is this plan regularly reviewed? Yes ☐ No ☐

4.18. Are cleaning products stored in a location that is separate from the processing areas?

Yes ☐ No ☐

4.19. Is production waste collected in clearly identifiable receptacles for removal to specific collection points outside the buildings?

Yes ☐ No ☐

4.20. Is production waste removed from the manufacturing areas throughout the day?

Yes ☐ No ☐

4.21. How often is waste removed from the site?

Daily ☐ Weekly ☐

4.22. Does the disposal of waste comply with EU legislation on waste, as implemented nationally?

Yes ☐ No ☐

4.23. Is all waste disposal appropriately documented?

Yes ☐ No ☐

Receiving and despatch areas

4.24. Do the receiving and despatch areas provide protection from the weather for materials or product in transit?

Yes ☐ No ☐

4.25. Is there a defined deboxing/debagging area for those materials which arrive in external packaging?

Yes ☐ No ☐

Personnel hygiene facilities

4.26. Are the following provided:

– Changing facilities segregated from production area?

Yes ☐ No ☐

– Toilet and hand washing facilities segregated from manufacturing areas?

Yes ☐ No ☐

– Separate accommodation for clothing and footwear not being worn during working hours?

Yes ☐ No ☐

– First Aid facilities and an accident book?

Yes ☐ No ☐

– A rest and refreshment room segregated from production area, for recreation and eating?

Yes ☐ No ☐

4.27. Is the rest and refreshment room the only place where eating or drinking is allowed?

Yes ☐ No ☐

– If No, please specify other areas where eating or drinking is permitted:

.....

4.28. Is the whole site designated non-smoking?

Yes ☐ No ☐

– If No, please specify approved smoking areas:

.....

Pest control

4.29. Is Pest Control practiced? Yes ☐ No ☐

4.30. Is pest control contracted out? Yes ☐ No ☐

– If No, are there appropriate procedures in place for in-house pest control?

Yes ☐ No ☐

4.31. What steps are taken to protect against the entrance and harbouring of vermin, birds, pests and pets in all buildings on site?

.....

.....

Equipment

4.32. Are all surfaces and materials in contact with raw materials and finished product:

– Inert to the raw materials / product? Yes ☐ No ☐

– Microbiologically cleanable, smooth and non-porous?
Yes ☐ No ☐

– In compliance with EU Materials and Articles in Contact with Food legislation?
Yes ☐ No ☐

– Visible for inspection (or equipment is easily dismantled for inspection)?
Yes ☐ No ☐

– Easily dismantled and readily accessible for cleaning?
Yes ☐ No ☐

4.33. Are there detailed cleaning procedures in place for all equipment?
Yes ☐ No ☐

4.34. Is all equipment cleaned and serviced immediately after use?
Yes ☐ No ☐

4.35. Are fumes from power driven equipment, heaters etc. ventilated away from the manufacturing areas?
Yes ☐ No ☐

4.36. Are there maintenance procedures in place for all equipment?
Yes ☐ No ☐

4.37. Is all equipment regularly serviced and calibrated?

Yes ☐ No ☐

– If Yes, are appropriate records maintained?

Yes ☐ No ☐

– Are these regularly checked to ensure calibration is up to date and equipment is working accurately?

Yes ☐ No ☐

4.38. Are there procedures in place outlining the action to be taken in the event of a recognised malfunction of the inspection and testing equipment?

Yes ☐ No ☐

Water supply

4.39. Is the water supply monitored and controlled?

Yes ☐ No ☐

4.40. Is potable water used for all manufacturing purposes?

Yes ☐ No ☐

4.41. Is the water that is used for all manufacturing purposes periodically analysed, where required nationally?

Yes ☐ No ☐ N/A ☐

4.42. Where both potable and non-potable water are used on the premises, are the two water supplies clearly identified and kept separate from each other?

Yes ☐ No ☐

4.43. If the products being manufactured are vulnerable to microbiological contamination, are filtering or disinfection systems installed on the water supply?

Yes ☐ No ☐ N/A ☐

Section 5: Product and Process Development

5.1. Are checks carried out on all new products to establish whether the ingredients and formulation are suitable, safe and legal for all intended markets?

Yes ☐ No ☐

5.2. Are the same checks as above carried out when any significant change is proposed e.g. change of raw material or equipment?

Yes ☐ No ☐

5.3. Has stability been checked (either through actual stability tests or the use of previously confirmed data) and the shelf life correctly determined for:

– All products? Yes ☐ No ☐

– Risk products? Yes ☐ No ☐

5.4. Is shelf life testing a requirement of the product development programme?

Yes ☐ No ☐

5.5. Are proposed labels checked to ensure they conform to all relevant labelling legislation?

Yes ☐ No ☐

5.6. Are all proposed claims checked to ensure they comply with current legislation?

Yes ☐ No ☐

5.7. For all new or revised products, is the appropriateness and legality of the packaging checked to ensure compliance?

Yes ☐ No ☐

5.8. Are all new and revised products checked to ensure that the planned methods and procedures are suitable and that consistent quality products can be produced?

Yes ☐ No ☐

Section 6: Manufacture

6.1. Does each product have:

– A defined and authorised Master Formula?

Yes ☐ No ☐

– Defined and authorised Master Manufacturing Instructions?

Yes ☐ No ☐

– Related Standard Operating Procedures?

Yes ☐ No ☐

6.2. Are all instructions and operating procedures clear and unambiguous and written in the official working language of the manufacturing facility?

Yes ☐ No ☐

6.3. Have appropriate trials been undertaken for each product to confirm that the formulation, methods and procedures specified in the Master Manufacturing Instructions:

– are suitable for factory production? Yes ☐ No ☐

– are capable of consistently yielding products within the Finished Product Specification?

Yes ☐ No ☐

6.4. Are periodic checks undertaken to ensure the Master Manufacturing Instructions are being followed and that they are still applicable and relevant?

Yes ☐ No ☐

6.5. Have the following been developed and brought to the attention of all relevant personnel:

– Written operating procedures for each piece of equipment / instrument?

Yes ☐ No ☐

– Written instructions detailing the action to be taken in the event of stoppages, breakdowns or other unexpected events?

Yes ☐ No ☐

– Formal procedures setting out the action to be taken in the event of foreign body contamination at any stage during the manufacturing process?

Yes ☐ No ☐

Production

6.6. Prior to production commencing, are all materials, bulk containers and major items of equipment to be used indentified (e.g. labelled) with relevant information regarding the product to be processed?

Yes ☐ No ☐

6.7. Does this identification also indicate the stage of manufacture and status, where applicable?

Yes ☐ No ☐

6.8. Does the status label of the manufacturing area and equipment contain information regarding the previous product manufactured and the cleaning status when at rest?

Yes ☐ No ☐

Raw materials

6.9. Are detailed specifications held for all raw materials?

Yes ☐ No ☐

6.10. Are internal identification numbers allocated to all raw materials upon delivery?

Yes ☐ No ☐

6.11. Are the contents of all containers identified?

Yes ☐ No ☐

6.12. Are raw materials entering the premises quarantined until they appropriately checked and a decision made on their status i.e. whether approved or rejected?

Yes ☐ No ☐

6.13. Are all raw material lots (batches) tested?

Yes ☐ No ☐

– If No, specify what proportion are tested?

.....

6.14. Are Certificates of Analysis (CoA) for raw materials checked to confirm compliance with the specifications?

Yes ☐ No ☐

– If Yes, are periodic checks undertaken to verify the quality of the supplier's CoAs?

Yes ☐ No ☐

6.15. Are stocks of raw materials in the storage areas:

– Inspected regularly? Yes ☐ No ☐

– Tested / sampled where appropriate?

Yes ☐ No ☐

6.16. Are the temperature and humidity for storing raw materials controlled and recorded?

Yes ☐ No ☐

– If Yes, what are the tolerances?

.....

6.17. Are there procedures in place for issuing raw materials from store?

Yes ☐ No ☐

6.18. Is correct stock rotation followed when issuing raw materials from store?

Yes ☐ No ☐

6.19. Is there a procedure in place for the reconciliation of the quantities of raw materials issued against the quantity ofproduct manufactured?

Yes ☐ No ☐

Packaging and labelling materials

6.20. Are packaging materials certified for food contact use (i.e. in conformance with current legislation on materials and articles in contact with food)?

Yes ☐ No ☐

6.21. Are all aspects of current national packaging and packaging waste legislation complied with?

Yes ☐ No ☐

6.22. Is there a procedure in place to ensure that changes in product formulation are reflected in the label copy?

Yes ☐ No ☐

6.23. Are internal reference codes allocated to each delivery or lot/batch of packaging material?

Yes ☐ No ☐

6.24. Is packaging material entering the premises quarantined until it is appropriately checked and a decision made on its status i.e. whether approved or rejected?

Yes ☐ No ☐

6.25. Are stocks of packaging materials in store inspected regularly to check their condition?

Yes ☐ No ☐

6.26. Is stock rotation followed when issuing packaging materials from store?

Yes ☐ No ☐

6.27. Are all packaging materials inspected immediately before use?

Yes ☐ No ☐

6.28. Are procedures in place for:

– the issue of packaging materials from store?

Yes ☐ No ☐

– the return of part-used lots of packaging to store?

Yes ☐ No ☐

– the re-sealing of part-used boxes of packaging, to prevent foreign body contamination?

Yes ☐ No ☐

– the reconciliation of all printed packaging component stock from quantity issued, quantity used, wastage and that returned to store?

Yes ☐ No ☐

– the removal and destruction of superseded packaging or labels?

Yes ☐ No ☐

Processing and packaging

6.29. Are multiple packaging lines (where present) segregated to avoid the risk of cross-contamination?

Yes ☐ No ☐ N/A ☐

6.30. Are the following checks always carried out before the start of any process:

– The name and appropriate reference to the product being processed is clearly displayed on each production line?

Yes ☐ No ☐

– The production area is clean and free from any items not relevant to the process to be undertaken?

Yes ☐ No ☐

– The correct materials and documents have been issued?

Yes ☐ No ☐

– The correct machine settings have been made?

Yes ☐ No ☐

– All plant and equipment is clean and ready for use?

Yes ☐ No ☐

6.31. Are in-process conditions monitored (e.g. by sensory, instrumental and / or laboratory testing)

Yes ☐ No ☐

6.32. Are samples analysed:

– During production? Yes ☐ No ☐

– After production? Yes ☐ No ☐

– If Yes, are these samples tested:

In-house ☐

Contract Laboratory? ☐

– Are the samples during production tested according to pre-set specifications?

Yes ☐ No ☐

– Are the samples after production tested according to pre-set specifications?

Yes ☐ No ☐

6.33. Are intermediate products quarantined until checked and approved by Quality Control?

Yes ☐ No ☐

6.34. Are packed finished products quarantined until checked and approved by Quality Control?

Yes ☐ No ☐

6.35. Are there procedures in place for the management of non-conforming products?

Yes ☐ No ☐

Disposal of waste and effluent

6.36. Is the disposal of printed packaging materials, raw materials and reject product appropriately controlled?

Yes ☐ No ☐

6.37. Is a reconciliation carried out on quantities of materials or product used and/or produced against those being disposed of?

Yes ☐ No ☐

6.38. Are all waste materials and effluent disposed of by a route appropriate to the class of material?

Yes ☐ No ☐

Section 7: Recovery or Re-Working of Materials

7.1. Is recovered material quarantined until checked by Quality Control and a disposition decision is made?

Yes ☐ No ☐

7.2. Are there procedures in place for the following to be undertaken on recovered materials:

– Acceptance? Yes ☐ No ☐

– Sampling? Yes ☐ No ☐

– Tests? Yes ☐ No ☐

– Treatments? Yes ☐ No ☐

– Authorisation or rejection? Yes ☐ No ☐

7.3. Is there a system in place to ensure that contaminated materials or product are not recovered, re-worked or re-processed but are destroyed?

Yes ☐ No ☐

7.4. Are there procedures in place to control the use of recovered or reworked materials?

Yes ☐ No ☐

7.5. Are validated methods used for re-processing?

Yes ☐ No ☐

7.6. Are finished products that have been returned from the market assessed and released by Quality Control before consideration is given for re-sale ?

Yes ☐ No ☐

7.7. Is the recovery, re-working or re-processing of materials or products clearly documented and these records retained for a designated period of time?

Yes ☐ No ☐

Section 8: Storage

Access to storage areas

8.1. Is access to material and product storage areas restricted to those working in these areas and to other authorised persons?

Yes ☐ No ☐

8.2. Is there a formal list of persons who are authorised to access these areas?

Yes ☐ No ☐

8.3. Is there a suitable curtain at all entrances and exits of the storage area?

Yes ☐ No ☐

8.4. If the storage area connects to the manufacturing area, is a buffer area/pass box provided between the two areas?

Yes ☐ No ☐

Temperature and lighting

8.5. Is temperature mapping and recording carried out in the storage area(s)?

Yes ☐ No ☐

8.6. Do lighting appliances have shatterproof protective covers?

Yes ☐ No ☐

Materials and product storage

8.7. Is a stock rotation system followed? Yes ☐ No ☐

8.8. Are all aisles in the storage area(s) kept clear?

Yes ☐ No ☐

8.9. Are pallets regularly checked for structural integrity?

Yes ☐ No ☐

8.10. Are packed products stored in conditions necessary for safe storage, appropriate to their specifications?

Yes ☐ No ☐

8.11. Are stored materials and product clearly identifiable, even when stacked?

Yes ☐ No ☐

8.12. Is there a specific quarantine area for material deliveries / product batches awaiting results of testing?

Yes ☐ No ☐

Damaged goods

8.13. Is there a specific holding area for damaged goods, awaiting Quality Control inspection?

Yes ☐ No ☐

Cleaning of storage areas

8.14. Are the storage facilities periodically inspected:

– For cleanliness? Yes ☐ No ☐

– For pest infestation? Yes ☐ No ☐

– To identify stock exceeding its shelf life?

Yes ☐ No ☐

8.15. Are such inspections documented and any corrective actions noted?

Yes ☐ No ☐

8.16. Are there procedures in place for cleaning of the storage premises and equipment?

Yes ☐ No ☐

Section 9: Transport and Distribution

9.1. Are vehicle / container interiors inspected:

– before loading materials / products? Yes ☐ No ☐

– on unloading materials / products? Yes ☐ No ☐

9.2. Do the inspections include checks for the following:

– Cleanliness? Yes ☐ No ☐

– Moisture? Yes ☐ No ☐

– Foreign materials? Yes ☐ No ☐

– Insect or rodent infestations? Yes ☐ No ☐

– Objectionable odours? Yes ☐ No ☐

9.3. Are contaminated vehicles and/or containers kept apart from those that are clean?

Yes ☐ No ☐

9.4. Are security measures in place that:

– Help deter tampering with goods in storage and distribution?

Yes ☐ No ☐

– Show whether any tampering has occurred?

Yes ☐ No ☐

9.5. Is there a written procedure to deal with damages occurring to goods during storage and distribution?

Yes ☐ No ☐

9.6. Are audits carried out on contracted-out transport facilities and procedures, where relevant?

Yes ☐ No ☐

9.7. Are the relevant personnel informed when particular care is needed to reduce large temperature fluctuations during transport and delivery?

Yes ☐ No ☐

9.8. Are fire appliances easily accessible and appropriate for use on the materials / products concerned?

Yes ☐ No ☐

9.9. Are fork lift and other trucks used within the storage areas battery driven or otherwise equipped to prevent fume or fuel contamination?

Yes ☐ No ☐

Section 10: Hazard Analysis Critical Control Points (HACCP)

10.1. Is there a HACCP system in place, as required under EU Regulation (EC) No. 852/2004 on Food Hygiene?

Yes ☐ No ☐

10.2. Have all HACCP team members been trained in how to utilise the HACCP Principles?

Yes ☐ No ☐

10.3. How many of the HACCP team members have received formal HACCP training?

.....

10.4. Has the HACCP system been verified by someone other than the person responsible for the monitoring and corrective actions?

Yes ☐ No ☐

10.5. Is there a procedure in place to ensure the HACCP plan is amended as required if any changes occur, e.g to formulation, supplier, process equipment etc?

Yes ☐ No ☐

10.6. Even if no obvious changes have been made, is your HACCP plan re-assessed at least once a year?

Yes ☐ No ☐

10.7. How regularly is the HACCP standard operating procedure reviewed?

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Section 11: Stability and Shelf Life

11.1. Are the products' shelf lives based on an assessment of relevant data?

Yes ☐ No ☐

11.2. Is this data obtained from:

– An appropriate stability study on the specific product?

Yes ☐ No ☐

– Extrapolation of data from stability studies on similar products?

Yes ☐ No ☐

– Bibliographical references from scientific literature?

Yes ☐ No ☐

– Combinations of the above? Yes ☐ No ☐

11.3. Are overages used to ensure claimed levels are met at the end of shelf life?

Yes ☐ No ☐

If Yes, have these been assessed to ensure:

– The minimum overage required is used?

Yes ☐ No ☐

– The total input amount of ingredient does not exceed any recognised / legally defined upper safe levels?

Yes ☐ No ☐

11.4. Are the appropriate tests undertaken to assess product stability under anticipated environmental storage conditions?

Yes ☐ No ☐

11.5. Is microbiological testing carried out on:

– Products that have a high moisture content?

Yes ☐ No ☐

– Where it is known that raw materials may carry a high microbial load?

Yes ☐ No ☐

– If Yes to the above, does this include 'in use' testing?

Yes ☐ No ☐

11.6. Are the following undertaken:

– Organoleptic assessments? Yes ☐ No ☐

– Physical tests appropriate to the supplement composition and form?

Yes ☐ No ☐

– Chemical tests appropriate to the supplement composition and form?

Yes ☐ No ☐

Section 12: Documentation

12.1. Is there a written procedure covering the complete documentation system?

Yes ☐ No ☐

If Yes, does this include procedures for the:

– Issue of documents? Yes ☐ No ☐

– Authorisation of documents? Yes ☐ No ☐

– Distribution of documents? Yes ☐ No ☐

– Periodic review of documents? Yes ☐ No ☐

– Revision of documents? Yes ☐ No ☐

12.2. Are relevant personnel given appropriate training on how to complete the documents?

Yes ☐ No ☐

– If Yes, is this training regularly reviewed?

Yes ☐ No ☐

12.3. Are there safeguards in place to restrict the entering of data to authorised persons only?

Yes ☐ No ☐

12.4. Are any amendments to documentation clearly corrected and authorised?

Yes ☐ No ☐

12.5. Are superseded documents removed from active use and a copy retained, clearly marked as superseded?

Yes ☐ No ☐

12.6. Has a manual been prepared that describes the overall Quality Assurance system, the procedures employed and the documents used?

Yes ☐ No ☐

If Yes, is this manual:

– Fully integrated with the HACCP documentation?

Yes ☐ No ☐

– Accessible to all relevant personnel? Yes ☐ No ☐

Electronic documentation

12.7. Are there safeguards in place to ensure that:

– Data is entered correctly? Yes ☐ No ☐

– Sufficient back-ups are made and retained?

Yes ☐ No ☐

– Unauthorised access is prevented? Yes ☐ No ☐

12.8. Are there procedures in place outlining the action to be taken in the event of system failure or breakdown?

Yes ☐ No ☐

12.9. How often are all safeguards, back-up systems and procedures checked and updated?

.....

Retention of documents

12.10. In general, for how long are records retained?

.....

12.11. Has it been confirmed that this complies with any legal requirements?

Yes ☐ No ☐

12.12. Are lot (batch) records retained for the shelf life of the product, plus one year?

Yes ☐ No ☐

12.13. Is personnel data retained in accordance with national laws on such data?

Yes ☐ No ☐

12.14. Is a Controlled Records List utilised? Yes ☐ No ☐

12.15. Are there safeguards in place to protect all documentation (both electronic and paper copy) in the event of a fire?

Yes ☐ No ☐

Section 13: Complaints procedure, Product Recall and Emergency Procedure

Complaints

13.1. Are there procedures in place for handling product-related complaints?

Yes ☐ No ☐

13.2. Are personnel appropriately trained to ensure that all complaints are recognised, communicated and recorded?

Yes ☐ No ☐

13.3. Are complaints, when received, assessed and separated into those with no potential health impact and those that may have a health impact?

Yes ☐ No ☐

13.4. Is the Quality Control Manager kept fully informed and closely consulted on all complaints relating solely to manufacturing issues?

Yes ☐ No ☐

13.5. Is there a procedure in place for handling complaints specifically related to adverse events?

Yes ☐ No ☐

– If Yes, is there a designated person who is responsible for implementing and monitoring this procedure?

Yes ☐ No ☐

13.6. Is complaint analysis carried out at periodic intervals?

Yes ☐ No ☐

– If Yes, at what frequency?

.....

13.7. Are summaries of complaints and / or trends sent to key senior personnel?

Yes ☐ No ☐

Product withdrawal and recall

13.8. Are there procedures in place for:

– product withdrawal? Yes ☐ No ☐

– product recall? Yes ☐ No ☐

13.9. Is there a nominated, responsible person and nominated deputies to co-ordinate recall activities?

Yes ☐ No ☐

13.10. Has a crisis management team been established?

Yes ☐ No ☐

13.11. Has the withdrawal/recall system been tested?

Yes ☐ No ☐

13.12. Are there procedures in place regarding the proper treatment of withdrawn or recalled material or product?

Yes ☐ No ☐

Emergency procedure

13.13. Are there procedures in place for responding to emergencies?

Yes ☐ No ☐

Section 14: Self-inspections

14.1. Is there a prearranged programme for self-inspections of all systems?

Yes ☐ No ☐

– If Yes, how frequently are these conducted:

.....

14.2. Are records made of all:

– Observations? Yes ☐ No ☐

– Corrective measures? Yes ☐ No ☐

– The subsequent action taken? Yes ☐ No ☐

14.3. Are the self-inspections periodically reviewed by senior management?

Yes ☐ No ☐

Section 15: Sub-Contracting operations

15.1. Is your company a Contract Giver? Yes ☐ No ☐

If Yes, please go to question 15.3.

15.2. Is your company a Contract Acceptor? Yes ☐ No ☐

If Yes, please go to question 15.4.

15.3. Contract Giver:

a) Is there a programme for auditing the key suppliers i.e. those who supply 'risk' materials?

Yes ☐ No ☐

b) Are all suppliers assessed by means of:

– A site audit? Yes ☐ No ☐

– A self-assessment form? Yes ☐ No ☐

c) Are detailed product specifications agreed with every supplier?

Yes ☐ No ☐

d) Are any special quality control / GMP requirements agreed with every supplier?

Yes ☐ No ☐

e) Is there a technical agreement in place with every supplier?

Yes ☐ No ☐

15.4. Contract Acceptor:

a) Are detailed product specifications agreed with every customer?

Yes ☐ No ☐

b) Are any special quality control / GMP requirements agreed with every customer?

Yes ☐ No ☐

c) Is there a technical agreement in place with every customer?

Yes ☐ No ☐

Section 16: Laboratory Testing

16.1. Is there an in-house company laboratory?

– If No, please go to question 16.5.

– If Yes, is the laboratory accredited? Yes ☐ No ☐

– If Yes, please specify:

.....

16.2. Is all laboratory equipment and instrumentation regularly serviced and calibrated?

Yes ☐ No ☐

– If Yes, are appropriate records maintained?

Yes ☐ No ☐

16.3. Are there written operating procedures for each piece of equipment / instrument?

Yes ☐ No ☐

16.4. Is there adequate storage space for storage of samples at the appropriate temperature?

Yes ☐ No ☐

16.5. Does your company use a contract laboratory?

Yes ☐ No ☐

– If Yes, is the laboratory accredited? Yes ☐ No ☐

16.6. Does the laboratory use appropriate analytical methods?

– In-house laboratory Yes ☐ No ☐ N/A ☐

– Contract laboratory Yes ☐ No ☐ N/A ☐

16.7. Is the performance of the laboratory monitored and analysed?

– In-house laboratory Yes ☐ No ☐ N/A ☐

– Contract laboratory Yes ☐ No ☐ N/A ☐

Declaration

To the best of my knowledge and belief, the details given above are correct.

Signed ..... Date .....

Name .....

Position within company .....

The European food supplement sector brings together many of the most innovative and dynamic companies in the food area, making a substantial contribution to Europe's public health goals.

Food Supplements Europe combines the unique expertise of associations and companies committed to building partnership with regulatory, scientific and consumer bodies to help shape the future regulatory and policy framework in this area and to ensure that consumers can benefit from safe and high quality products.

food supplements europe

International Non-Profit Organisation

Rue de l'Association 50
1000 Brussels

Tel: +32 2 209 11 51
Fax: +32 2 219 73 42
secretariat@foodsupplementseurope.org
www.foodsupplementseurope.org