EHPM QUALITY GUIDE CHECKLIST FOOD SAFETY

Self-Evaluation/Audit Checklist for Food Supplement Manufacturers

This checklist has been developed by the EHPM quality working group. It combines work carried out by EHPM various national associations in developing national best practice in the area of quality. The EHPM Quality Guide cover the various aspects of ensuring the production of high quality and safe dietary food supplements. This checklist is intended to assist companies in measuring their own performance against the standards set out in the EHPM quality guide and identifying areas for improvement. It has been designed so that it can be used both by a company itself or if preferred by an independent auditor. As European and national legislative requirements are constantly evolving, it is crucial that the European food supplement industry pioneers the development of best practice and works with regulators to ensure high quality products are delivered to consumers.

Checklist Layout

1. Food Safety Management System

1.1 General Requirements			
Is there a self-audit system in place to guarantee food safety based on the HACCP principles?	Yes	No	Comments:
Are the elements of the company's food safety management system supported by documents?	Yes	No	Comments:
Have the elements of the company's food safety management system been implemented?	Yes	No	Comments:
Are the elements of the company's food safety management system applied at all times?	Yes	No	Comments:
Are the elements of the company's food safety management system reviewed regularly?	Yes	No	Comments:
1.2 Food Safety Policy			
Does the company have a clear, succinct and documented food safety policy?	Yes	No	Comments:
1.3 Food Safety Manual			
Does the company have a food safety manual (quality manual)?	Yes	No	Comments:
1.4 Responsibility of company management (operator)			
Is there a company organisation chart (roles, qualifications, deputies)?	Yes	No	Comments:
Have tasks/responsibilities/competences been established?	Yes	No	Comments:

1.5 Commitment of company management (operator)			
Does the management team work to develop and improve the management system with regard to food safety (date of last update)?	Yes	No	Comments:
1.6 Review by company management (including HACCP plan)			
Is the food safety management system regularly reviewed by senior management?	Yes	No	Comments:
1.7 Management of material/human resources and information			
Are all of the necessary material and human resources and information provided by senior management?	Yes	No	Comments:
Are all of these material and human resources and this information provided in good time by senior management?	Yes	No	Comments:
1.8 General requirements regarding documentation			
Is the system put in place for document management satisfactory?	Yes	No	Comments:
1.9 Specifications			
Have specifications been drawn up for finished products?	Yes	No	Comments:
1.10 Procedures			
Are all of the procedures necessary for demonstrating compliance with legislation in place?	Yes	No	Comments:
Are all of the procedures necessary for demonstrating product safety compliance in place?	Yes	No	Comments:
1.11 Internal audit and internal control			
Is the procedure for carrying out internal audits satisfactory?	Yes	No	Comments:

1.12 Corrective action			
Is the procedure in place for implementing corrective measures satisfactory?	Yes	No	Comments:
1.13 Checking of nonconformities			
Does the company ensure that any products that do not meet requirements are clearly identified and checked to prevent accidental use or delivery?	Yes	No	Comments:
1.14 Product Release			
Does the company have a product release procedure in place that ensures that the product is not released unless all of the specific requirements have been met?	Yes	No	Comments:
1.15 Purchasing			
Does the goods-in inspection procedure guarantee that purchased products comply with specifications?	Yes	No	Comments:
1.16 Monitoring of supplier services			
Is there a list of suppliers?	Yes	No	Comments:
Is the supplier evaluation procedure satisfactory (criteria, warnings, recall measures)?	Yes	No	Comments:
1.17 Traceability			
Does the operator have systems or procedures for recording incoming products (type, identification and quantity of product, date of receipt and identification of the originating establishment)?	Yes	No	Comments:
Does the operator have systems or procedures for recording outgoing products (type, identification and quantity of product, delivery date and identification of the destination establishment)?	Yes	No	Comments:
Does the operator have systems or procedures for establishing relationships between incoming and outgoing products?	Yes	No	Comments:

Are products that have been reworked identified again?	Yes	No	Comments:
1.18 Complaint Handling			
Is the complaints management system satisfactory?	Yes	No	Comments:
1.19 Product Recall & Returns			
Does the company have a system for recalls and returns?	Yes	No	Comments:
Does the company have a system for handling recalled products and returns?	Yes	No	Comments:
1.20 Inspection of measuring and monitoring equipment			
Does the company have procedures in place for calibrating equipment used for measurements relating to food safety?	Yes	No	Comments:
1.21 Product Analysis			
Does the company have a system for taking the samples required by law?	Yes	No	Comments:
Does the company have an appropriate procedure in place for performing or outsourcing the relevant raw material analyses in preparation for confirming the safety of the product?	Yes	No	Comments:
Does the company have an appropriate procedure in place for performing or outsourcing the relevant finished product analyses in preparation for confirming the safety of the product?	Yes	No	Comments:
1.22 Mandatory Notification(s)			
Can you provide proof that the mandatory notifications to the relevant authorities when placing food supplement products on the market in accordance with Directive 2002/46/EC on foo food supplements have been carried out?	Yes	No	Comments:
Does your company have systems in place to ensure that the relevant authorities are notified immediately as required by law in the event of non-conformities being discovered for products that have been placed on the market?	Yes	No	Comments:

1.23 Approvals (Where Relevant)			
Can the authorisation(s) provided for by the law be for the manufacturing of food supplements at your premise(s) be produced?	Yes	No	Comments:
Are all the manufacturing activities carried out at your premises covered by the authorisation(s) you have received from the relevant national authorities?	Yes	No	Comments:
If your country applies an approval system for the placing of food supplement products on the market, can you provide the relevant approval certifications for all products?	Yes	No	Comments:
1.24 Labelling			
Do the goods have the required labels?	Yes	No	Comments:
Do the labels include the required information?	Yes	No	Comments:

2. Good Manufacturing & Distribution Practices

2.1 Company Environment			
Is the company situated in a clean environment to prevent any contamination and enable safe products to be produced?	Yes	No	Comments:
2.2 Environment of buildings			
Are the undeveloped areas of the site on which the company's buildings are constructed well maintained?	Yes	No	Comments:
2.3 Layout and product flow			
Is the layout designed in such a way as to manage the risk of product cross-contamination?	Yes	No	Comments:
2.4 Layout of premises (handling of raw materials, manufacture, processing, packing, packaging and warehouses)			
Are the premises organised in such a way that is suitable for their intended use?	Yes	No	Comments:
2.5 Equipment			
Is the type of equipment used suitable for ensuring the safety of the products?	Yes	No	Comments:
Is the equipment installed in such a way that cleaning and disinfection work can be done all around the equipment?	Yes	No	Comments:
2.6 Maintenance			
Is there a maintenance system in place for all of the equipment components that may affect the safety of the products?	Yes	No	Comments:
2.7 Social Areas			
Does the layout of social areas guarantee the safety of the products?	Yes	No	Comments:

2.8 Risk of physical, chemical and (micro)biological contamination of the product			
Are the necessary procedures in place to manage the risks of physical, chemical or (micro) biological product contamination?	Yes	No	Comments:
Are temperature requirements met at all times?	Yes	No	Comments:
2.9 Separation and cross-contamination			
Are the necessary procedures in place for managing the risk of cross-contamination?	Yes	No	Comments:
2.10 Stock Management (rotation)			
Are the necessary procedures in place to ensure that the oldest raw materials, packaging materials and finished products or those nearing their expiry date are used first?	Yes	No	Comments
Are the necessary procedures in place to ensure that raw materials, packaging materials and finished products are used in accordance with their use-by dates?	Yes	No	Comments:
2.11 Housekeeping, cleaning and hygiene			
Are appropriate rules regarding upkeep followed at all times?	Yes	No	Comments:
Are appropriate rules regarding cleaning followed at all times?	Yes	No	Comments:
Are appropriate rules regarding hygiene followed at all times?	Yes	No	Comments:
Does the company carry out visual cleaning and disinfection inspections?	Yes	No	Comments:
2.12 Water Quality Management			
Is the quality of water that comes into contact with food regularly checked and is it of "drinking water" quality?	Yes	No	Comments:

2.13 Waste Management			
Are there adequate systems in place for collecting, storing and disposing of waste?	Yes	No	Comments:
Is waste management within the company satisfactory?	Yes	No	Comments:
2.14 Pest Control			
Does the company have a system in place for managing or preventing pests on the site or in the establishment?	Yes	No	Comments:
2.15 Use of pesticides, herbicides and fungicides			
Is waste management within the company satisfactory?	Yes	No	Comments:
2.15 Transport			
Are general transport requirements met?	Yes	No	Comments:
Are all of the vehicles used to transport raw materials (including packaging material), semi-finished products and finished products fit for purpose?	Yes	No	Comments:
Are all of the vehicles used to transport raw materials (including packaging material), semi-finished products and finished products properly maintained?	Yes	No	Comments:
Are all of the vehicles used to transport raw materials (including packaging material), semi-finished products and finished products cleaned in accordance with legal requirements?	Yes	No	Comments:
Are specific requirements regarding tanker transport met?	Yes	No	Comments:
2.16 Personal hygiene, protective clothing and medical examination			
Does the company have documented rules relating to hygiene and management of product contamination risks and are personnel familiar with these rules?	Yes	No	Comments:

2.17 Training			
Does the company have a system for ensuring that all workers are properly trained, receive correct instructions and are subject to surveillance with regard to food safety?	Yes	No	Comments:
2.18 Checks on behalf of Third Parties			
Does the company comply with legislation that has to be checked on behalf of third parties?	Yes	No	Comments:

3. Hazard Analysis & Critical Control Points (HACCP)

3.1 Composition of the HACCP team			
Is there sufficient knowledge and experience specific to the products to be able to draw up an effective HACCP plan?	Yes	No	Comments:
Has the scope of the HACCP plan been described?	Yes	No	Comments:
Does this description indicate which segments of the food production industry are affected?	Yes	No	Comments:
Does it indicate to which general risk categories attention needs to be paid?	Yes	No	Comments:
3.2 Product Description			
Has a full description of the product been produced, including in particular the relevant safety information?	Yes	No	Comments:
3.3 Identification of Intended Use			
Does the intended use take into account how the end user or consumer can normally be expected to use the product?	Yes	No	Comments:
3.4 Establishment of a production process diagram			
Have all of the stages been included in the diagram?	Yes	No	Comments:
At each stage of the process, are the relationships between the previous and following stages taken into account?	Yes	No	Comments:
3.5 On-site confirmation of the diagram			
Has the HACCP team compared the manufacturing process with the diagram at every stage?	Yes	No	Comments:

Has the diagram been adapted where necessary?	Yes	No	Comments:
3.6 Establishment of a list of all of the possible hazards at each stage, performance of a risk analysis and consideration of measures designed to manage the hazards identified (HACCP principle 1)			
Has the HACCP team drawn up a list of all of the hazards it feels may reasonably occur at each stage?	Yes	No	Comments:
Has a note been made of those hazards identified that must be prevented, removed or reduced to an acceptable level to produce safe foodstuffs?	Yes	No	Comments:
3. 7. Identification of critical control points (HACCP principle 2)			
Has it been indicated at which stages of the process these hazards must be prevented, removed or reduced to an acceptable level?	Yes	No	Comments:
3.8 Setting of critical limits (HACCP principle 3)			
Have these limits been approved?	Yes	No	Comments:
3.9 Creation of a monitoring system for each CCP (HACCP principle 4)			
For each CCP, is there a programmed monitoring system in place concerning the critical limits so that it is immediately clear if a CCP is not being controlled?	Yes	No	Comments:
Can the system correct the loss of control before it exceeds the limits set?	Yes	No	Comments:
3.10 Corrective measures (HACCP principle 5)			
Have corrective measures specific to each CCP been established in the HACCP system to ensure that any deviations beyond the limits can be put right?	Yes	No	Comments:
3.11 Verification procedures (HACCP principle 6)			
Have procedures been put in place to check the system?	Yes	No	Comments:

3.12 Compilation of documentation and record keeping (HACCP principle 7)			
Are the HACCP procedures supported by documents and records?	Yes	No	Comments:
Are these documents and records appropriate to the nature and the scope of the process?	Yes	No	Comments:
3.13 Sampling and analysis plans			
Have sampling and analysis plans been established (where necessary) to ensure the validity of the self-audit system?	Yes	No	Comments: