Sub-Contractor Questionnaire

Introduction:

This questionnaire 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 the performance of their sub-contractors 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.

Questionnaire Layout

1. Company Description

1.1 - Company			
Company Name			
Country			
Address			
Telephone Number			
Fax Number			
Email			
Website			
Focal Point (person)			
Position in the Company			
Production Site Location	Urban Areas		
	Extra Urban Areas		
Place of Origin of raw materials (ingredients)	EU (Please list countries and relative % share)	1. 2. 3. 4.	_____ % _____ % _____ % _____ %
	Outside of EU (Please list countries and relative %)	1. 2. 3. 4.	_____ % _____ % _____ % _____ %

1.2 Organisation (General)	
Please provide an organogram (if available). Please provide precise answers to the following:	
1) What is the total number of employees and the organizational structure within the company including the names of the key management figures?	Answer:
2) How is the Quality Control (QC) unit organised and how many employees does it have?	Answer:
3) How is the Quality Assurance unit organised and how many employees does it have?	Answer:
4) How is the Research and Development (R&D) unit organised (if it exists) and how many employees does it have?	Answer:
5) How many employees work in the production process?	Answer:
6) How many employees work in logistics?	Answer:

Leading Officials:			
Please provides the details of the official responsible for activities listed below			
	Name	Phone	Email
Sales			
Production			
Logistics/Warehouse			
Purchasing			
Quality Control (QC)			
Quality Assurance			
Research & Development			
Claims & Recall			

Other Information:			
What is the legal form of the company?			
Total Turnover (over last 3 years)?			
Does the company participate in a holding?			
When was your company founded?			
Do you allow us to perform a supplier audit of your company?		Yes	No
Do you have subsidiaries in your company organisation?		Yes	No
If YES, please list the names and location (city and nation) of any subsidiaries			
Is any part of the production process designated to local business (for the national market)?		Yes	No
If YES, please specify the percentage			_____%
What percentage of production is designated for export?			_____%
If exporting, please list the main export destinations (continental areas and countries)			1. 2. 3. 4.
Is part of your production private label?		Yes	No
Are new ingredients submitted or a preliminary evaluation by the national authorities before being placed on the market?		Yes	No
Is technical assistance available for customers?		Yes	No
What is the minimum and maximum time for delivery of products?		Minimum:	Maximum:

Company Activity Profile		
Type of activity:	Production	Packaging or repackaging
	Warehousing	Distribution
Is there a general description of the company's areas of activity available? Please enclose or specify below.		

Which categories of materials does your company sell?		
Cosmetics Pharmaceutical		
Which categories of materials/products does your company deal with or sell for nutritional or supplementation purposes?		
Vitamins	Enzymes	Fish oil
Minerals	Amino acids	Vegetable oil
Botanicals extracts	Fibres	Milk and dairy ingredients
Probiotics	Additives	Starch, carragenins, cellulose
Others (please specify)		Gelatine and collagen
		Eggs and its derivatives
Do you allow us to receive on request a short description of all manufacturing processes and of your production methods (techniques)?		Yes No
Is any part of your process sub-contracted? If Yes, please provide a brief description		Yes No

Location	
What are the site(s) for production / warehousing / re-packaging? _____ _____ _____	
Does the company have authorisation for production/warehousing/re-packaging officially recognised or provided by the relevant local authority or national ministry? If Yes, please specify:	Yes No

2. Quality Management

2.1 General Requirements	
Does the company have a food safety manual (quality manual)?	Yes No

The following are some general requirements concerning quality management that all sub-contractors are required to conform with. Please read carefully and then confirm your company's compliance with these requirements by ticking the appropriate box:

- All dietary supplements are manufactured, packaged, labelled and warehoused by persons who are duly qualified, as a result of their studies, professional training or experience, to carry out the tasks assigned to them.
- Management must undertake to:
  - Provide relevant and ongoing training in food hygiene and the best practice applicable to dietary supplements to each person recruited, including seasonal or temporary staff, with the emphasis on the practices that apply to the person's position, as required by regulations. Personnel must be familiar with the manufacturing stages of the products and how their work affects product quality. Refresher training must be given as often as is necessary. This training also concerns quality control managers, the management team and any persons present on the site and/or involved in manufacturing, such as office staff, maintenance workers and cleaning teams.
  - Provide relevant training in procedures, record keeping and registrations.
- Monitoring, handling and/or requirements for training must be adapted to the work of employees in contact with food and to those working nearby whose activity may affect food safety (what is relevant for certain activities is not necessary relevant for others).
- Personnel are informed about the issues of cross contamination:
  - Knowledge of the procedures for avoiding contact between toxic chemicals and the dietary supplement. e.g. cleaning products
  - Knowledge of the procedures for limiting the risk of foreign bodies. e.g. glass or metal
- In addition to the training provided to employees involved in production and quality control, appropriate training must be given to anybody present on the site and/or involved in manufacturing, such as maintenance personnel and cleaning teams.
- Training is planned and a record kept for each employee.
- The people providing the training are qualified.

Do you confirm that your company complies with the general quality management requirements listed above?	Yes No

2.2 Internal Audit Programme	
Is there an internal audit programme for the various departments?	Yes No
Is a written report produced after each audit?	Yes No
If Yes, is the report written using a specific report format provided by the quality assurance department?	Yes No
Does the internal audit programme cover at least the following? - hygiene, - traceability, - HACCP,	Yes No

- batch recall and withdrawal test	
Are internal audits conducted regularly by authorised persons from within the company or by third-party auditors that are sufficiently well qualified to assess compliance with quality requirements?	Yes No

2.3 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
2.4 Mandatory Notification	
Is the mandatory notification provided for in the self-audit system?	Yes No
2.5 Labelling	
Do the goods have the required labels?	Yes No
Do the labels include the required information?	Yes No
Are the specific requirements with regard to the labelling of dietary supplements met?	Yes No
2.6 Traceability	
Do you have a documented system for traceability?	Yes No
2.7 Raw Materials	
If you are a distributor, do you have a standard procedure for the qualification of your supplier of raw materials distributed?	Yes No
If Yes, please specify the method used:	Audit Questionnaire Other (Please specify):_____ _____ _____ _____
If you are a manufacturer, do you have a standard procedure for the qualification of your suppliers?	Yes No
If Yes, please specify the method used:	□ Audit □ Questionnaire □ Other (Please specify):_____ _____ _____ _____
Product Recall & Complaints	
Do you have a standard procedure for the recall of products?	Yes No
Do you have a standard procedure for processing complaints?	Yes No

3. Quality Control

3.1 Quality Control	
Are all the specifications of the raw materials freely available to us, included under a controller system and promptly available any time for your customer?	Yes No
For each batch delivered, will you provide us a full certificate of analysis in advance or accompanying the product/raw material? Please attach an example of a certificate of analysis	Yes No
Do you have a leading official responsible (qualified person) for approval of materials and for the release of products? If yes, please specify qualification and position within your company: _____	Yes No
Do you have a standard procedure for qualification of each machinery, installation and manufacturing equipment?	Yes No
Do you have a standard procedure for validation of manufacturing processes?	Yes No
Do you have in-process control?	Yes No
Do you check and retain reference samples (according to statistical sampling procedures) of finished products at the end of each batch production?	Yes No
Do you have a technical dossier for each product that is open to personnel reporting all technical characteristics of the product and description of the manufacturing steps including instructions for personnel about machinery, rate of production, effectiveness of the process, checking points to operate.	Yes No
Do you have a batch record for every batch, undersigned and dated, reporting rate of production, registration of production steps, registration of control and release by the qualified person?	Yes No
If Yes, are batch records kept under controlled access?	Yes No
If Yes, how long do you retain batch records? _____	
If Yes, how long do you retain reference samples? _____	
If Yes, does the distributor have access to the batch records retained by the producer?	Yes No
Does your company declare that different batches of the same ingredient will not be delivered to us?	Yes No
Do you accept that you may only deviate from this after obtaining written consent from our QA Manager	Yes No
Do you have a standard procedures system in place to prevent cross-contamination among different batches of the same ingredient/or among different products/ingredients	Yes No
If Yes, please provide a brief description or ad the Standard Operating Procedure _____ _____ _____	

_____ _____	
Is there a complete Certification of packaging material?	Yes No
Are you willing to provide us with a copy of your certificate of packaging?	Yes No
Are Methods of Analysis (MoA) used to check the quality of any product/ingredient you deal with? : Please ticks the boxes below where you apply the particular MoA:	Yes No
- Physical and Chemical Characteristics	PF (Product) RM (Raw Material)
- Assay (Standardization)	PF (Product) RM (Raw Material)
- Microbiological profile	PF (Product) RM (Raw Material)
- Any contaminant (including impurity)	PF (Product) RM (Raw Material)
- Heavy metal	PF (Product) RM (Raw Material)
Do you agree to retain for 1 year after the expiry date of products you supply to us, documentation concerning quality control (including methods, calculation, registration, results, Certificates of Analysis undersigned by the quality control manager)? Yes No	
Do you agree to provide us with all analytical methods (in full text and not only abstract) on request?	Yes No
Do you have an internal quality lab? If Yes, please list and specify which MoAs are done internally _____ _____	Yes No
Do you sub-contract your analytical control to an independent Quality Lab? If Yes, please specify the name/s and add the certification of the lab/s? _____ _____ _____	Yes No

4. Legislation

4.1 Legislation		
Do you belong to any kind of local or international association that guarantees you receive constant updates on legislative developments? If Yes please specify: _____	Yes	No
Does your company deliver only products/ingredients that conform to the relevant EU legislation concerning contaminants such as: Aflatoxin Residual Solvent Pesticides PAHs (poly-aromatic hydrocarbons, i.e. benzopyrene) Others (please list): _____	Yes Yes Yes Yes Yes Yes	No No No No No No
Does your company supply only products that do not contain only non-genetically modified ingredients?	Yes	No
If your company provides products containing GMO ingredients, do you taken responsibility for ensuring the relevant indications confirming the presence of GMO ingredients are provided on labelling (Regulations 1829/2003 and 1830/2003)?	Yes	No
In instances where we have agreed that you will only supply products containing no GMO ingredients, do you accept that you may only deviate from this agreement after obtaining prior written consent from our Quality Assurance manager?	Yes	No
Will you confirm that, if products are used which contain doping agents, these will be specified on the Technical Data Sheet or on the Certificate of Analysis, provided in advance or along with the material? See also World Anti-Doping Agency (WADA) See also www.wada-ama.org and www.necedo.nl	Yes	No
Does your company only deliver animal derived components (like organs, organ extracts or gelatine) provided with a written BSE/TSE-free statement and free of risk of contamination by non-conventional virus?	Yes	No
Does your company deliver allergen-free products/ingredients (according to Regulation (EC) No 1169/2011 on food information to consumers and Regulation (EU) No 828/2014 for gluten free food and according to your national regulations)	Yes	No
Does your company deliver only products/ingredients routinely checked for their microbiological profile? The results should be detailed on the Certificate of Analysis of the batch concerned.	Yes	No
Does your company deliver only products that are regularly checked for heavy metal content? The results should be detailed on the Certificate of Analysis of the batch concerned.	Yes	No

5. Premises

5.1 Premises	
Does the company have in place an air conditioning system? If Yes please provide details on the system in place: _____ _____	Yes No
Does the company have in place an air filtering/treatment system? If Yes please provide details on the system in place: _____ _____	Yes No
Does the company have a pest control system in place as required by legislation	Yes No

6. Standard Operating Procedures (SOP)

6.1 Standard Operating Procedures (SOP)	
Do you have a SOP for retaining all quality documentation under a controlled access system?	Yes No
Are all SOPs available for employees	Yes No
Do you perform self-inspection on a regular basis (timing planning) and by authorised and qualified personnel?	Yes No
Do you retain records of checks done after ordinary or extraordinary maintenance?	Yes No
Do you have written job descriptions describing the required qualifications and training needed for each job?	Yes No
Are there written job descriptions for each leading position within the organisation?	Yes No
Do you have a standard procedure system for cleaning and sanification of floors, walls, rooms and machinery?	Yes No
Do you record all cleaning and sanitizing activity in a specific model form?	Yes No
Do you have specific registration instrument to keep under control temperature/humidity condition parameters of the ambient and the process of manufacturing?	Yes No
Do you have a SOP for testing the stability of raw materials?	Yes No
Do you have a SOP for the receipt, testing and release applied to materials on its arrival and your premises?	Yes No
Do you have a SOP for the reception and identification of goods (raw materials)?	Yes No
Do you have a standard identification system for machinery?	Yes No
Do you have a standard maintenance system for machinery?	Yes No

Do you have a standard identification system for recipients?	Yes No
Do you have SOPs and controls in place to prevent cross contamination?	Yes No
Do you follow First Expired First Out (FEFO) for materials in stock?	Yes No
Do you have a control system in place for the expiration date, retest date, and shelf life of ingredients?	Yes No
Do you have a SOP in place for calibration?	Yes No
Do you have a pest control programme in place? If Yes, is it supplied by internal personnel or an external contractor? Internal External (if it is performed by an external contractor, please provide the name and address) _____ _____	Yes No
Does the warehouse have separate and clearly identified areas for Approved, Quarantined and Rejected products?	Yes No
Please add a brief description of "Quarantine". _____ _____	
Do you have a computer system in place?	Yes No
Is there appropriate security to limit the access to computerised systems, protect records from tampering and prevent data alteration by ID (name and user name) and password?	Yes No
Which system or activities are subject to computerised control? _____ _____ _____ _____	
Do you perform a backup of data? If Yes, please indicate frequency _____	Yes No
Do you have a SOP for non-conformity?	Yes No
Do you have a Change Control Programme (Change Management)?	Yes No
Do you have SOPs for preventive and corrective actions? Is there an adequate system described in the SOP, for controlling changes to methods, documents, and equipment, and requiring evaluation of need for re-qualification or re-validation?	Yes No
Do you have standard procedure for qualification of freight of goods? If Yes, please add the SOP or a brief description _____	Yes No

7. Hazard Analysis and Critical Control Point (HACCP) Management

7.1 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
Has the scope of the HACCP plan been described?	Yes No
Does this description indicate which segments of the food production industry are affected?	Yes No
Does it indicate to which general risk categories attention needs to be paid?	Yes No
7.2 Product Description	
Has a full description of the product been produced, including in particular the relevant safety information?	Yes No
7.3 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
7.4 Establishment of a production process diagram	
Have all of the stages been included in the diagram?	Yes No
At each stage of the process, are the relationships between the previous and following stages taken into account?	Yes No
7.5 On-site confirmation of the diagram	
Has the HACCP team compared the manufacturing process with the diagram at every stage?	Yes No
Has the diagram been adapted where necessary?	Yes No
7.6 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
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
7. 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
7.8 Setting of critical limits (HACCP principle 3)	
Have these limits been approved?	
7.9 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
Can the system correct the loss of control before it exceeds the limits set?	Yes No
7.10 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
7.11 Verification procedures (HACCP principle 6)	
Have procedures been put in place to check the system?	Yes No

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