
Recommendations

**Good manufacturing standards
for food supplements**

November
2018

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1. PURPOSE AND SCOPE OF APPLICATION

The purpose of this document is to provide technical indications that meet the specific needs of the industries that produce food supplements with regard to the correct application of good manufacturing practices (GMP).

The definition of this document originates from the specific characteristics of this sector. In this regard, it should be taken into account that the basic ingredients that can be used in a food supplement are varied and include: vitamins and minerals, essential or polyunsaturated fatty acids, fibre, plant extracts, probiotics and prebiotics, and other substances with a nutritive or physiological effect.

The ministerial guidelines on food supplements, published on the Ministry portal (www.salute.gov.it), define the minimum and maximum allowances of vitamins and minerals, the criteria for the use of probiotics and prebiotics, and the (non-exhaustive) list of other substances with a nutritive or physiological effect that are suitable for use, at the relevant conditions where applicable.

The use of plant substances and preparations, so-called "botanicals", is instead governed by (It.) Ministerial Decree, 9 July 2012, which from 9 January 2019 will be repealed and replaced by (It.) Ministerial Decree 10 August 2018.

It being understood that substances without a significant consumption history are configured as novel foods, according to regulation (EU) 2015/2283, and therefore cannot be used in supplements if not after possible authorization at European level pursuant to the aforementioned regulation.

This document has been prepared in accordance with current national and EU legislation on food hygiene and in particular to facilitate the harmonization and application of the so-called Prerequisite Programs (PRP) as set out in the *Commission Communication (2016/C 278/01) on the implementation of food safety management systems relating to prerequisite programs (PRP) and procedures based on the principles of the HACCP system, including implementation facilitation/flexibility in certain food businesses*.

DEFINITIONS

Accredia (official site <https://www.accredia.it>)

Single national accreditation body, recognized by the State with Decree of 22 December 2009.

Accreditation (Regulation 765/2008/EC)

Certification by a national accreditation body certifying that a specific conformity assessment body meets the criteria established by harmonized standards and, where appropriate, any other additional requirements, including those defined in the relevant sectoral programs, to carry out specific conformity assessment.

Food (Regulation 178/2002/EC Article 2)

"Food" (or "foodstuff") shall mean any substance or product that has been processed, partially processed or unprocessed, intended to be ingested, or reasonably expected to be ingested, by humans. This includes drinks, chewing gum and any substance, including water, intentionally incorporated into food during their production, preparation or processing.

It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directive 80/778/EEC and 98/83/EC.

The following are not included:

- a) feed;
- b) live animals unless they are prepared for placing on the market for human consumption;
- c) plants prior to harvesting;
- d) medicinal products within the meaning of Council Directives 65/ 65/EEC (1) and 92/73/EEC;
- e) cosmetics within the meaning of Council Directive 76/768/EEC;
- f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
- g) narcotic or psychotropic substances within the meaning of United Nations Single Convention on Narcotic Drugs of 1961 and the United Nations Convention on Psychotropic Substances of 1971;
- h) residues and contaminants.
- i) medical devices in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council

Accuracy (EURACHEM Guide/CITAC CG 4 - 2nd Edition - 2000)

Degree of agreement between the result of a measurement and the true value of the measurand.

Allergen (UNI EN 15633-1 2009)

Antigen with special properties to induce an allergic reaction.

Competent authority (Regulation 852/2004/EC article 2, paragraph 1, letter d)

Central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country.

Corrective action (UNI EN ISO 9000:2005)

Establish corrective actions when monitoring indicates that a critical control point is not under control.

Purchase specification

Document containing the characteristics of the raw materials/ingredients/materials.

Packaging (Regulation 852/2004/EC Article 2, paragraph 1, letter j)

Placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself (primary packaging).

Secondary packaging

Placement of a foodstuff in containers that contain the primary packaging (e.g. cases for bottles).

Control (Codex Alimentarius CAC/RCP 1-1969 Rev.4-2003)

Correct implementation of an operation or a procedure in the manner envisaged.

Validation (Commission Communication 2016/C278/01)

Acquisition of evidence related to a control measure able to manage the danger in order to achieve a certain result

Disinfection (Codex Alimentarius CAC/RCP 1-1969 Rev.4-2003)

The reduction by chemical agents and/or physical methods, of the number of micro-organisms in the environment at a level that does not compromise the integrity or wholesomeness of food.

First In First Out (FIFO)

Procedures related to the handling of the material in a warehouse for which the material stored for a long time is used before the same material stored for a shorter time.

First Expire, First Out (FEFO)

Procedures for material handling in a warehouse whereby a material with a shorter expiration date is used before the same material with a longer expiration date.

GHP (good hygiene practices) and GMP (good manufacturing practice) (Commission Communication 2016/C278/01)

Collection of procedures to guarantee the safety of foodstuff produced. GHPs refer to the hygienic aspects of production.

The GMPs refer to the implemented work methods.

Hazard analysis and critical control point (HACCP) (Codex Alimentarius CAC/RCP 1-1969 Rev.4-2003; Regulation 852/2004/EC article 5)

System that identifies, assesses, monitors the risks that are significant for food safety.

Food hygiene(Regulation 852/2004/EC Article 2, paragraph 1, letter a)

The measures and conditions necessary for monitoring hazards and ensuring the suitability for human consumption of a food product taking into account the intended use.

Food business: (Regulation 178/2002/EC Article 3, paragraph 2)

Every public or private, profit or non-profit party, which carries out any of the activities connected to one of the phases of production, transformation and distribution of food.

Ingredients (Regulation 1169/2011/EC article 2, paragraph 2, letter f)

Any substance or product including flavourings, food additives and enzymes, and any constituent of a compound ingredient used in the manufacture or preparation of a food and still present in the finished product, even if in a modified form; the residues are not considered as ingredients.

Critical limit (Regulation 852/04/EC Article 5, paragraph 2, letter c)

Value or range of values, at critical control points, which separate acceptability from unacceptability for the prevention, elimination or reduction of identified risks.

Production batch (Directive 2011/91/EU)

Unit of sales of a foodstuff produced, manufactured or packaged under virtually identical circumstances.

Good practice manuals (Regulation 852/04/EC)

Tool to help food business operators comply with hygiene standards at all levels of the food chain and in applying the principles of the HACCP system.

Preventive or control measures (Codex Alimentarius CAC/RCP 1-1969 Rev.4-2003)

Actions and activities that can be taken to prevent or eliminate a risk to the foodstuff or reduce it to an acceptable level.

Monitoring (Regulation 882/2004/EC Article 2, point 8)

Conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with food law.

Non-compliance (EN ISO 9001: 2008 point 8.3)

Non-fulfilment of a requirement, specified in the law, regulations, or system documents, specifications, contracts.

Food business operator (FBO) (Regulation 178/2002 / EC Article 3, point 3)

The natural or legal person responsible for ensuring compliance with the provisions of food law in the food business placed under his/her control.

Organization chart

The organization chart is the formalization of structures, units and departments and briefly describes functions, tasks and hierarchical relationships existing within a given organizational structure.

Danger or hazard element (Regulation 178/2002/EC Article 3, point 14)

Biological, chemical or physical agent contained in a food or feed, or condition in which a food or feed is found, capable of causing a harmful effect on health.

HACCP Plan (Codex Alimentarius CAC/RCP 1-1969 Rev. 4-2003; Regulation 852/2004/EC Article 5)

Document, possibly in electronic format, which provides a complete description of the procedures based on the HACCP system. The HACCP plan is updated in case of production changes and supplemented with the records of the results of the monitoring and the audit and with the corrective actions taken.

Precision (EURACHEM Guide/CITAC CG 4 - 2nd Edition - 2000)

Degree of agreement between independent test results obtained under the established conditions.

Prerequisites Programs (PRP) (State-Regions Agreement 13 January 2015; UNI EN ISO 22000:2005)

Development, implementation and documentation of procedures that control the operating conditions in an establishment. The main procedures concern cleaning and disinfection (GHP) and good manufacturing practices (GMP) together with the structural and behavioural conditions of the operators.

Operational PRP (State-Regions Agreement January 13, 2015, UNI EN ISO 22000:2005)

Point in the production process, identified by the hazard analysis as essential to control the likelihood of introducing food safety hazards and where the risk to food safety is lower than a CCP.

Critical Control Point (CCP) (Codex Alimentarius CAC/RCP 1-1969 Rev.4-2003)

A phase of the production process in which the control can be put in place and is essential to prevent, eliminate or reduce to an acceptable level a danger to food safety.

Quarantine

State of isolation of raw materials/ingredients/materials pending the results of the controls envisaged by the business.

Quality Control Manager (QCM)

Graduate professional responsible for Quality Control and all phases of the production process.

Complaint

Communication concerning a reservation regarding the characteristics, quality, status of an ingredient/ product.

Effective yield

Quantity actually produced at any manufacturing or packaging stage.

Theoretical yield

Quantity that would be produced at each stage of manufacturing or packaging of a particular product, based on the quantity of ingredients or packaging to be used without considering losses or errors in actual production.

Product recall (Official Journal 294 of 12/19/2005)

Any measure of withdrawal of the product also addressed to the final consumer, to be implemented when other measures are insufficient to achieve a high level of health protection.

Traceability (Regulation 178/2002/EC)

Ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

Risk (Regulation 178/2002/EC Article 3, point 9)

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

Withdrawal of the product (Official Journal 294 of 12/19/2005)

Any measure, by the operator or by the competent authority, aimed at preventing the distribution and supply to the consumer of a product that does not comply with food safety requirements.

Plant substance and preparation (Guidelines on the documentation supporting the use of plant substances and preparations [botanicals] in food supplements as per (It.) Ministerial Decree of 9 July 2012)

Shall mean: a plant ingredient or the "plant drug" or the whole plant or its parts (whole, pieces or cut) in untreated form, generally dried; a plant preparation obtained by subjecting the plant ingredient to various processes (for example: extraction, distillation, pressing, fractionation, purification, concentration, fermentation, grinding and pulverizing).

Establishment (Regulation 852/2004/EC Article 2, paragraph c).

Each unit of a business in the food sector.

Calibration (ISO/IEC 17000)

The operation used to determine, within known limits of precision, the law of correspondence between the indications of the instrument and the values of the quantity that the instrument must measure.

Validation (UNI CEI EN ISO/IEC 17025:2005)

Confirmation through examination and contribution of objective evidence, that the particular requirements for the intended use are satisfied.

2. REGULATIONS

(It.) Legislative Decree no. 111 of 27 January 1992 concerning foodstuffs intended for particular nutritional uses.

(It.) Presidential Decree no.131 of 19 January 1998 Regulation on the implementation of regulations of (It.) Legislative Decree no. 111 of 27 January 1992 concerning foodstuffs for particular nutritional uses.

(It.) Legislative Decree no. 169 of 21 May 2004 implementation of Directive 2002/46/EEC concerning food supplements.

(It.) Legislative Decree no. 31 of 2 February 2001 implementation of Directive 98/83/EEC concerning the quality of water intended for human consumption.

Regulation (EC) no. 852/2004 of the European Parliament and of the Council of 29/4/2004 and subsequent amendments, on the hygiene of food products.

Regulation (EC) no. 853/2004 of the European Parliament and of the Council dated 29/4/2004 and subsequent amendments, which establishes specific rules on hygiene for food of animal origin.

Regulation (EC) no. 854/2004 of the European Parliament and of the Council of 29/4/2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

Regulation (EC) no. 178/2002 of the European Parliament and of the Council, dated 28/2/2002 which establishes the general requirements of food law, establishes the European Food Safety Authority and establishes procedures in the field of food safety.

Ministry of Health Decree of 23 February 2006 Technical requirements and general criteria for the qualification for the production and packaging of food supplements.

Regulation (EC) no. 1924/2006 of the European Parliament and Council of 20/12/2006 (and subsequent amendments) concerning nutrition and health indications provided on food products.

Regulation (EC) no. 1925/2006 of the European Parliament and of the Council of 20/12/2006 on the addition of vitamins and minerals and of certain other substances to foods.

(It.) Legislative Decree no. 109 of 27 January 1992 implementation of directives no. 89/395/EEC no. 89/396/EEC on the labelling, presentation and advertising of foodstuffs.

Agreement of 29 April 2010 Agreement between the Government, the regions and the autonomous provinces related to "Guidelines for the application of Regulation no. 852/2004 EC of the European Parliament and of the Council on the hygiene of food products".

Regulation (EU) no. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

Regulation (EU) 2015/2283 on new foods

Agreement 8 July 2010 Agreement established by the State-Regions Conference (no. 78/CSR) on the document concerning the operating procedures for recording, updating, deletion from the regional lists of laboratories and procedures for the execution of uniform inspections for the conformity assessment of laboratories.

Health Ministry Decree of 9 July 2012 "Discipline for the use in food supplements of herbal substances and preparations".

Health Ministry Decree of 27 March 2014 update of Ministerial Decree of 9 July 2012 which defines plants and their derivatives that can be used in the sector of food supplements, in addition to specific labelling rules.

(It.) Legislative Decree no. 158 of 13 September 2012 Setting forth "urgent provisions to promote the development of the country through a higher level of health protection".

(It.) Legislative Decree no. 189 of 8 November 2012 Conversion into law, with amendments, of the (It.) Decree Law of 13 September 2012, no. 158, containing urgent provisions to promote the development of the country through a higher level of health protection.

Permanent Conference for Relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano of 7 May 2015 "Guidelines for the official control of laboratories carrying out analyses in the area of self-control of food businesses".

UNI CEI EN ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories".

Regulation (EC) 882/2004 of the European Parliament and of the Council of 29/4/2004 on official controls intended to verify compliance with feed and food law and the rules on health and animal welfare.

UNI EN ISO 7218 rev. May 2014 Food and Feed Microbiology - General Requirements and Guidance for microbiological analysis.

(It.) Presidential Decree no. 254 of 15 July 2003 Regulations concerning the management of sanitary waste according to article 24 of (It.) Law 31 July 2002, no. 179.

(It.) Legislative Decree no. 152 of 3 April 2006 Environmental regulations.

UNI EN ISO 22000: 2005 Food safety management systems. Requirements for any organization in the food supply chain.

COMMISSION COMMUNICATION, EU Official Journal (2016/C 278/01)

on the implementation of food safety management systems relating to prerequisite programs (PRP) and procedures based on the principles of the HACCP system, including implementation facilitation/flexibility in certain food businesses.

3. FOOD SAFETY MANAGEMENT SYSTEM *

The food safety management system (Food Safety Management System - FSMS) means "*an interdisciplinary system of prevention, preparation and self-control activities for the management of food safety and hygiene in a food business*". It must therefore be considered as a practical tool for controlling the environment and the production process in order to guarantee food safety.

The system includes:

- good hygiene practices (GHP) and good manufacturing practices (GMP) which together are called Prerequisite Programs (PRP);
- the procedures based on the HACCP system;
- traceability and recall systems.

Also the compliance with regulation (EC) no.178/2002 is a fundamental requirement of an FSMS.

*Prerequisite Programs (PRP) ***

They are part of the FSMS system and include, in addition to GHP and GMP, all other correct operating practices to obtain optimal conditions in order to ensure safe production.

PRPs are the basis for effective implementation of the HACCP system and should be implemented before the realisation of any procedure of the HACCP plan is implemented.

4. STRUCTURES, AREAS AND WATER SUPPLY

The establishment must be located in an area where there is no pollution or unhealthy conditions that may compromise the characteristics of the finished product.

The FBO must have a plan of the establishment to be updated in case of structural changes.

4.1. Production areas***

All processing must be carried out in the production and packaging areas.

The premises must be in number and size proportional to the expected production activity, in order to allow all the operational phases to be carried out in compliance with all the hygiene conditions.

In particular, the production and packaging areas must be designed, constructed and arranged in such a way as to ensure unidirectional production flow and to allow adequate maintenance and cleaning and/or disinfection and to avoid or minimize contamination transmitted by air and to prevent contamination between and during the various processing operations.

*COMMISSION COMMUNICATION, EU Official Journal (2016/C 278/01) *on the implementation of food safety management systems relating to prerequisite programs (PRP) and procedures based on the principles of the HACCP system, including implementation facilitation/flexibility in certain food businesses.*

** ISO 22000: 2005 on Food Safety Management Systems

*** Regulation (EC) No. 852/2004 Annex II - Chapter I: General requirements applicable to facilities for food art. 1 and art. 2 paragraphs a) b) c) d), points 5,6,7,8; Chapter II: specific requirements applicable to premises where foodstuffs are prepared, processed or transformed.

The premises also must:

- be subjected to periodic maintenance to ensure the continuation of adequate hygienic conditions;
- be constructed in such a way as to prevent the accumulation of dirt and the formation of condensation or mould on the raised surfaces, above all in the ceilings and/or in the inner part of the roof;

- be provided with an adequate ventilation system. The mechanical ventilation systems must be such as to allow easy access to the filters and other parts subject to cleaning and maintenance. The natural ventilation systems must have windows and other openings to the outside provided with suitable protection systems (against pests) that can be removed to allow cleaning;
- have adequate natural and/or artificial lighting;
- be equipped with floors made of durable, non-absorbent, washable, non-toxic material, continuous or without breakages, non-slip;
- with easy to clean walls and, if necessary, to be disinfected, made of resistant, non-absorbent washable, non-toxic material with a smooth surface up to a suitable height;
- be fitted with lights equipped with appropriate explosion protection;
- be fitted with non-absorbent smooth surface doors, possibly fitted with automatic opening and closing systems to avoid contact contamination;
- to have non-potable water pipes (fire fighting, refrigeration and other similar cases), if they are present in separate production areas, not connected to each other and easily identifiable*.

Discharge systems must be suitable for the purpose, as well as designed and constructed to avoid the risk of contamination by preventing the flow travelling from a contaminated area to a clean food handling area (e.g. siphoned drains).

4.2. Storage areas**

The storage areas for raw materials/ingredients/materials/finished products must be located in rooms or dedicated areas in order to ensure easy identification of the dedicated spaces.

In the case of establishments that carry out, in addition to the production of supplements, also different productions, such as for example other foods, the areas destined to storage, even coexisting in a single room, must be suitably identifiable.

The areas must be of a proportional size to the activities carried out, easy to clean and disinfect and equipped with suitable equipment for the storage of goods, with temperature and humidity such as to ensure their proper preservation. Where necessary, adequate temperature-controlled storage facilities must be available, designed so that the temperature can be controlled and, where appropriate, recorded.

These premises must be organized in such a way as to ensure appropriate controls on raw materials and finished products with the related storage methods. For the resulting non-compliant products, appropriate management methods must be provided.

* Regulation (EC) No. 852/2004 Annex II - Chapter VII: Water supply.

**Regulation (EC) No. 852/2004 Annex II - Chapter I: General requirements applicable to facilities for food art. 1 and art. 2 paragraph d).

4.3. Waste management*

The establishment must have at least one area destined for the storage of waste similar to urban waste and an area reserved for special or toxic waste to be disposed of according to specific regulations**.

The waste must be stored in appropriate identifiable containers and kept in good hygienic conditions. Where appropriate, the person responsible for disposal operations and collection/removal procedures should be specified.

4.4. Water supply***

Each establishment must have an adequate hot and/or cold water supply.

The water used as a component in the formulations and/or used in the cleaning of equipment and systems, must meet the drinking water requirements provided for by (It.) Legislative Decree 31/2001 and subsequent updates.

Water can come from public supplies and/or self-supply (e.g. corporate well).

In the second case, the business is subject to the obligations deriving from being a water service manager pursuant to (It.) Legislative Decree no. 31/2001, in particular regarding the treatments necessary to make it compliant with drinking water requirements and to make it suitable for the uses envisaged in the establishment. Drinking water may be collected, before its use, in storage tanks connected to a distribution circuit, provided that the storage conditions do not jeopardize compliance with the potability requirements.

The company is required to perform systematic checks at the various establishment collection points in order to verify compliance with the potability requirements through chemical, chemical/physical and microbiological checks. The methods (sampling points, sampling techniques), the frequencies of the checks carried out and the relative records (results of the checks) must be reported in the HACCP plan; the related recordings must be kept.

Specific procedures must be provided for the correct management of the water treatment plant and for the periodic calibration of any measurement equipment.

* Regulation (EC) No. 852/2004 Annex II - Chapter VI: Food waste

** (It.) Presidential Decree 15 July 2003 no. 254; (It.) Legislative Decree of 3 April 2006 no. 152 "Environmental regulations"

*** Regulation (EC) No. 852/2004 Annex II - Chapter VII: Water supply

5. EQUIPMENT AND MACHINERY *

The equipment must be quantitatively and qualitatively capable of ensuring the planned production. The equipment and tools used in the various stages of processing must be:

- designed in such a way as to facilitate cleaning;
- made with a material suitable to prevent deterioration, in particular, for parts in direct contact with food components or products, as well as non-toxic, in compliance with the regulations in force for materials in direct contact with foodstuffs;
- built to withstand the conditions of the environment in which they are used, the action of cleaning products and sanitizing agents.

The equipment and tools must be dismantled, if necessary, for maintenance, cleaning and sanitization. Disassembled and not immediately used parts, as well as tools, must be stored in such a way as to prevent contamination, for example kept in closed clean plastic bags.

The cold rooms and refrigerators must be equipped with a thermometer or a temperature recording device that indicates and records, or allows the temperature inside the compartment to be accurately recorded by hand and must also be equipped with an alarm system.

The measuring instruments (e.g. scales, autoclave thermometers and stoves) must be of an appropriate number, calibrated and checked.

Maintenance and calibration operations must be carried out and recorded according to prescriptive procedures.

The registration documentation must include:

- the identification code of the equipment or of the instrument;
- the date of execution of the operations;
- the reference material used in calibration operations;
- the data and the relative outcome of the maintenance and calibration activities carried out;
- The name of the operator who performed the operation;

All documentation concerning the maintenance and calibration of instruments must be carefully stored.

6. PERSONNEL

6.1. Organization chart

The business must report in an organization chart the organizational structure identifying the specific functions performed by the staff.

6.2. Quality Control Manager (QCM)**

The Manager of Quality Control in food supplement production establishments and for all the stages of the production process must hold a degree in biology, chemistry, chemistry and pharmaceutical technology, pharmacy, medicine, science and food technology.

* Regulation (EC) No. 852/2004 Annex II - Chapter V: Requirements applicable to equipment

**Legislative Decree 111/92 article 10 paragraph 5.

Quality Control Manager: *

- develops and updates self-control plans;
- ensures that production is carried out in accordance with good hygiene practice and in accordance with the HACCP plan prepared;
- defines and implements appropriate procedures regarding the purchase, acceptance and traceability of raw materials and packaging;
- monitors the general conditions of hygiene and efficiency of the establishment;
- prepares and updates production records;
- informs the competent health authority for the territory, as well as the owner of the establishment, of any substantial irregularity detected, as well as any substantial change in relation to the activities carried out regarding the machinery, plants and analyses performed;
- take part in the inspections prepared by the competent health authority for the territory, or by other supervisory authorities;
- communicates, for the purposes of supervision, to the competent health authority for the territory, if different productions coexist, the production schedules;
- verifies compliance with the current regulations of production batches on the basis of the results of the checks carried out.

The QCM must be formed and properly updated.

6.3. Training **

The FBO must assess the education and training needs of the personnel involved in the production and packaging operations. To ensure this, the FBO must plan training activities and periodically verify their effectiveness taking into account the specific tasks performed by the employee.

Staff training must include at least the following topics:

- notions of food hygiene;
- HACCP principles;
- GMP and GHP principles;
- notions of occupational safety;
- specific information related to the tasks assigned, including tool and machinery cleaning and sanitation operations.

A distinction can be made between general hygiene training (intended for all employees) and specific HACCP training for employees who handle and manage CCPs. Training should be commensurate with the nature and size of the business**.

The Quality Control Manager prepares and manages the training activities.

*Ministry of Health Decree of 23 February 2006 - Technical requirements and general criteria for the qualification for the production and packaging of food supplements.

**Regulation (EC) No. 852/2004 Annex II - Chapter XII: Training; Commission Communication, (EU) 216/ C 278/278/01)

7. PRODUCTION

7.1. Providers

The raw materials necessary for production must comply with the specifications of purchase data to suppliers in which the FBO establishes the hygienic-sanitary characteristics and any other additional parameters.

The FBO must select suppliers through the adoption of an effective system of evaluation of the same with criteria and methods codified in a procedure. The list of selected suppliers must be updated or amended if necessary.

The above procedure must also include actions to be taken against a supplier who delivers material detected as non-compliant.

7.2. Description of the production process

The phases of the production process (Figure 1) can be summarized as follows:

- receipt, acceptance of raw materials/ingredients/materials and delivery to the goods warehouse (*Phase 1*);
- sampling of raw materials/ingredients/materials; (*Phase 2*);
- production and packaging of solid/liquid products (*Phase 3*);
- sending of the finished product to distribution (*phase 4*);
- storage of finished products and exit from the establishment (*Phase 5*).

As regards the presence of allergens, they represent a danger and therefore should be considered part of the FSMS system.

The FBOs must identify the type of allergens pertinent for a given product.

The prevention strategy can be based on two criteria:

- avoid their presence in the production areas on the basis of the guarantees given by the suppliers of raw materials and various ingredients;
- carefully monitor the production process to avoid cross-contamination, through specific operating procedures and also through appropriate information to production workers.

Reception phase (Phase 1)

In the reception and acceptance phase of raw materials/ingredients/materials, the following must be carried out:

- a) perform a visual inspection of the packaging to check for any damage to the packages, verify through the transport document whether the delivery of the goods has taken place correctly (with respect to the expected delivery time) and, in the case of refrigerated products, compliance with the temperatures envisaged;
- b) verify, through the accompanying goods documentation, the correspondence to what is reported in the relative purchase specifications;
- c) send the goods, which are compliant in the reception phase, to the raw materials/ingredients/materials storage area.

Storage in storage areas is a static phase in which raw materials, semi-finished products and packaging materials must be well preserved, the handling of the stored material must take place ensuring an adequate system of use/selection of raw materials according to the "First in First Out "(FIFO) and" First Expire, First Out "(FEFO) method, where the material stored for a long time must be used earlier

than the one stored for the shortest time; the expiry must also be taken into account when sending raw materials with a shorter expiry period to production.

The areas must have temperature and humidity such as to guarantee the correct preservation of the products. If necessary, adequate monitoring of these parameters must be ensured by providing preferably automatic alarm devices.

The goods must be stored in an orderly manner and not placed directly on the floor and against the walls.

A label/data sheet showing the following information must be affixed on all incoming goods:

- product identification;
- weight of the package;
- batch number;
- receipt and expiry date.

Sampling phase (Phase 2)

Sampling must be performed in a way that ensures the quality of data relating to analytical investigations to be carried out on raw materials and/or finished products.

In the event of any detected non-conformity, adequate management measures must be ensured in order to avoid the marketing of non-compliant batches.

Production and packaging phase (Phase 3)

This phase must take place in specially equipped areas and in compliance with the provisions of the prerequisite programs (PRP).

Establishment storage/exit phase (Phase 4)

Approved batches must be sent to the finished products warehouse.

The FBO must prepare a procedure in which the methods of exit from the establishment of the compliant batches and the relative recording criteria are defined (documentation certifying the date and/or exit of the batch from the establishment).

In addition a procedure must be prepared in which the methods, place and time of preservation of the samples relative to each batch of finished product are defined.

Non-compliant products

For non-compliant batches there must be a procedure for the management of non-compliance with the corrective actions to be taken to avoid the recurrence of the detected irregularity.

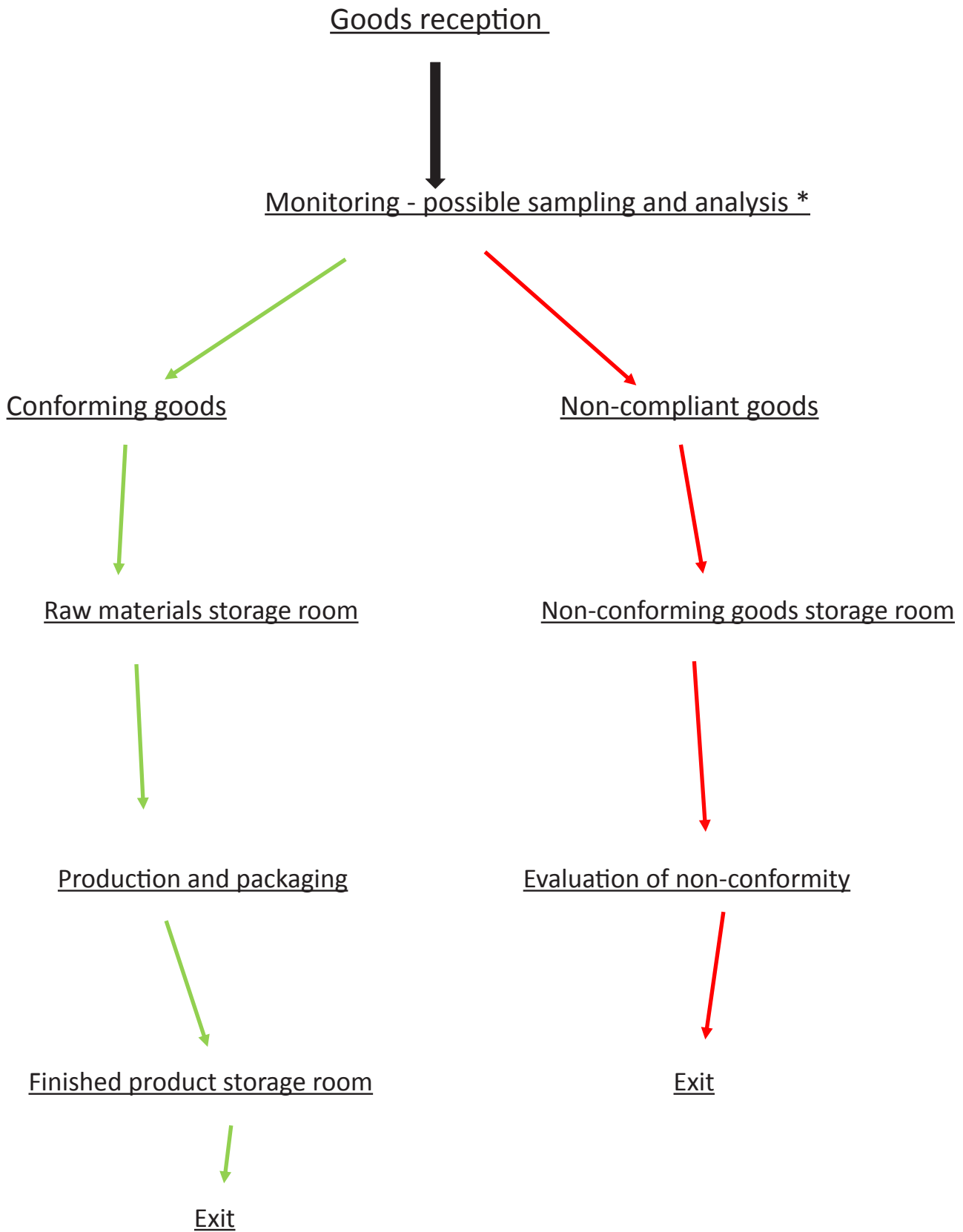
7.3. Batch, traceability, withdrawal and recall management procedures.

The FBO must ensure the traceability and the implementation of efficient withdrawal/recall* systems that prevent the circulation of non-complying batches.

The FBO must prepare specific procedures for handling complaints to verify the reasons and grounds for taking appropriate corrective actions.

* Regulation (EC) no. 178/2002.

Figure 1. Example of the organization of production activities



***In accordance with what is provided in the self-control plan**

8. HACCP*

HACCP (*Hazard Analysis of Critical Control Points*) means the systematic approach to the identification, assessment and control of the hazards and risks associated to each phase of the production, distribution and administration of food and beverages and the definition of the tools for their control.

The HACCP system is based on the identification, evaluation and monitoring of critical control points of the entire production cycle.

Before applying HACCP-based procedures, the FBO must implement the prerequisite programs (PRP).

The Prerequisite Programs (PRP) are part of the food safety management system (FSMS) and include, in addition to GHP and GMP, all other correct operating practices to obtain optimal conditions in order to ensure safe production.

The PRP represent the basis upon which an effective HACCP system is established.

HACCP-based procedures are established on seven principles:

1. Identify any danger in order to prevent it, eliminate it or reduce it to acceptable levels (hazard analysis).
2. Identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a risk or to reduce it to acceptable levels.
3. Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified risks.
4. Establish and implement effective monitoring procedures at critical control points.
5. Establish the corrective actions to be taken when monitoring indicates that a specific critical point is not under control.
6. Establish the procedures, to be applied regularly, to verify that the measures outlined in principles 1) to 5) are working effectively.
7. Prepare documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in principles 1) to 6).

If an important change occurs in the formulation of the product, in the production process or in any other phase of production, the system must be updated.

When preparing a HACCP plan, the manuals of good hygiene practices approved and available for your own product sector can also be used as a reference.

* Regulation (EC) No. 852/2004; Commission Communication, (EU) 216/ C 278/01-ann. II

9.1 Descriptions of the phases of the HACCP process (Ann. 2 chapter 3 of C278/01)

The phases of the HACCP) can be summarized as follows:

- 9.1.1 group formation;
- 9.1.2 description of the product;
- 9.1.3 identification of the intended use;
- 9.1.4 construction of the flow chart (description of the manufacturing process) (Fig. 1);
- 9.1.5 list of the hazards;
- 9.1.6 determination of the CCP;
- 9.1.7 determination of critical limits for each CCP;
- 9.1.8 determination of a surveillance system for each CCP;
- 9.1.9 corrective actions;
- 9.1.10 audit/validation procedures
- 9.1.11 documentation and records

9.1.1.Group formation (Ann. 2-3.1 of C278/01)

The working group has a multidisciplinary nature, it must plan, make operational and verify the correct application of the self-control system set up according to the principles established by the FSMS and the HACCP. The group must be composed of experts and technicians competent both on the specific characteristics of the product and on the different phases of the production process. The group should act with the support of the company executives who are responsible for both the FSMS and the HACCP.

9.1.2.Description of the product (Ann. 2-3.2 of C278/01)

A complete description must be made of the ingredients and the final composition as well as the type of food supplement to be produced (see annex).

9.1.3.Identification of the intended use (Ann. 2-3.3 of C278/01)

The intended use of the supplement must be indicated according to the use by vulnerable groups of the population.

9.1.4.Implementation of the flow chart (description of the production process) (Ann. 2-3.4 of C278/01)

A flow chart should be prepared that includes all the phases of the production process, from reception of raw materials to the placing on the market of the product.

Once this diagram has been drawn up, the HACCP group should ascertain its correspondence on site during plant operation.

9.1.5.List of hazards* (Ann. 2-4.1 of C278/01)

All the chemical, physical and biological hazards that can potentially be present in the different production phases from raw materials to the finished product must be identified and listed. The HACCP group, through appropriate control measures, must manage potential dangers to identify those to be eliminated or reduced to acceptable levels.

*EC Regulation no.178/2002 art. 3, paragraph 4

Many control measures are contained in the PRPs (GHP and GMP). The control measures must be validated and supported by specific procedures in order to guarantee their applicability and effectiveness.

Among the hazards should be included the assessment of any inadvertent presence of allergens.

9.1.6.Determination of CCP (Ann. 2 Chapter 5 of C278/01)

Critical Control Points (CCP) must be identified, if present.

To this end, it is necessary to carry out a hazard analysis and identify which of these can cause a risk that requires its elimination or reduction to acceptable levels.

The following is required to identify a CCP:

- Identify the hazards for all phases of the production process by examining the flow chart.
- Verify the presence of control measures and establish the critical limits to be complied with.
- Establish the corrective actions to be taken should the critical limits are exceeded.

A useful tool for the identification and management of CCPs is represented by decision flowcharts in which the answers to the questions concerning the management of hazards on the entire production process are provided in sequence (appendix 3 A-B of C278/01)

For the phases of the production cycle not identified as CCP and corresponding to low and intermediate levels of risk, the following applies, in the first case compliance with the provisions of the PRP and, in the second case, to the so-called operational PRPs.

9.1.7.Determination of critical limits for each CCP (Ann. 2 Chap. 6 of C278/01)

For each CCP the critical limits must be specified, which define the acceptability or unacceptability of observable and measurable parameters such as temperature, time, humidity, pH, chemical contaminants, biological etc. that can demonstrate that the critical point is under control. Critical limits must be validated and have clear and specific values.

9.1.8.Determination of a monitoring system for each CCP (monitoring) (Ann. 2 Chap.7 of C278/01)

The monitoring procedure must be able to identify any differences at a CCP in order to undertake the appropriate corrective actions and to maintain control of the process.

The corrective actions and instructions given must both be documented.

It is essential that procedures are available to manage any problems related to the supplements produced. It is also necessary that there is also a procedure for the management of those supplements which may be produced during the period of time in which a CCP was out of control.

The methods the frequency of measurements/observations and the recording procedure for CCP monitoring must be reported in the HACCP plan.

Specification of the personnel responsible for carrying out such measurements is required.

9.1.9.Corrective Actions (Ann. 2 Chap.8 of C278/01)

The corrective actions must be planned in advance by the HACCP group in order to be adopted promptly in case of critical limit anomalies.

Corrective actions must identify:

- those responsible for applying the corrective measure;
- the method to correct the detected irregularity;
- how the manufactured products are managed during the time period in which a CCP was out of control;
- the record data sheet containing all the measures taken, including date, time, responsibility and subsequent audit inspection.

If several corrective actions are frequently applied for the same procedure, a review of the whole control process must be carried out.

9.1.10. Audit or validation procedures (Ann. 2, Chap. 9 of C278/01)

The audit or validation procedures mean the set of procedures implemented by the HACCP group, with a fixed frequency, in order to verify the correct operation of the system.

The audit/validation procedures are based on:

- audit of the procedures of the entire HACCP system;
- inspection of production operations;
- confirmation that the CCP monitoring system is valid and functioning
- examination of the anomalies verified with the relative corrective actions taken;

The audit is implemented through:

- evaluation of recording systems and anomalies found;
- checks on the monitoring managers of the various production stages;
- monitoring of the process being monitored;
- calibration of the instruments used for monitoring.

The audit operations should be performed by personnel other than those performing the monitoring. If this task cannot be entrusted to internal staff, the business can contact qualified external experts. The audit/validation procedure must also be changed in the event of changes to the HACCP process (for example change in raw materials, use of the product, use of new machinery, etc.).

Validation: the validation tests are suitable to demonstrate that the control measures examined (PRP, operational PRP, CCP) are suitable. These tests must be carried out before starting a production process or changing it.

Monitoring: is carried out in real time at the point of the production flow in which the control measure is applied.

Audit: this activity is carried out periodically in order to demonstrate that the desired aim has been achieved.

9.1.11. Documentation and records (Ann. II, chapter 10 of C278/01)

The documentation and records must be appropriate to the nature and extent of the activities performed. They must be under the control of the QCM and kept beyond the expiry date of the product for the purposes of traceability, as well as to allow the supervisory authorities to carry out Audit operations and the QCM to periodically review the procedures.

The records represent a very important tool for the auditing of the FSMS applied by the business and must be adapted to the production characteristics according to the provisions of Annex III of C278/01 regarding the flexibility in the application of the FSMS in relation to the nature and size of the establishment.

The flexibility evaluation cannot disregard the assessment of the hazards "*which justify, on the basis of the risk, the reason for which it be necessary not to consider CCPs and that shows that the PRPs are sufficient to control the hazards.*"

For more information, refer to the provisions of Annex III of C278/01.

10. ANALYSIS LABORATORIES

Food supplement producers must use a laboratory for analytical investigations.

The analysis laboratories can be internal or external to the establishment; it is the right of the company, which has an internal analysis laboratory, to entrust the performance of one or more tests to an external laboratory in compliance with the provisions of the law.

10.1. Internal analysis laboratory

Internal establishment laboratories that perform analyses for the purposes of self-control are not expressly required, at present, to be accredited to the standard UNI CEI EN ISO/IEC 17025. In any case, these laboratories must ensure the quality of the tests carried out as part of the self-control activities, taking into account the requirements of the aforementioned technical standard.

In addition to management, the functions and responsibilities relating to the technical-administrative sector and the analytical sector must be defined.

The workflow within the laboratory must be outlined in accordance with the following sequence:

- sampling: sample collection and transport, recording, documentation management;
- sample management: receipt of sample and related documentation, subdivision in rates, preservation, transfer to departments and/or other laboratories;
- analytical tests: sample management, documentation management and related activities (calibration, validation of methods, quality control);
- management of the test report and issue of conformity opinion
- archiving.

The laboratory must be suitable from a structural point of view in relation to the activities performed. The environmental conditions within the analytical sections must be adequate for the correct storage and preparation of the samples and for carrying out the analytical determinations, ensuring the due operation of the instruments as well as the safety of the operators. To this end, without prejudice to specific requirements for the different types of controls within the analytical sections, the existence of adequately separated areas, according to a rational workflow, related to the following activities must be ensured:

- sample preservation (freezing refrigerators, etc.)
- weighed on scales,
- sample preparation;
- management of reagents/materials (areas equipped with cabinets, refrigerators and freezers compliant with the law);
- documentation management (administrative activity, archiving of analytical data);
- glassware processing and conditioning;
- analytical and instrumental determinations (microbiological/chemical/chemical-physical analyses);
- management of waste similar to urban waste and toxic waste according to regulations*.

The lighting and environmental conditions must be such as to facilitate the execution of the analyses. The laboratory must monitor, control and record environmental conditions, especially when they could compromise the results of the analyses.

In relation to the type and number of analyses carried out, the laboratory must provide for the division into sectors for which the structure and environmental requirements are adequate for the correct operation of the activity and such as to guarantee the quality of the results produced.

Specific attention must be paid when sampling and analysis activities are carried out in places other than the laboratory location.

The microbiology laboratory must include an area for the preparation of culture media, an area for the sterilization of said soils, an area for the execution of analyses equipped with a suitable laminar flow hood and incubator, an area for the sterilization of infected material and for the disposal of waste.

The laboratory must also be equipped with continuous worktops which can be washed and disinfected easily.

The use of precise procedures in particular for the transportation and disposal of contaminated materials (culture media, syringes, etc.) and for the maintenance of laminar flow hoods and autoclaves must be ensured.

The chemical laboratory must use instrumentation and materials suitable for the purpose of the controls, must provide for the division into different areas based on the different activities performed and the instrumental techniques used. An adequate separation of the sections is required where analytical determination takes place from the sample and storage preparation areas.

The chemical laboratory must be equipped with counters with worktops in differentiated materials on the basis of the different intended use (e.g. resistant to heat, acids and bases, organic solvents, etc.), cabinets for the containment of flammable and harmful reagents.

Environmental conditions such as air conditioning, humidity and brightness must be such that the results are not affected.

The human resources necessary for the correct operation of the structure must be established taking into account the volume of analysis to be carried out

The laboratory must ensure that the personnel are in possession of adequate training and knowledge appropriate to the type of checks; it must also guarantee constant training updates for better specialization.

Among the staff members those who are authorized to perform specific tests and to use particular types of equipment must be identified.

*(It.) Legislative Decree no. 152 of 3 April 2006, Environmental regulations.

The instrumentation must be adequately maintained and/or calibrated and calibration programs must be established for the quantities that have a significant value on the results. The equipment must be used by authorized personnel and records must be maintained with the appropriate information.

The laboratory must have an updated list of all the equipment used.

The laboratory must employ, where possible, analytical methods established in Community and/or national legislation; if not available they should preferably use standard methods.

All the methods used must be previously validated and adequate internal quality control must be guaranteed and participation in inter-laboratory circuits where possible.

If the analytical methods are validated in "house", the validation must be carried out following the indications of international organizations (e.g. Eurachem, FDA etc.), the analytical procedures and the validation procedures must be written and be available to the laboratory operators.

All activities performed must be carried out adequately according to written procedures (prescriptive documents) and registered procedures (registration documents).

The documentation relating to the laboratory's activity must be communicated and made available to be understood and applied by the competent staff.

10.2. External analysis laboratory

The laboratories not annexed to the food industries that carry out analyses in the self-control procedures for the food industries, must be registered in the appropriate regional registers prepared by the regions/provinces according to the agreement between the Government, the Regions and the autonomous Provinces of 7 May 2015 on "Operating procedures for recording, updating, deletion from the regional lists of laboratories and procedures for carrying out uniform inspections for the assessment of compliance of laboratories".

Pursuant to the aforementioned agreement, in order for the laboratories to be enrolled in the regional list they must comply with the general criteria for the operation of the testing laboratories established by the European standard UNI CEI EN ISO/IEC 17025 and must be accredited, for individual tests or groups of tests, by the accredited and recognized national accreditation body that complies with the general requirements established by the UNI CEI EN ISO/IEC 17011 standard.

The responsibility that the analyses performed for self-control are performed by laboratories registered in the regional register and of the FBO.

The company must also keep all documentation concerning the certification of the laboratory to which the test has been performed available for the competent territorial bodies and control bodies.w