



Requirements for a HACCP based Food Safety System

Compiled by the National Board of Experts-HACCP
The Netherlands

September 2002

S P E C I F I C A T I O N

**REQUIREMENTS
FOR A
HACCP BASED
FOOD SAFETY SYSTEM**

Compiled by the
National Board of Experts – HACCP
The Netherlands.

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This is the authorised English translation of the specification “Eisen voor een op HACCP gebaseerd voedselveiligheids-systeem” (3rd version, September 2002), being one of three documents which regulate the Certification Scheme for operational HACCP based food safety systems. The two other documents; the “Certification Regulations” and the “Regulations for the National Board of Experts – HACCP” are also published by the National Board of Experts – HACCP.

Certifying Bodies operating the Certification Scheme for operational HACCP based food safety systems have to comply with the “Requirements for Certification Bodies”, also established and published by the National Board of Experts – HACCP.

The Certification Scheme for HACCP based Food Safety Systems is maintained by the National Board of Experts - HACCP.

Certification/Registration of HACCP based Food Safety Systems on the basis of the preceding versions of this specification has been accredited by the Dutch Accreditation Council (RvA) since 1997.

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1 INTRODUCTION

Reference documents; legislation; background information

Food safety is a global concern. Not only because of the continuing importance for public health, but also because of its impact on international trade. Effective Food Safety Systems shall therefore manage and ensure the safety and suitability of foodstuffs.

In many countries world-wide, legislation on the safety and suitability of foodstuffs requires “HACCP” to be put in place by any food business or organisation, whether profit-making or not and whether public or private, carrying out any or all of the following activities: preparation, processing, manufacturing, packaging, storage, transportation, distribution, handling or offering for sale or supply of foodstuffs. According to EU Directive 93/43/EEC on Food Hygiene all food business operators in the European Union shall implement HACCP¹. They shall ensure that adequate safety procedures are identified, documented, maintained and reviewed on the basis of the principles used to develop the system of HACCP (“Hazard Analysis and Critical Control Point”).

The Joint FAO/WHO Codex Alimentarius Commission describes a series of steps, including the 7 HACCP principles giving guidance for the application of the HACCP system².

Also, Codex advises that minimum hygiene measures should be in place before HACCP is implemented: *“Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation.”*

These prerequisite programs should be well specified and documented, fully operational and verified in order to facilitate the successful application and implementation of HACCP. The General Principles of Food Hygiene³, as recommended by Codex, form an intrinsic part of this document “Requirements for a HACCP based Food Safety System”.

Specific food safety requirements are detailed in legislation, hygiene codes, customer or consumer specifications. Where specific requirements do not exist, the General Principles on Food Hygiene will be applied (see Annex I). Furthermore, the 7 principles and the guidelines for the application of HACCP have been combined in this Specification with basic elements of quality management systems (ISO 9000) to establish “The Requirements for a HACCP based Food Safety System”.

The reference documents used to formulate the “Requirements” have been specified in Chapter 3.

The “Requirements” are primarily focused on actions and activities to ensure food safety. The assurance of food suitability is considered to be an obligatory part of a quality management system, unless deviations may lead to unsafe foodstuffs.

The need for a Standard or Specification

The specification “Requirements for a HACCP based Food Safety System” has been developed by and is placed under the authority of the National Board of Experts – HACCP in order to make a normative document/standard available. All parties involved in the food chain are represented on the National Board of Expert - HACCP.

The specification can be used by Certifying Bodies to assess the continuous compliance of HACCP-based Food Safety Systems as developed and implemented by food business operators.

¹ EU Directive 93/43/EEC on the Hygiene of Foodstuffs, dated 14 June 1993 (PbEC L175).

² Codex Alimentarius Commission, “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application”, Annex to CAC/RCP 1-1969, Rev. 3 (1997).

³ Codex Alimentarius Commission, “General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 3 (1997), amended 1999.

Of course, a food business operator may also use the “Requirements” to develop its HACCP-based Food Safety System.

Certification/Registration (e.g. of HACCP-based Food Safety Systems) signifies that by means of a formal statement (a certificate) and/or mark, notice is given with justified confidence that a product, process or service or system is in conformance with a pre-defined standard or (technical) specification. This includes the ability of the company to maintain conformance with the standards or specifications.

In order to issue such a formal statement, the HACCP-based Food Safety System of a food business operator needs to be assessed. Certification and repetitive surveillance audits are to be effectively performed by a Certifying Body which is an independent institution (whether or not governmental) that has both the authority as well as the confidence to operate a certification system within which the interests of all involved parties are represented.

For *confidence* the Certifying Body must use the published “Requirements” and the “Certification Regulations” in an agreed manner. The “Requirements” are documented in such a way to allow an effective assessment of the status and performance of the HACCP-based Food Safety System, as implemented by the food business operator. In the “Certification Regulations”, specific criteria are stated which have to be met by the Certifying Body when selecting a competent HACCP audit team, and rules which govern the way the certification process is designed and offered (e.g. the minimum auditor time) have to be followed.

Authority is obtained when the Certifying Body is formally accredited by a recognised Body to operate the certification system for HACCP based Food Safety Systems⁴ and is audited regularly by this Accreditation Body. Accreditation concerns the reliability and competence of the Certifying Body. The document “Requirements for Certification Bodies” elaborates the accreditation requirements.

It must be understood that certification of a HACCP-based Food Safety System is not a guarantee of a food business operator’s continuous food safety performance. The value added to a food business operator with a certified HACCP-based Food Safety System lies in the efforts made by the operating company to maintain that HACCP system and its commitment to continuously improve its food safety performance.

Requirements for a HACCP based Food Safety System

The requirements in this Specification provide a basis for compliance of a HACCP-based Food Safety System with (inter)national legislation and codes of practice. They include the necessary management system requirements. The structure, the sequence and interaction of the assessment process is detailed in Figure 1.

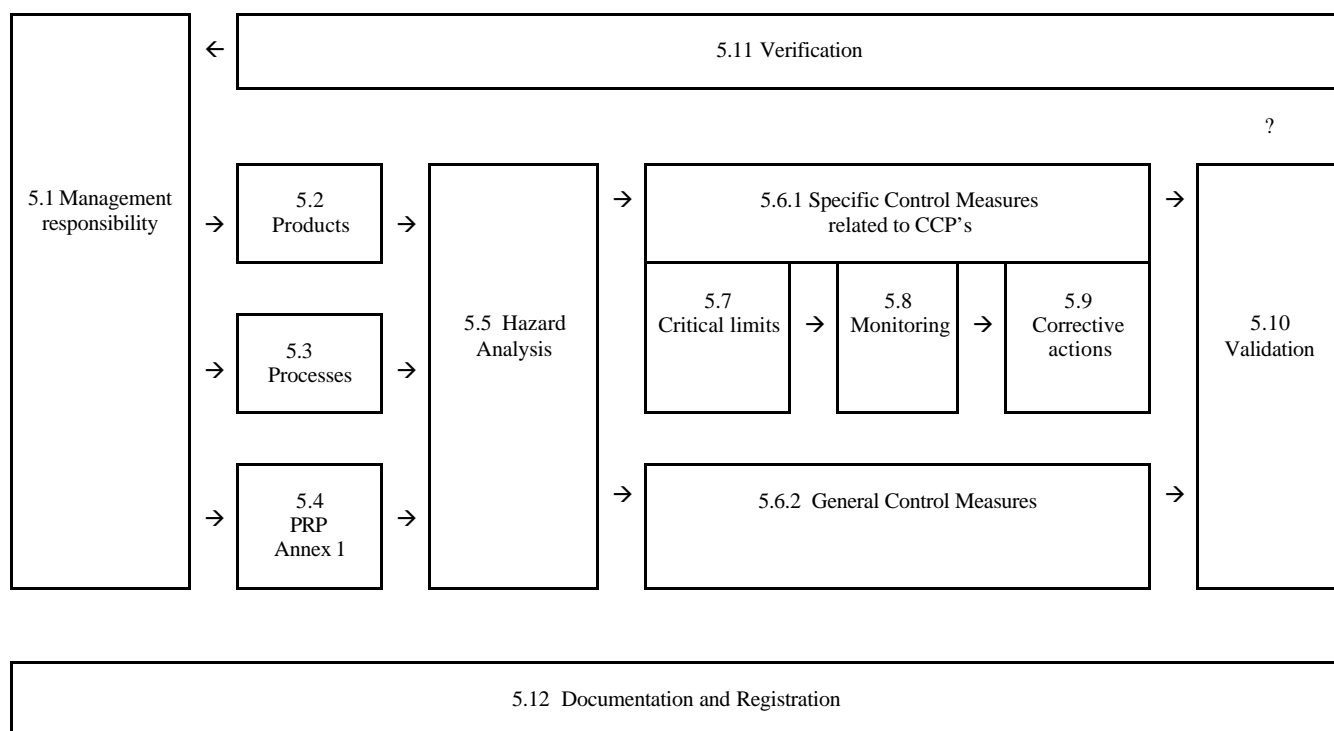
In the description of every clause, the scope of the requirements is detailed. Using these clauses, the audit team assesses the documented HACCP-based Food Safety System as well as the implementation and operation of the system on the 'shop floor'.

The “Requirements” lay down a generic set of requirements. An operational HACCP-based Food Safety System shall be, as a minimum, in compliance with these Requirements. In Annex II of this document each heading or paragraph of the “Requirements” refers to the corresponding text in the HACCP guidance document of Codex Alimentarius⁵.

⁴ The certification bodies must meet “General requirements for bodies operating assessment and certification / registration of quality systems”, ISO/IEC Guide 62:1996 (EN 45012) and the Standards for auditing (ISO 10011, Part 1, 2 and 3).

⁵ Codex Alimentarius Commission, “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application”, Annex to CAC/RCP 1-1969, Rev. 3 (1997).

Figure 1. The structure of a HACCP-based Food Safety System



In order to make the system transparent and enable assessment, the food business operator shall provide information as indicated in these “Requirements”. For each specific condition (product / product group / process / sector), specific requirements shall be detailed by the food business operator. The audit team shall assess this complete system of generic and company specific requirements.

The first version of these “Requirements” (then called “Criteria”) has been developed in co-operation with several Certification Bodies in the Netherlands in the area of food materials and processing, under the authority and responsibility of the National Board of Experts - HACCP. The 1st version was published on May 15, 1996.

Due to the modification of the Codex Alimentarius (Alinorm 97/13A, Appendix II) in 1997, a revision of the Requirements became necessary. The National Board of Experts - HACCP was also able to draw on their experience in order to improve the quality of the “Requirements”. The 2nd version of the “Requirements” was published in September 1998 and translated into English in February 1999.

Recent developments with respect to HACCP-based Food Safety System and developments within Codex, as well as new proposals for Food Hygiene Regulations (thereby repealing the current referenced EU Directives and Regulations), have necessitated a further revision: this 3rd version!

2 SCOPE of APPLICATION

In this document, requirements have been specified to be used during the assessment of operational HACCP systems (HACCP-based Food Safety Systems) which ensure the safety of foodstuffs during preparation, processing, manufacturing, packaging, storage, transportation, distribution, handling or offering for sale or supply in any sector of the food chain.

The “Requirements” are basically applicable to all food businesses or organisations, whether profit-making or not, and whether public or private.

Obviously, the food business operators shall have identified any step in their activities which is critical to ensure food safety and shall have developed, implemented, maintained and reviewed adequate safety procedures, applying the principles of HACCP, including the general principles of food hygiene, and where appropriate the relevant codes of practice and the food safety legislation.

These “Requirements” are not intended for application by suppliers and / or service companies to food businesses, like suppliers of packaging materials, food equipment, industrial cleaning services, etc..

3 REFERENCE DOCUMENTS

The “Requirements for a HACCP-based Food Safety System” are based on the following reference documents:

1

World-wide:

Joint FAO/WHO Codex Alimentarius Commission,

- General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 3 (1997), amended 1999.
- Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Annex to CAC/RCP 1-1969, Rev. 3 (1997).

2

International level:

European Union

2a

General Food law

Regulation (EC) no 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, dated 28 January 2002.

2b

Council Directive 93/43/EEC on the Hygiene of Foodstuffs, dated 14 June 1993 (PbEC L175); Specific legislation and regulations concerning food safety and hygiene have been laid down in Council Directives such as 64/433/EEC for fresh meat, 71/118/EEC for poultry meat, 89/437/EEC for egg products, 92/46/EEC for dairy products, 92/5/EEC for meat products, 91/493/EEC for fishery products, 94/65/EEC for minced meat, etc..

2c

Documents under 2b will be repealed by:

Proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs, COM/2000/0438 final, 14 July 2000 (COD 2000/0178), and others.

3

National level:

Netherlands, Food and Commodity Act:

Warenwetregeling Hygiëne van Levensmiddelen, 12 december 1994 (DGVgz/VVP/L 942587).

4

Where appropriate:

Numerous (International, a/o. Codex) Codes of Practice, Food Commodity Standards and (national) Hygiene Codes (generic HACCP / hygiene plans).

4 TERMS and DEFINITIONS

Action-limit value : A value for the product or process parameter under consideration, deduced from the critical limit value, which indicates that an intervention in the process is required.

Aspect: An element of the food business operation (products, processes, PRP, services) that can interact with the food safety.

Certification: Action by a third party demonstrating that adequate confidence is given that a duly identified product, process or service conforms with a specific standard or other normative document.

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure : Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Control measure, general: A measure to control a specific part of the PRP.

Control measure, specific: A measure to control a CCP.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): A step at which it is essential that a specific control measure is applied to prevent or eliminate a food safety hazard or reduce the risk to an acceptable level (see also Control measure, specific) .

Critical limit: A criterion which separates acceptability from non-acceptability.

Note: This criterion defines the limiting values for the product or process parameter(s) under consideration for monitoring (see action-limit values and target values).

Flow diagram: A systematic representation of the sequence of steps or operations used in the preparation, processing, manufacturing, packaging, storage, transportation, distribution, handling or offering for sale of a particular food item.

Food business operator: The person or persons responsible for ensuring that the requirements of the food legislation are met within the food business under his/their control.

Food handler: Any person who directly handles packaged or unpacked food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

Food hygiene : All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Food safety: Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability: Assurance that food is acceptable for human consumption according to its intended use.

General Control Measure: see: Control measure, general

HACCP (Hazard Analysis and Critical Control Point): A system which identifies, evaluates and controls hazards which are significant for food safety.

HACCP audit: A systematic and independent examination to determine whether the HACCP system, including the HACCP plan and related results, comply with planned arrangements, are implemented effectively and are suitable for the achievement of its objectives.

Note: Examination of the Hazard Analysis is an essential element of the HACCP audit.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

HACCP based Food Safety System: (a HACCP system): The organisational structure, procedures, processes and resources needed to execute the HACCP plan(s) and meet its objectives.

HACCP team: Group of individuals (multi-disciplinary) who develop, implement and maintain a HACCP system.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence, to decide which are significant for food safety and should therefore be addressed in the HACCP plan.

Monitoring: The act of conducting a planned sequence of observations or measurement of control parameters to assess whether a CCP is under control.

Pre-Requisite Programme (PRP): Any specified and documented activity or facility implemented in accordance with the Codex General Principles of food hygiene, good manufacturing practice and appropriate food legislation, in order to establish basic conditions that are suitable for the production and handling of safe food at all stages of the food chain.

Preventive action: Any measure or activity that will be used to prevent, to eliminate or to reduce the recurrence of causes for existing deviations, defects or any other undesired situation with respect to food safety.

Primary production: Those steps in the food chain up to and including harvesting, hunting, fishing, milking and all stages of animal production prior to slaughter.

Products, unprocessed: Foodstuffs which have not undergone a treatment, including products which have been, for example, divided, parted, severed, boned, minced, skinned, ground, cut, cleaned, trimmed, husked or milled, chilled, frozen or deep-frozen.

Products, processed: Foodstuffs resulting from the application to unprocessed products of a treatment such as heating, smoking, curing, maturing, pickling, drying, marinating, extraction, extrusion, etc. or a combination of these processes and/or products; substances necessary for their manufacture or for giving specific characteristics to the products may be added.

Risk: The probability of causing an adverse health effect caused by the occurrence and the severity of a particular hazard in food when prepared and consumed according to its intended use.

Target value : The value of the product or process parameter(s) to be monitored, targeted within action-limit values (the range of acceptable variations) and certainly within critical limit values, thus securing a safe product.

Step: A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption.

Validation: Obtaining evidence (in advance) that the specific and general control measures of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the specifications laid down in the HACCP plan and the effectiveness of the HACCP-based Food Safety System.

5 HACCP SYSTEM REQUIREMENTS

5.1 Management responsibility

The food business operator is responsible for the safety (and suitability) of the produced food. Therefore, the food business operator shall include the policy with respect to food safety in the policy of the organisation. The food business operator has ultimate responsibility for the policy of the organisation and shall document, support and communicate this policy. Periodically, the Food business operator shall verify the implementation of the policy and review the outcome.

The HACCP system enables the food business operator to demonstrate his commitment and his responsibility with respect to the supply of safe products. The HACCP system ensures that all required activities are effectively defined, implemented and maintained.

5.1.1 Policy

The food business operator shall define and document (in writing) the policy of the organisation with regards to food safety. It will demonstrate the commitment of the organisation to safe food.

The policy shall demonstrate that the organisation is fully aware of its position in the food chain. It will reflect the “farm-to-fork” approach, starting with the purchase and acceptance of raw materials. The policy shall be focused on the safety of foodstuffs and shall respond to the expectations and needs of its customers and consumers.

The policy shall include concrete objectives⁶ (proposed actions) to ensure and improve food safety for the period under consideration.

The food business operator shall ensure that the policy is understood, implemented and maintained at all levels in the organisation.

5.1.2 Scope of the HACCP system

The food business operator shall define the extent (the scope) of the HACCP system.

The scope shall comprise that part of the food chain and those activities of the food business for which the food operator is responsible and can be held liable:

- The part of the food chain for which the food business operator is responsible begins where the responsibility of the suppliers of raw materials and ingredients ends; the responsibility of the food business operator ends where another food business in the food chain takes over the responsibility. The scope shall therefore conform with purchase and sales contracts;
- All locations and process lines where food is manufactured and/or stored by the food business shall be properly indicated and be available for assessment;
- All products which are supplied to the market by the food business, whether processed or handled, shall be properly specified;
- All subcontracted activities (outsourced services, like packaging, storage, transport) shall be properly dealt with.

For practical reasons the total product assortment may be clustered into product groups. However it is important that:

- Specific differences between individual end products have been critically evaluated;
- Manufacturing and storage conditions are comparable;
- Important aspects for food safety are not overlooked.

A key principle is that no part of the operation of the food business can be excluded from the scope of the HACCP system; all activities must be available for assessment.

⁶ SMART objectives are Specific, Measurable, Acceptable, Realistic objectives, defined in Time.

5.1.3 Tasks, responsibilities and authorities

The food business operator shall provide appropriate documentation with respect to the tasks, responsibilities and authorities of food business operator's employees who are in positions which involve handling food and / or controlling and ensuring the safety and suitability of the food.

An organisation chart and the organisation's reporting structure shall be documented.

5.1.4 HACCP team(s)

The food business operator shall assemble a HACCP team (or various HACCP teams if so required). The HACCP team shall develop, implement and maintain the HACCP system.

The organisation shall demonstrate that the members of the HACCP team have the knowledge, expertise and different disciplines available which are required to develop, implement and maintain a HACCP system covering the total scope of the HACCP system.

Minimum qualification criteria, including required expertise, shall be defined and documented for all members of the HACCP team. In addition, the assignment (including tasks, responsibilities and authorities) shall be documented for the team members.

Whenever more than one HACCP team has been assembled, a co-ordinator shall be appointed to co-ordinate the development, implementation and maintenance of the HACCP system.

5.1.5 Resources

The food business operator shall examine the requests and provide, in a timely manner, all the resources needed by the HACCP team(s) to develop, implement and maintain the HACCP system.

When corrective actions, verification procedures or customers indicate that operational improvements are necessary, the food business operator shall examine the issues and provide appropriate resources to ensure food safety.

5.1.6 Management Review

The food business operator shall review the HACCP system at planned intervals, of no more than 12 months, to ensure continuing suitability, adequacy and effectiveness. The review shall evaluate the need for changes to the HACCP system, including product safety, policy and objectives.

The review shall provide evidence of the commitment to improve the HACCP system and its performance.

5.2 Product Information

5.2.1 Product Characteristics

Each product (or a group of similar products: see 5.1.2) shall be fully specified and documented, including its sensitivity to and potential for safety risks.

This description of the safety of the product shall encompass the food chain, ranging from raw materials used to the distribution of the finished products.

The traceability of the raw materials up to and including final supply shall be described.

An extensive specification of the end products is required to ensure a comprehensive assessment of the food safety procedures. This specification shall clearly define the following product characteristics:

- A general product description;
- Raw materials and ingredients used (composition);
- General product specifications such as appearance, weight, etc.;
- Specific product specifications such as chemical, microbiological and physical characteristics;
- Specific requirements such as appropriate legislation, customer requirements;
- General control of (chemical, microbiological and physical) safety;
- Packaging, storage conditions, labelling (shelf life, product identification);
- Identification of potential mishandling of the product.

5.2.2 Intended use

The intended use of the product (or product group) shall be identified and documented since it has a direct influence on the required product characteristics. For instance, the product may require:

- Additional preparation methods (e.g. heating) before consumption, and/or
- Cooling and storage at specific temperatures, and/or
- An indication of the ultimate day of use, especially after breaking the packaging, and/or
- The product may be intended for use by specific (vulnerable) groups of the population, such as babies and children, pregnant women, elderly people, allergenic or sick people.

The intended use of the product shall be continually reviewed; relevant legislation and regulations shall be documented. When necessary, the product characteristics and manufacturing processes may need to be adapted to conform with special legislation. Information on the label, including directions for use, may also need to be adapted. These changes shall be recorded.

If mishandling or misuse of the product can result in unsafe products the products shall bear appropriate information to ensure that adequate and accessible information is available to the next persons in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly. It shall be easy to identify the lot or batch when recall is required.

The food business operator shall demonstrate that it has evaluated whether the intended use or misuse should include Critical Control Points such as storage conditions and preparation before consumption.

5.3 Process information

5.3.1 Flow Diagrams

The food business operator shall make available a complete and actual description of the operation in the form of flow diagrams (process steps) and layouts (production facilities). When applying HACCP to a given operation, consideration shall be given to steps preceding and following the specified operation. These descriptions shall be drawn up and verified by the HACCP team.

The flow diagrams provide a schematic overview of the operation and will describe all the steps in sufficient detail to provide the HACCP team with adequate information for the HACCP.

The flow diagrams shall take into account all relevant process steps, such as the manufacturing of the product, including critical points like:

- Buffer and interim storage;
- Transport pipes, distribution valves, etc.;
- Loops for reworking and recycling;
- Facilities for cleaning and disinfection of equipment and tools, including cleaning-in-place;
- Provision for start up / shut down / emergency stops, etc..

5.3.2 Layout

All facilities which are part of the infrastructure of the food business, such as the production lines, storage areas and personnel facilities, shall be depicted in a layout plan.

In the layout the following items shall be indicated:

- The routing of products, personnel and air flows (in the case of 'high care' rooms);
- The areas where cross contamination of and incidental contact with in-process and finished products by raw materials, additives, lubricants, cooling agents, personnel, packaging, pallets and containers, cannot be excluded;
- The areas and facilities for personnel use.

5.3.3 Control and Verification of Process Information

Prior to the execution of changes in the production process and layout that could adversely affect food safety, these changes shall be reported to the HACCP team in order to evaluate potential hazards to food safety and take preventive actions accordingly.

In any case the accuracy and actuality of the flow diagrams and layout shall be verified by the HACCP team for compliance with the documented situation. This verification shall be repeated periodically (at least annually) in order to identify and document modifications to the process installation and layout. These periodic verifications shall be part of the verification procedure.

5.4 Pre-requisite program

The food business operator shall make available a complete and actual description of the pre-requisite program (PRP) of the organisation. The procedures belonging to the PRP shall be well established (appropriately specified and documented), fully operational and integrated in the HACCP system, and be verified.

The Codex General Principles of Food Hygiene lay a firm foundation for ensuring food safety and suitability. The food business operator shall decide which food hygiene principles, good manufacturing practices and food legislation must be included in the PRP of the organisation⁷. The basic requirements related to the prerequisite program have been reviewed in annex I and are summarised in Figure 2.

Figure 2: Summary of the Codex General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3 (1997), Amended 1999)

1 Primary production 1.1 Environmental hygiene 1.2 Hygienic production of food sources 1.3 Handling, storage and transport 1.4 Cleaning, maintenance and personal hygiene	5 Establishment: personal hygiene 5.1 Health status 5.2 Illness and injuries 5.3 Personal cleanliness 5.4 Personal behaviour 5.5 Visitors
2 Establishment: design and facilities 2.1 Location 2.2 Premises and rooms 2.3 Equipment 2.4 Facilities	6 Transportation 6.1 General 6.2 Requirements 6.3 Use and maintenance
3 Control of operation 3.1 Control of food hazards 3.2 Key aspects of hygiene control systems 3.3 Incoming materials requirements 3.4 Packaging 3.5 Water 3.6 Management and supervision 3.7 Documentation and records 3.8 Recall procedures	7 Product information and consumer awareness 7.1 Batch identification 7.2 Product information 7.3 Labelling 7.4 Consumer education
4 Establishment: maintenance and sanitation 4.1 Maintenance and cleaning 4.2 Cleaning programmes 4.3 Pest control 4.4 Waste management 4.5 Sanitation systems	8 Training 8.1 Awareness and responsibilities 8.2 Training programs 8.3 Instruction and supervision 8.4 Refresher training

Like the products and the processes, (the procedures belonging to) the PRP will be subjected to the hazard analysis (see section 5.5) in order to identify potential hazards and to decide in which way the hazards (risks) need to be controlled (see section 5.6).

⁷ Codex, General Food Principles state in this respect:
... there will be inevitably situations where some of the food hygiene requirements are not applicable. The fundamental question in every case is "what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"
... in deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach!"

5.5 Hazard Analysis⁸

The food business operator (HACCP team) shall identify, analyse and evaluate all potential (biological, chemical and physical) hazards that can have an adverse effect on the safety of the products.

Whenever the food business operation changes in a manner that could adversely affect food safety all relevant steps of the Hazard Analysis shall be up-dated.

5.5.1 Hazard identification

The food business operator (HACCP team) shall identify and register all potential (biological, chemical and physical) hazards that can have an adverse effect on the safety of the products. The identification shall include all aspects of the operations within the scope of the HACCP system.

The operations to be evaluated include all products, all processes and the pre-requisite program of the legal owner of the products. For service organisations (not legal owner, but holder of the products), the hazard identification and analysis is restricted to the services provided, for instance, cold/frozen storage, packaging and transport.

The hazard identification shall include aspects like:

- Raw materials and ingredients: specifications, process control at suppliers, etc.;
- Characteristics of interim and end products: intrinsic product specifications, etc.;
- Characteristics of used processes, including subcontracted services, etc.;
- Prerequisite program (PRP), including aspects like:
 - layout of the facility, production lines, installations and equipment;
 - location of rooms, routing, storage and separation of raw materials, interim products, end products, ventilation, etc.;
 - production processes, like: purchasing, cleaning and disinfection, packaging, maintenance, pest control, waste management, etc.;
 - personnel (including arrangements for visitors and external service providers, e.g. mechanics): hygiene, knowledge with regard to food hygiene and food safety, requirement to notify diseases and infections, etc..

5.5.2 HACCP analysis (risk)

The food business operator (HACCP team) shall conduct a HACCP analysis to identify which hazards are of such a nature that their elimination or reduction and control at acceptable levels is essential to the production of safe food.

In conducting the HACCP analysis, the following shall be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- the survival or multiplication of micro-organisms of concern;
- the production or persistence of toxins, chemicals or physical agents in foods;
- the conditions leading to the above.

⁸ The notion “hazard analysis” consists of two elements, namely the identification of potential hazards and the execution of a “HACCP analysis”. During the “HACCP analysis” the involved risk is assessed which may cause an adverse health effect when the food is prepared and consumed according to its intended use.

The term “risk analysis” is reserved for the process defined by Codex (“Principles and guidelines for the conduct of microbiological risk assessment”, CAC/GL-30, 1999) which consists of three components (risk assessment, risk management and risk communication) and which has the overall objective to ensure public health protection.

The results of the analysis shall be documented, including the concepts and principles utilised for determining/estimating the risks.

The food business operator shall define permissible levels of risks. These levels (concentrations, product or process criteria) must comply, as a minimum, with legal requirements. When conducting the HACCP analysis, practical experiences, experimental data, professional literature, etc., shall be taken into account and be documented.

5.6 Control Measures

The HACCP team shall identify and document the control measures that are to be applied or implemented when the hazard identification and HACCP analysis concludes that the risk of an identified hazard is significant and needs to be eliminated or reduced and controlled at an acceptable level.

The HACCP team shall conduct an assessment of every step in the process, for example with the use of a decision tree. The assessment shall be based on, amongst other things, the differing expertise within the team and shall utilise external and internal information.

For each step, including all products, all processes and all parts of the Pre-Requisite Program the assessed aspects shall be identified. The reasons for deciding whether it is a CCP (critical control point) or not, shall be documented and traceable.

More than one control measure may be required to control a hazard and more than one hazard may be controlled by a control measure.

Control measures shall be classified as specific or general control measures.

5.6.1 Specific Control Measures

Control measures related to CCP's shall be classified as specific control measures. Specific control measures are actions or activities, often measurable in terms of physical or chemical parameters such as temperature, time, moisture, pH, Aw, available chlorine, and sensory parameters such as visual appearance and texture.

Specific control measures based on subjective parameters, as in the case of visual inspection of a product, process, handling, etc., shall be supported by instructions or specifications, education and training.

Specific control measures shall be monitored, be provided with corrective actions, validated and verified (see subsequent paragraphs).

5.6.2 General Control Measures

Control measures not related to CCP's shall be classified as general control measures. General control measures are actions or activities which are part of the prerequisite program (see section 5.4). In general, these measures will achieve control at acceptable levels.

General control measures shall be documented in specifications (raw materials, products, process, etc.), instructions (process, control, operations) and procedures or plans, e.g. purchase plan, hygiene plan (including personal), maintenance plan, cleaning and disinfection plan, and supported by education and training plans, operator-specific aspects, supervision, etc..

General control measures shall be validated (see section 5.10) in order to demonstrate the proper functioning of (the specific part of) the PRP and will subsequently be approved by the HACCP team.

The effectiveness in controlling the identified hazards of the general control measures shall be verified (see section 5.11) at pre-defined, regular intervals.

5.7 Parameters and Critical Limits

5.7.1 Critical process and product parameters

For each specific control measure related to a CCP the process and/or product parameters must be identified which are meant to demonstrate that control at the step is being maintained.

The food business operator shall document the parameters to be applied as well as the arguments for using these parameters.

5.7.2 Target values, action-limit values and critical limits

Further, the food business operator shall define for the various parameters the critical limit(s) which must be met at all times during the operation.

Also, normal operational target values are indicated for the various parameters as well as the action-limit values which indicate when intervention in the operation is required in order to continuously meet the critical limits.

When determining the critical limits and the deduced action-limit and target values, the requirements of the relevant legislation and regulations and/or internal risk analysis for the safety of foodstuffs must be considered as (contractual) requirements.

The food business operator must establish and maintain adequate provisions/procedures for the monitoring of the target values (see section 5.8) and the corrective actions (see section 5.9) to be executed whenever the critical limits are exceeded.

In addition the effectiveness of the established parameters and operational values shall be validated (see section 5.10) to ensure food safety.

5.8 Monitoring and measuring

The food business operator shall establish and maintain a monitoring (measuring) system for effective and efficient control of the Critical Control Points.

The system includes all planned measurements, observations and analysis of the control parameters determining that the CCP's are under control.

The justification for the development of the monitoring system shall be documented.

The monitoring (measuring) devices shall be identified.

The methodology of measurement and/or the instructions for measuring and recording of measurements shall be documented.

In addition, the method for establishing the reliability of the measurements and/or the equipment (calibration) shall be documented.

Measurements and product tests by subcontractors shall only be accepted where these subcontractors comply with the relevant criteria of ISO 17025, ISO 17020 or ISO/IEC Guide 65, or the equivalent European or National standards.

The results of the monitoring shall be documented by means of records and the practices shall be described in the process control plans. The records shall include:

- Monitoring reports (dated and signed);
- Records of deviations which have occurred (action limits and critical limits) and corrective actions taken.

5.9 Corrective Actions

For each Critical Control Point, the food business operator shall document the corrective actions to be taken in case an action-limit value or critical limit is exceeded. The procedure will include the process to investigate the cause of the deviation.

A documented justification for the corrective action to be taken shall be available, including the responsibilities and authorities of the personnel which is involved. The actions to be taken must be established in advance. This could also involve the formation of a so-called 'emergency team'. This team shall evaluate the causes of the deviation and shall decide which additional preventive actions are to be taken (see also section 5.11).

The food business operator shall also establish arrangements that provide procedures for recall of the products from the market place and/or from end consumers. Proper product identification and a “tracing & tracking” system shall be operational.

All corrective actions taken, the causes and consequences, and the individuals involved in the corrective actions shall be recorded.

The effectiveness of the corrective actions, for both the process and the product, shall be evaluated.

Products resulting from the process while the critical limit has been exceeded shall be treated as non-conforming products. The corrective actions may include:

With respect to the product:

- Actions ranging from blockades to product recall;
- Temporary hold of the product/batch;
- Identification of non-conforming products;
- Re-work of the product;
- Disposal/destruction of the product/batch.

With respect to the process:

- Adjusting the process;
- Adjustment/correction of process conditions.

5.10 Validation

Validation is not a part of verification, but a separate activity prior to authorising the HACCP plan ⁹.

The objective of validation is to ensure that the hazards originally identified by the HACCP team are complete and correct and that they will be effectively controlled under the proposed plan. To meet the objectives of validation it is necessary to review the effectiveness of the supporting evidence used in the HACCP study as well as the general and specific control measures, the monitoring system and corrective actions.

Each time when the food business operation changes in a manner that could adversely affect food safety this review shall be up-dated.

To ensure absence of bias, the food business operator shall form a validation team. The validation team may include members of the HACCP team, but must also include independent reviewers e.g. from within the food business operation, who have not been directly involved in the establishment of the HACCP plan.

Validation is performed by demonstrating that:

- The established list of potential hazards is based on sound scientific data and has included all hazards;
- The questions used to assess the significance are answered using sound scientific and technical knowledge;
- The control measures (general or specific) are appropriate to control the hazards, i.e. to prevent or eliminate, to reduce or maintain at an acceptable level;
- Fluctuations of the control parameters (equivalent to a process criterion) within the defined critical limits will not affect the safety of the product;
- The parameters and methods used to monitor the control measures are appropriate;
- Corrective actions are appropriate and will prevent the release of unsafe products and provide evidence that the situation can be corrected immediately.

Food business operators may have produced safe food for many years before the introduction of the HACCP system. Therefore, historical results from on-line Quality Control monitoring, end product testing, customer or consumer complaints may be used as evidence when validating HACCP plans. It is important to note that the data must be quantifiable and objective if it is to be useful.

The composition of the validation team and the activities undertaken shall be clearly documented. The food business operator shall demonstrate satisfactory completion of validation.

⁹ In the document “Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application” (Annex to CAC/RCP 1 –1969, Rev.3, 1997) Codex Alimentarius Commission include validation as a part of verification. There is, however, a clear distinction between the two because they are separate actions. The distinction lies in justifying what a food business operator plans to do (validation) and then checking conformity with the planned actions and objectives (verification).

Validation is an essential part of the HACCP process. It is concerned with obtaining objective evidence that the elements of the HACCP plan will be effective. Validation should be targeted at the assessment of the scientific and technical inputs into the HACCP plan; it should ensure that the information supporting the HACCP plan is correct – that the food business operator is “going to do the right things”. Validation needs to be performed before approval of the HACCP plan by the food business operator and before its implementation.

5.11 Verification

The food business operator shall establish, document and implement procedures for verification of the HACCP system. The main purpose of verification is to determine compliance with the specifications of the HACCP system and to confirm that the HACCP system is working effectively through the application of (auditing) methods, procedures, tests (including random sampling and analysis) and other evaluations, in addition to monitoring (see section 5.8).

Procedures for verification shall be documented and shall include as a minimum:

- Purpose;
- Methods, standard operating procedures or tests applied;
- Tasks and responsibilities;
- Frequency;
- Records.

The verification procedure shall address, as a minimum, the following topics:

- Review of the HACCP system and its corresponding records;
- Analysis of (near) recalls and product dispositions;
- Assessment of all specific control measures, deviations and corrective actions taken to seek confirmation of implementation and effective control of CCP's;
- Assessment of all general control measures to seek confirmation of implementation and to demonstrate an effective control of associated hazards;
- Compliance of the actual flow diagrams and layout with the documented situation;
- Compliance of the PRP documents with the operational situation;
- Analysis of customer and consumer complaints related to hygiene and food safety;
- Review of analytical outcome of random sampling and analysis of products;
- Evaluation of conformity with applicable legislation and regulations (as well as conformity to foreseeable changes in legislation and regulations) and identification of changes in legislation and regulations concerning food safety;
- Review of gaps between current and desired level of knowledge, awareness and training of staff with respect to hygiene and food safety, resulting in effective (on-the-job) training sessions;
- Consistency of the current documentation.

Internal audit

The food business operator shall determine whether the HACCP system:

- Conforms with the planned arrangements:
 - with the “Requirements for a HACCP-based Food Safety System” and
 - with the requirements established by the food business operator itself.
- Is effectively implemented and maintained.

The food business operator shall plan an internal audit scheme, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined, taking into consideration the status and importance of the processes and area's to be audited, as well as the results of previous audits. Selection of auditors and the conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, for reporting results and maintaining records shall be defined in a documented procedure.

Management review

The food business operator shall review and evaluate the results of the entire verification process at planned intervals, of no more than 12 months (see par. 5.1.6). Therefore, the frequency of verification and internal audits shall be such that the food business operator can ensure continuing suitability, adequacy and effectiveness of the HACCP-based Food Safety System. Some requirements are to be verified with a higher frequency than other requirements. For instance, the effective control of CCP's (5.6.1) may be evaluated with a frequency of at least twice a year, whereas a frequency of once a year may be sufficient to verify the actuality of process lines and layout (5.3.3).

The food business operator shall collect and analyse the resulting data to evaluate where improvement is needed.

The food business operator shall ensure that preventive actions (see 5.9) are taken without undue delay to eliminate the causes of (potential) non-conformities in order to prevent recurrence (occurrence). The preventive actions shall be appropriate to the effects of the (potential) non-conformities encountered.

The effectiveness of the preventive actions taken shall be validated.

Follow-up actions shall include the verification and review of actions taken.

5.12 Documentation and records

5.12.1 Documents and document control

The food business operator shall establish a documented HACCP system and shall maintain the HACCP system and corresponding documentation in order to ensure conformity with the requirements of this specification and the applicable legislation and regulations.

Documentation should be appropriate to the nature and size of operation.

The food business operator shall establish and maintain a HACCP manual that includes

- The policy of the food business operator with respect to food safety (see par. 5.1.1) and the scope of the HACCP-based Food Safety System (see par. 5.1.2).
- The documented specifications, procedures and instructions established for the HACCP-based Food Safety System, or reference to them
- A description how the food business operator has fulfilled the requirements of this Specification. If any requirement of this Specification is considered as inapplicable to the operator, justification shall be provided in the HACCP manual.

Documents required by the HACCP-based Food Safety System shall be controlled. A documented procedure shall be established to define the controls needed:

- to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,
- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,
- to ensure that documents of external origin are identified and their distribution controlled,
- to prevent the unintended use of obsolete documents, and to suitably identify them if they are retained for any purpose

5.12.2 Records

Efficient and accurate record-keeping is essential to the application of a HACCP system.

Records shall be established and maintained to provide evidence of conformity with the requirements and with the effective operation of the HACCP-based Food Safety System. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for identification, storage, protection, retrieval, retention time and disposal of records.

Records that shall be available are:

- Records to demonstrate that the members of the HACCP team have adequate knowledge, expertise and different disciplines available;
- Records concerning management reviews and, if needed, related actions;
- Records of the hazard analysis and information sources (legislation, standards, literature, hygiene-codes, GMP, Codex) used by the HACCP teams to identify and evaluate the hazards and risks;
- Records of the assessment of every step in the process and the reasons for establishing the Specific Control Measures (CCP related) and General Control Measures;
- Monitoring reports (dated and signed) of the Specific Control Measures to demonstrate the control of the related CCP's;
- Records of deviations occurred (exceeded action limits and critical action limits) of the Specific Control Measures and the corrective actions taken;
- Records related to the verification program (including internal audits) and their evaluation;
- Records that are relevant to ensure traceability of food stuffs.

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6. ANNEX I Pre-requisite program (PRP)

(Reference: Codex Alimentarius, "General Principles of Food Hygiene", CAC/RCP 1-1969, Rev. 3 (1997), Amended 1999)

1 Primary production	
1.1 Environmental hygiene	1.1.1 Primary food production shall not be carried out in areas where the presence of potentially harmful substances will lead to an unacceptable level of such substances in food. Potential sources of contamination from the environment shall be considered.
1.2 Hygienic production of food sources	1.2.1 The potential effects of primary production activities on the safety and suitability of food shall be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimise that probability.
	1.2.2 As far as practicable, measures shall be implemented to: <ul style="list-style-type: none"> - control contamination from air, soil, water, feedstuffs, fertilisers (including natural fertilisers), pesticides, veterinary drugs or any other agent used in primary production; - control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product; - protect food sources from faecal and other contamination.
	1.2.3 In particular, care shall be taken to manage waste and store harmful substances appropriately.
	1.2.4 On-farm programmes which achieve specific food safety goals are becoming an important part of primary production and shall be encouraged.
1.3 Handling, storage and transport	1.3.1 Procedures shall be in place to: <ul style="list-style-type: none"> - sort food and food ingredients to segregate material which is evidently unfit for human consumption; - dispose of any rejected material in a hygienic manner; - protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.
	1.3.2 Care shall be taken, so far as is reasonably practicable, to prevent deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.
1.4 Cleaning, maintenance and personal hygiene	1.4.1 Appropriate facilities and procedures shall be in place to ensure that: <ul style="list-style-type: none"> - any necessary cleaning and maintenance is carried out effectively; - an appropriate degree of personal hygiene is maintained.
2 Establishment: design and facilities	
2.1 Location	
2.1.1 Establishments	2.1.1.1 Establishments shall not be located anywhere where it is clear that there is a threat to food safety or suitability. In particular, establishments shall normally be located away from: <ul style="list-style-type: none"> - environmentally polluted areas and industrial activities which pose a serious threat to contamination of food; - areas subject to flooding unless sufficient safeguards are provided; - areas prone to infestations of pests; - areas from which waste, either solid or liquid, cannot be removed effectively.
	2.1.2 Equipment
2.2 Premises and rooms	
2.2.1 Design and layout	2.2.1.1 Where appropriate, the internal design and layout of food establishments shall permit good food hygiene practices, including protection against harmful cross-contamination.

2.2.2 Internal structures and fittings	2.2.2.1 Structures within food establishments shall be soundly built of durable materials and be easy to maintain, clean and where appropriate, disinfect.
	2.2.2.2 The surfaces of walls, partitions and floors shall be made of impervious materials with no toxic effect in intended use.
	2.2.2.3 Walls and partitions shall have a smooth surface up to a height appropriate to the operation.
	2.2.2.4 Floors shall be constructed to allow adequate drainage and cleaning.
	2.2.2.5 Ceilings and overhead fixtures shall be constructed and finished to minimise the build up of dirt and condensation and the shedding of particles.
	2.2.2.6 Windows shall be easy to clean, constructed to minimise build up of dirt and where necessary, fitted with removable and cleanable insect-proof screens. Where necessary windows shall be fixed.
	2.2.2.7 Doors shall have smooth, non-absorbent surfaces and shall be easy to clean and disinfect.
	2.2.2.8 Working surfaces that come into direct contact with food shall be of sound condition, durable and easy to clean, maintain and disinfect. They shall be made of smooth, non-absorbent materials and inert to food, detergents and disinfectants under normal operating conditions.
2.2.3 Temporary / mobile premises; vending machines	2.2.3.1 Premises and structures shall be located, designed and constructed to avoid, as far as is reasonably practicable, contaminating food and harbouring pests.
	2.2.3.2 Any food hygiene hazards associated with such facilities shall be adequately identified and controlled to ensure the safety and suitability of food.
2.3 Equipment	
2.3.1 General	2.3.1.1 Equipment and re-usable containers coming into contact with food shall be designed and constructed to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food.
	2.3.1.2 Equipment and containers shall be made of materials with no toxic effect in intended use.
	2.3.1.3 Where necessary, equipment is durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.
2.3.2 Food control and monitoring equipment	2.3.2.1 In addition to the general requirements in paragraph 2.3.1, equipment used to cook, heat treat, cool, store or freeze food shall be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and to be effectively maintained.
	2.3.2.2 Such equipment shall also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment shall have effective means of controlling and monitoring humidity, air-flow and any other condition likely to have a detrimental effect on the safety or suitability of food.
2.3.3 Containers for waste and inedible substances	2.3.3.1 Containers for waste, by-products, and inedible or dangerous substances shall be identifiable, suitably constructed and where appropriate made of impervious material.
	2.3.3.2 Containers used to hold dangerous substances shall be identified and, where appropriate, shall be lockable to prevent malicious or accidental contamination of food.
2.4 Facilities	
2.4.1 Water supply	2.4.1.1 An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, shall be available whenever necessary. Potable water shall, as a minimum, meet the specifications published in the WHO Guidelines for Drinking Water Quality.
	2.4.1.2 Separate non-potable water systems (e.g. fire control, steam production, refrigeration) shall be identified and shall not connect with, or allow reflux into, potable water systems.
2.4.2 Drainage and waste	2.4.2.1 Drainage and waste disposal systems shall be available, designed,

disposal	constructed and maintained in such a way as to avoid contamination of food products and potable water supply.
2.4.3 Cleaning	2.4.3.1 Adequate facilities, suitable designated, are provided for cleaning food utensils and equipment. If necessary these facilities shall have an adequate supply of hot and cold potable water.
2.4.4 Personnel hygiene facilities and toilets	2.4.4.1 Adequate means of hygienically washing and drying hands, including wash basins and a supply of cold and hot (suitable temperature) water are provided.
	2.4.4.2 Lavatories of appropriate hygienic design are provided.
	2.4.4.3 Adequate changing facilities for personnel are provided.
	2.4.4.4 The afore-mentioned facilities are suitable located and designated.
2.4.5 Temperature control	2.4.5.1 Facilities for heating, cooling or freezing food products, or storing refrigerated or frozen foods are suitable to meet the specified conditions for ensuring food safety.
2.4.6 Air quality and ventilation	2.4.6.1 Mechanical or natural ventilation ensures: <ul style="list-style-type: none"> - minimisation of air-borne contamination of food (e.g. from aerosols and condensation droplets) - control of ambient temperatures - control of humidity
	2.4.6.2 Ventilation systems are designed and constructed so that air does not flow from contaminated areas to clean areas and they can be adequately maintained and cleaned.
2.4.7 Lighting	2.4.7.1 The intensity and colour of the lighting is sufficient to ensure the production and handling of safe food products.
	2.4.7.2 Where appropriate, lighting fixtures are protected to ensure that food products are not contaminated by breakage.
2.4.8 Storage	2.4.8.1 Adequate facilities for storage of food ingredients and non-food materials (e.g. cleaning materials, lubricants, fuels) are provided.
	2.4.8.2 Food storage facilities are designed and constructed to: <ul style="list-style-type: none"> - permit adequate maintenance and cleaning ; - avoid pest access and harbourage; - enable food to be effectively protected from contamination; - provide the necessary environment to prevent spoilage.
	2.4.8.3 Facilities for storage are designed, constructed and maintained to ensure that malicious or accidental contamination of food products with harmful materials is prevented.
3 Control of operation	
3.1 Control of food hazards	3.1.1 Food business operators shall control food hazards through the use of systems such as HACCP. These systems shall be applied throughout the food chain to control food hygiene throughout the shelf life of the product.
3.2 Key aspects of hygiene control systems	
3.2.1 Time and temperature control	3.2.1.1 Control systems for temperature and time during heating, cooling and storage are in place where necessary for the production and handling of safe food. Control systems include critical limits, registration and testing of accuracy of measuring equipment.
3.2.2 Specific process steps	3.2.2.1 Other steps which contribute to food hygiene (and which must therefore be considered) may include chilling, thermal processing, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging.
3.2.3 Microbiological and other specifications	3.2.3.1 Where microbiological, chemical or physical specifications are relevant for food safety, such specifications shall be based on sound scientific principles and state, where appropriate, monitoring procedures, action limits and analytical methods.
3.2.4 Microbiological cross-contamination	3.2.4.1 Where appropriate, effective separation of raw, unprocessed food from processed food applies.
	3.2.4.2 Where appropriate, access to processing areas are restricted or controlled. Access and control procedures are defined and documented.
	3.2.4.3 All surfaces, utensils, equipment, fixtures and fittings are cleaned and where necessary, disinfected after contact with raw food, to prevent contamination.

3.2.5 Physical and chemical contamination	3.2.5.1 Systems are in place to prevent contamination of food products by foreign bodies (e.g. glass, metal, dust, harmful fumes) and hazardous chemicals. 3.2.5.2 Suitable and effective detection or screening devices are used where necessary.
3.3 Incoming materials requirements	
3.3.1 Specifications	3.3.1.1 No raw material or ingredient shall be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials shall be identified and applied.
3.3.2 Control at reception	3.3.2.1 Raw materials or ingredients shall, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests shall be carried out to establish fitness for use. Only sound, suitable raw materials or ingredients shall be used.
3.3.3 Stock rotation	3.3.3.1 Stocks of raw materials and ingredients shall be subject to effective stock rotation.
3.4 Packaging	
3.4.1 Design and materials	3.4.1.1 Packaging design and materials shall provide adequate protection for products to minimise contamination, prevent damage and accommodate proper labelling.
3.4.2 "Food-grade" materials and gases	3.4.2.1 Packaging materials and gases shall be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions, storage and use.
3.4.3 Reusable packaging	3.4.3.1 Re-usable packaging shall be suitably durable, easy to clean and, where necessary, disinfect.
3.5 Water	
3.5.1 Water in contact with food	3.5.1.1 Only potable water shall be used in food handling and processing, with the following exceptions: - for steam production, fire control and similar purposes not connected with food - in certain processes (e.g. chilling) and in food handling areas provided it does not constitute a hazard to the safety of food (e.g. use of clean sea-water).
3.5.2 Reuse of re-circulated, treated water	3.5.2.1 Re-circulated water for re-use shall be treated and maintained in such a condition that no hazards for food safety occur. The treatment process shall be effectively monitored.
3.5.3 Reuse of re-circulated, non-treated water	3.5.3.1 Re-circulated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.
3.5.4 As an ingredient	3.5.4.1 Potable water shall be used.
3.5.5 Ice and steam	3.5.5.1 Ice shall be made from water complying with section 2.4.1. Ice and steam shall be produced, handled and stored to protect them from contamination. 3.5.5.2 Steam used in direct contact with food or food contact surfaces shall not contain any agent which is hazardous for food safety.
3.6 Management and supervision	
3.6.1 Type of control and supervision	3.6.1.1 The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved.
3.6.2 Knowledge required	3.6.2.1 Managers and supervisors shall have enough knowledge of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.

3.7 Documentation and records	
3.7.1 Retain records	3.7.1.1 Where necessary, appropriate records of processing, production and distribution shall be kept and retained for a period that exceeds the shelf life of the product.
3.7.2 Effectiveness and credibility	3.7.2.1 Documentation can enhance the credibility and effectiveness of the food safety control system.
3.8 Recall procedures	
3.8.1 Effective procedures	3.8.1.1 Managers shall ensure that effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated batch of finished food from the market.
3.8.2 Tracing & tracking	3.8.2.1 Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, shall be evaluated for safety and may need to be withdrawn. The need for public warnings shall be considered.
3.8.3 Destroy or reprocess	3.8.3.1 Recalled products shall be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.
4 Establishment: maintenance and sanitation	
4.1 Maintenance and cleaning	
4.1.1 General	4.1.1.1 Establishments and equipment shall be kept in an appropriate state of repair and condition to: <ul style="list-style-type: none"> - facilitate all sanitation procedures; - function as intended, particularly at critical steps; - prevent contamination of food, e.g. from metal shards, flaking plaster, debris and chemicals.
	4.1.1.2 Cleaning shall remove food residues and dirt that may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning.
	4.1.1.3 Cleaning chemicals shall be handled and used carefully and in accordance with manufacturers' instructions
	4.1.1.4 Cleaning chemicals shall be stored, where necessary, separately from food, in clearly identified containers to avoid the risk of (malicious or accidental) contamination of food.
4.1.2 Cleaning procedures and methods	4.1.2.1 The cleaning and disinfecting method(s) shall be specified and documented. The water used will comply with section 2.4.1. Contamination of food with cleaning chemicals shall be prevented.
4.2 Cleaning programmes	
4.2.1 Specifications	4.2.1.1 Cleaning and disinfection programmes shall ensure that all parts of the establishment are appropriately clean, and shall include the cleaning of cleaning equipment. Where documented cleaning programmes are used, they shall specify: <ul style="list-style-type: none"> - areas, items of equipment and utensils to be cleaned; - responsibility for particular tasks; - method and frequency of cleaning; - monitoring arrangements. Where appropriate, programmes shall be drawn up in consultation with relevant expert advisors.
4.2.2 Monitoring and verification	4.2.2.1 Cleaning and disinfection programmes shall be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.
4.3 Pest control	
4.3.1 General	4.3.1.1 Good hygiene practices shall be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and effective monitoring can minimise the likelihood of infestation and thereby limit the need for pesticides.

4.3.2 Preventing access	4.3.2.1 Buildings shall be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites.
	4.3.2.2 Holes, drains and other places where pests are likely to gain access shall be kept sealed. Where sealing is not possible (e.g. open windows, doors and ventilators) measures like wire mesh screens shall be in place to reduce the problem of pest entry.
	4.3.2.3 Animals shall, wherever possible, be excluded from the grounds of factories and food processing plants.
4.3.3 Harbourage and infestation	4.3.3.1 Potential food sources shall be stored in pest-proof containers and/or stacked above the ground and away from walls.
	4.3.3.2 Areas both inside and outside food premises shall be kept clean. Where appropriate, refuse shall be stored in covered, pest-proof containers.
4.3.4 Monitoring and detection	4.3.4.1 Records of regular examination of establishments and surroundings shall be available.
4.3.5 Eradication	4.3.5.1 Pest infestations shall be dealt with immediately and shall be carried out without posing a threat to the safety or suitability of food.
4.4 Waste management	
4.4.1 Removal, storage	Suitable provision must be made for the removal and storage of waste. Waste must not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.
4.4.2 Cleaning	Waste stores must be kept appropriately clean.
4.5 Sanitation systems	
4.5.1 Monitoring	4.5.1.1 Sanitation systems shall be monitored for effectiveness
4.5.2 Verification	4.5.2.1. Sanitation systems shall be periodically verified by inspections or, where appropriate, by microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances.
4.5.3 Review	4.5.3.1 Sanitation systems shall be regularly reviewed and adapted to reflect changed circumstances.
5 Establishment: personal hygiene	
5.1 Health status	
5.1.1 Access prevention	5.1.1.1 A system shall be in place to prevent access to any food handling area by people known, or suspected to be suffering from, or to be a carrier of, a disease or illness likely to be transmitted through food.
	5.1.1.2 Any person so affected shall immediately report illness or symptoms of illness to the management. Medical examination of a food handler shall be carried out if clinically or epidemiologically necessary.
5.2 Illness and injuries	
5.2.1 Conditions to be reported	5.2.1.1 Conditions which shall be reported to management in order to assess the need for medical examination and/or possible exclusion from food handling, include: - jaundice - diarrhoea - vomiting - fever - sore throat with fever - visibly infected skin lesions (boils, cuts, etc.) - discharges from the ear, eye or nose
5.3 Personal cleanliness	
5.3.1 Protective clothing	5.3.1.1 Food handlers shall maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering and footwear.
5.3.2 Cuts and wounds	5.3.2.1 When personnel with a minor injury are permitted to continue working, cuts and wounds shall be covered by suitable waterproof dressings.

5.3.3 Washing hands	5.3.3.1 Personnel shall always wash their hands when personal cleanliness may affect food safety, for example: <ul style="list-style-type: none"> At the start of food handling activities; Immediately after using the toilet; after handling raw food or any contaminated material which could result in contamination of other food items; they shall avoid handling ready-to-eat food, where appropriate.
5.4 Personal behaviour	
5.4.1 Smoking, eating, sneezing	5.4.1.1 People engaged in food handling activities shall refrain from behaviour which could result in contamination of food, for example: <ul style="list-style-type: none"> Smoking; Spitting; Chewing or eating; Sneezing or coughing over unprotected food.
5.4.2 Jewellery	5.4.2.1 Personal effects such as jewellery, watches, pins or other items shall not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.
5.5 Visitors	
5.5.1 Cleanliness and behaviour	5.5.1.1 Visitors to food manufacturing, processing or handling areas shall, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.
6 Transportation	
6.1 General	6.1.1 Food shall be adequately protected during transport to assure food safety.
6.2 Requirements	6.2.1 Where necessary, conveyances and bulk containers shall be designed and constructed so that they: <ul style="list-style-type: none"> - do not contaminate foods or packaging; - can be effectively cleaned and, where necessary, disinfected; - permit effective separation of different foods or foods from non-food items where necessary during transport; - provide effective protection from contamination, including dust and fumes; - can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; - allow any necessary temperature, humidity and other conditions to be checked.
6.3 Use and maintenance	6.3.1 Conveyances and containers for transporting food shall be kept in an appropriate state of cleanliness, repair and condition.
	6.3.2 Where the same conveyance or container is used for transporting different foods or non-foods, effective cleaning and, where necessary, disinfection shall take place between loads.
	6.3.3 Where appropriate, particularly in bulk transport, containers and conveyances shall be designated and marked for food use only and be used only for that purpose.
7 Product information and consumer awareness	
7.1 Batch identification	7.1.1 Batch identification is essential in product recall and also helps effective stock rotation (section 3.2.3). Each container of food shall be permanently marked to identify the producer and the batch (see: Codex General Standard for the Labelling of Pre-packaged Foods, Codex STAN 1-1985).
7.2 Product information	7.2.1 All food products shall be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store, prepare and use the product safely and correctly.
7.3 Labelling	7.3.1 Pre-packaged foods shall be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely (see: Codex General Standard for the Labelling of Pre-packaged Foods, Codex STAN 1-1985).

7.4 Consumer education	7.4.1 Health education programmes shall cover general food hygiene. Such programmes shall enable consumers to understand the importance of any product information, follow any instructions accompanying products and make informed choices. In particular, consumers shall be informed of the relationship between time/temperature control and food-borne illness.
8 Training	
8.1 Awareness and responsibilities	8.1.1 All personnel shall be aware of their role and responsibility in protecting food from contamination or deterioration. 8.1.2 Food handlers shall have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals shall be instructed in safe handling techniques.
8.2 Training programs	8.2.1 Factors to take into account in assessing the level of training required include: - the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms; - the manner in which the food is handled and packed, including the probability of contamination; - the extent and nature of processing or further preparation before final consumption; - the conditions under which the food will be stored; - the expected length of time before consumption.
8.3 Instruction and supervision	8.3.1 Periodic assessments of the effectiveness of training and instruction programmes shall be carried out, as well as routine supervision and checks to ensure that procedures are being implemented effectively. 8.3.2 Managers and supervisors of food processes shall have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies (see section 3.5).
8.4 Refresher training	8.4.1 Training programmes shall be routinely reviewed and updated where necessary.
	8.4.2 Systems shall be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

7 ANNEX II

Relationship between the “Requirements” and Codex guidelines for the application of HACCP

HACCP SYSTEM REQUIREMENTS	CODEX
5.1 Responsibility of Management 5.1.1 Policy 5.1.2 Scope 5.1.3 Task, Responsibility, Authority 5.1.4 HACCP team 5.1.5 Resources 5.1.6 Management review	1. Assemble HACCP team The food operation shall assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. This may best be accomplished by assembling a multi-disciplinary team. Where such expertise is not available on site, expert advice shall be obtained from other sources. The scope of the HACCP plan shall be identified. The scope shall describe which segment of the food chain is involved and the general classes of hazards to be addressed.
5.2 Product Information 5.2.1 Product Characteristics 5.2.2 Intended use	2. Describe product A full description of the product shall be drawn up, including relevant safety information such as: composition, physical/chemical structure (including Aw, pH, etc.), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution. 3. Identify intended use The intended use shall be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.
5.3 Process Information 5.3.1 Flow Diagrams 5.3.2 Layout 5.3.3 Control / Verification of Process Information	4. Create flow diagram The HACCP team shall create the flow diagram. The flow diagram shall cover all steps in the operation. When applying HACCP to a given operation, consideration shall be given to steps preceding and following the specified operation. 5. On-site confirmation of flow diagram The HACCP team shall confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

5.4 Pre-Requisite Program (PRP)

Prior to application of HACCP to any sector of the food chain, that sector shall be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice and appropriate food safety legislation.

Inevitably, there will be situations where some of the food hygiene requirements are not applicable. The fundamental question in every case is “what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?” In deciding whether a requirement is necessary or appropriate, an assessment of the risk shall be made, preferably within the framework of the HACCP approach.

5.5 Hazard Analysis

5.5.1 Hazard Identification (potential contaminants)

5.5.2 HACCP Analysis (risk)

6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards. The HACCP team shall list all hazards which may reasonably be expected to occur at each step, from primary production, processing, manufacture and distribution until the point of consumption.

The HACCP team shall then conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food.

In conducting the hazard analysis, the following shall be included wherever possible:

the likely occurrence of hazards and severity of their adverse health effects;

the qualitative and/or quantitative evaluation of the presence of hazards;

survival or multiplication of micro-organisms of concern;

production or persistence in foods of toxins, chemicals or physical agents;

conditions leading to the above.

The HACCP team must then consider what control measures exist, if any, which can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

5.6 Control Measures

5.6.1 Specific Control Measures (CCP related)

5.6.2 General Control Measures

7. Determine Critical Control Points

There may be more than one CCP at which control is applied to address the same hazard.

The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree, which promotes a logical reasoning approach. Application of a decision tree should be flexible, whether the operation is for production, slaughter, processing, storage, distribution, etc. It should be used for guidance when determining CCP's. The decision tree example may not be applicable to all situations. Other approaches may be used.

Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step or any other, then the product or process shall be modified at that step, or at any earlier or later stage, to include a control measure.

Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. It is not always applicable to all food operations and therefore it should be used in conjunction with professional judgement and modified where appropriate.

5.7 Parameters and limits

5.7.1 Critical process and product parameters

5.7.2 Target values, action-limit values, critical limits

8. Establish critical limits for each CCP

Critical limits must be specified and validated, if possible, for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, Aw, available chlorine, and sensory parameters such as visual appearance and texture.

<p>5.8 Monitoring</p>	<p>9. Establish a monitoring system for each CCP Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Furthermore, monitoring shall ideally provide this information in time to make adjustments to ensure control of the process is maintained to prevent violation of the critical limits. Where possible, process adjustments shall be made when monitoring results indicate a trend towards loss of control at a CCP. These adjustments should be made before a deviation occurs. A designated suitably-qualified person must evaluate data derived from monitoring and have authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCP's will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCP's must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.</p>
<p>5.9 Corrective Actions</p>	<p>10. Establish corrective actions Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposal of the affected product. Deviation and product disposal procedures must be documented in the HACCP records.</p>
<p>5.10 Validation</p>	
<p>5.11 Verification</p>	<p>11. Establish verification procedures Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification shall be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include: Review of the HACCP system and its records; Review of deviations and product disposal; Confirmation that CCP's are kept under control. Where possible, validation activities shall include actions to confirm the efficacy of all elements of the HACCP plan.</p>
<p>5.12 Documentation and Records 5.12.1 Documents, Document Control 5.12.2 Records</p>	<p>12 Establish Documentation and Records: Efficient and accurate record-keeping is essential to the application of a HACCP system. HACCP procedures shall be documented. Documentation and record-keeping shall be appropriate to the nature and size of the</p>

operation.

Documentation examples are:

Hazard analysis

CCP determination

Critical limit determination

Record examples are:

CCP monitoring activities

Deviations and associated corrective actions

Modifications of the HACCP system