



HACCP certification scheme

HACCP Certification Scheme

concerning

**“The Requirements for a HACCP
based Food Safety System”**

Version 5.1 - June 2016

Management System Certification



HACCP certification scheme

HACCP certification scheme

This document contains the complete certification scheme concerning the Requirements for a HACCP based Food Safety System. Audits against this certification scheme are carried out by the Dutch Accreditation Council (RvA) accredited certification bodies since 1997.

Due to the dynamic content of this document the user of this document should always determine if the correct version is held. Future revisions of this document will always be published under the same name. The content will state all parts of the certification scheme and will state which ones are dynamic.

In case of questions of interpretation reports of stated case reviews of the yearly auditor day HACCP are available via the website: www.foodsafetymanagement.info

Cornelie Glerum
Secretary Dutch National Board of Experts HACCP

Gorinchem, June 2016



Content

REQUIREMENTS FOR A HACCP BASED FOOD SAFETY SYSTEM.....	5
HACCP CERTIFICATION REGULATIONS.....	46
REQUIREMENTS FOR CERTIFICATION BODIES.....	56
REGULATIONS FOR THE (DUTCH) NATIONAL BOARD OF EXPERTS HACCP.....	61



Requirements for a HACCP based Food Safety System

Compiled by the National Board of Experts-HACCP
The Netherlands

June 2016



HACCP certification scheme

Requirements for a HACCP based Food Safety System, June 2016

SPECIFICATION

REQUIREMENTS

FOR A

HACCP BASED

FOOD SAFETY SYSTEM

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

Gorinchem, The Netherlands: Version 5.1, June 2016



HACCP Certification Scheme
Requirements for a HACCP based Food Safety System, June 2016

This is the authorized English translation of the specification “Eisen voor een op HACCP gebaseerd voedselveiligheidssysteem” (version 5.1, June 2016), being one of six documents which regulate the Certification Scheme for operational HACCP based food safety systems.

The other documents; the “Certification Regulations”, “The requirements for Certification Bodies, the “Regulations for the National Board of Experts – HACCP”, the current list of decisions by the National Board of Experts and Certification cases presented by the Harmonization Committee (advisory, only in Dutch) 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. The National Board of Experts HACCP has at least three meetings yearly to maintain the Certification Scheme. After every meeting major and/or minor changes are decided on and will be directly published in the current list of decisions. It can be concluded that the scheme is updated after every meeting. Revisions of all relevant documents are yearly published and available for those interested.

The National Board of Experts will review the standard at least every 3 years and make a public statement on this revision or update.

Certification/Registration of HACCP based Food Safety Systems on the basis of the preceding versions of this specification are carried out by the Dutch Accreditation Council (RvA) accredited certification bodies since 1997.

In case of doubt or conflict, evaluation and resolution will be led by the Dutch HACCP certification scheme.

Copyright 2016, Foundation for Food Safety Certification, National Board of Experts - HACCP

All rights reserved. No part of this publication may be reproduced and/or published in any form, by means of printed matters, photocopy, microfilm, recording or any other method or technology, without preceding written approval by the National Board of Experts - HACCP.

Foundation for Food Safety Certification
National Board of Experts – HACCP
P.O. Box 693
4200 AR Gorinchem, The Netherlands
t +31- 183 822 952
f +31-183 621 161
w www.foodsafetymanagement.info
@ scv@atriumgroep.nl



Content

1.	INTRODUCTION.....	8
2.	SCOPE OF APPLICATION.....	12
3.	REFERENCE DOCUMENTS.....	13
4.	TERMS AND DEFINITIONS.....	14
5.	HACCP SYSTEM REQUIREMENTS.....	17
5.1	MANAGEMENT RESPONSIBILITY.....	17
5.1.1	<i>Policy.....</i>	17
5.1.2	<i>Scope of the HACCP system.....</i>	17
5.1.3	<i>Tasks, responsibilities and authorities.....</i>	18
5.1.4	<i>HACCP team(s).....</i>	18
5.1.5	<i>Resources.....</i>	18
5.1.6	<i>Management Review.....</i>	18
5.2	PRODUCT INFORMATION.....	19
5.2.1	<i>Product Characteristics.....</i>	19
5.2.2	<i>Intended use.....</i>	19
5.3	PROCESS INFORMATION.....	20
5.3.1	<i>Flow Diagrams.....</i>	20
5.3.2	<i>Layout.....</i>	20
5.3.3	<i>Control and Verification of Process Information.....</i>	20
5.4	PRE-REQUISITE PROGRAM.....	20
5.5	HAZARD ANALYSIS.....	22
5.5.1	<i>Hazard identification.....</i>	22
5.5.2	<i>HACCP – hazard analysis.....</i>	22
5.6	SPECIFIC CONTROL MEASURES.....	23
5.7	PARAMETERS AND CRITICAL LIMITS.....	23
5.7.1	<i>Critical process and product parameters.....</i>	23
5.7.2	<i>Target values, action-limit values and critical limits.....</i>	23
5.8	MONITORING AND MEASURING.....	24
5.8.1	<i>Monitoring and measuring.....</i>	24
5.8.2	<i>Product release.....</i>	24
5.9	CORRECTIVE ACTIONS.....	24
5.9.1	<i>Corrective actions.....</i>	24
5.9.2	<i>Product Recall.....</i>	25
5.9.3	<i>Tracking & Tracing.....</i>	25
5.10	VALIDATION.....	25
5.10.1	<i>General.....</i>	25
5.10.2	<i>Validation of the hazard identification and risk assessment.....</i>	26
5.10.3	<i>Validation of specific control measures.....</i>	26
5.10.4	<i>Modifications.....</i>	26
5.11	VERIFICATION.....	27
5.11.1	<i>General.....</i>	27
5.11.2	<i>Internal audit.....</i>	27
5.11.3	<i>Management review.....</i>	28
5.12	DOCUMENTATION AND RECORDS.....	29
5.12.1	<i>Documents and document control.....</i>	29
5.12.2	<i>Records.....</i>	29
6.	ANNEX I PRE-REQUISITE PROGRAM (PRP).....	31
7.	ANNEX II RELATIONSHIP BETWEEN THE “REQUIREMENTS” AND CODEX GUIDELINES FOR THE APPLICATION OF HACCP.....	40
8.	ANNEX III EXAMPLE OF DECISION TREE.....	45



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. This is stipulated in the Regulation (EC) 178/2002 of the European Parliament and the Council of 28 January 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 – issues.

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 organization, 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 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs all food business operators in the European Union shall implement HACCP 1. 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 system 2. 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 Pre-requisite program 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 non conformities may lead to unsafe foodstuffs.⁴

¹ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ EC 2004, L139 and L226).

² Codex Alimentarius Commission, “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application”, Annex to CAC/RCP 1-1969, Rev. 4 (2009).

³ Codex Alimentarius Commission, “General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4 (2009).

⁴ To illustrate the difference between safety and suitability; sour milk is safe, but not suitable.



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 in 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.

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 processes. 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 recognized Body to operate the certification system for HACCP based Food Safety Systems⁵ 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 the Food Safety Systems 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.

⁵ The certification bodies must meet ISO/IEC 17021



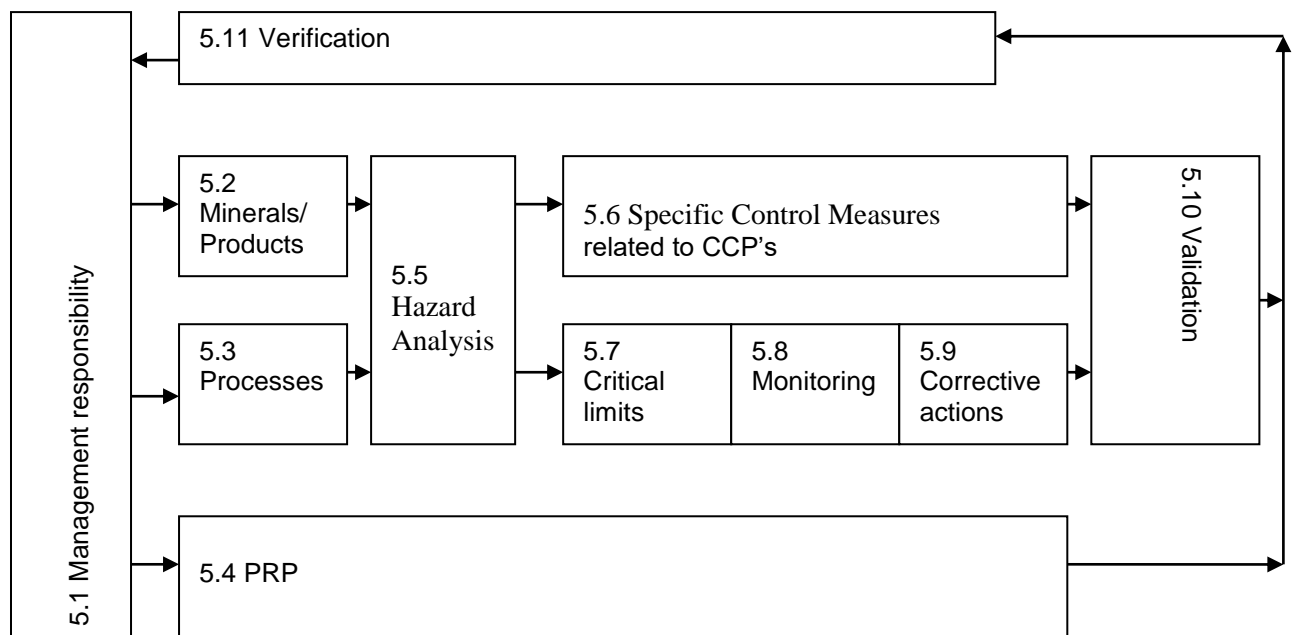
Requirements for a HACCP based Food Safety System

The requirements in this Specification provide a basis for compliance of processes 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 'work place'.

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 Alimentarius 6.

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



⁶ Codex Alimentarius Commission, "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application", Annex to CAC/RCP 1-1969, Rev. 4 (2009).



HACCP Certification Scheme

Requirements for a HACCP based Food Safety System, June 2016

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.

Developments with respect to HACCP-based Food Safety System and developments within Codex, new proposals for Food Hygiene Regulations (thereby repealing the current referenced EU Directives and Regulations) have necessitated a further revision: the 3rd version (2002)!

Further developments in establishing food hygiene regulations and the GFSI re-benchmark against the 4th edition of their Guidance Document have compelled an inevitable new revision: this 4th version (2006).

Due to the revision period there was a need for this version 5.1 (2016).



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 organizations, 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. 4 (2009).
 - Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Annex to CAC/RCP 1-1969, Rev. 4 (2009).

- 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 Regulation (EC) No 852/2004 of the European Parliament and Council of 29 April 2004 on the hygiene of foodstuff (replaces Directive 93/43/EEC (dated June 14, 1993) on Food Hygiene, which by this regulation was repealed).

- 3 National level:
Netherlands, Food and Commodity Act:
Warenwetbesluit Hygiëne van levensmiddelen van 3 oktober 2005 as in force per 1 January 2006.

- 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.

Category

Food categories according to ISO / TS 22003:2013.

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, specific

A measure to control a CCP. A certain part of the prerequisite program (e.g. cleaning of a production line between the production of allergen containing and allergen free products) also could be considered to be a specific control measure.

Corrective action

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

Corrective measure

Measure with respect to food safety which will be taken to eliminate the cause of a detected deviation, defect or other undesirable situation to avoid reoccurrence.

Deviation: not compliant to a specified requirement.

Defect: not compliant to a requirement or reasonable expectation regarding the use, including those applicable to food safety.

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 supplies 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.

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 organizational 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.

Non-Conformity

An observation, which leads to a minor non conformity report, relates to the missing of follow up, or control of implementation of a HACCP-requirement, in the situation that this does not effect the functioning of the HACCP system or the food safety of the product or service.



An observation, which leads to a major non conformity report, relates to insufficient implementation of one or more HACCP requirements or to a situation where the food safety of the product or service is not assured.

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 non conformities, 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.

Remark

An observation reported as a remark relates to an aspect which needs attention of the company, but is by no means a non conformity (NC) in relation to the HACCP-requirements

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.

(sub) category

Specific classification per category (for example: in the primary category of cattle breeding, 2 subcategories are distinguished: (1) cattle (game) breeding (meat) and (2) primary animal produce (milk, honey and eggs).

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 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 organization. The food business operator has ultimate responsibility for the policy of the organization 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 management shall ensure that

- customer requirements, and
- the requirements of laws and regulations on food safety are determined.

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 organization with regards to food safety. It will demonstrate the commitment of the organization to safe food. The policy shall demonstrate that the organization 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 objectives ⁷ (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 organization.

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.

⁷ SMART objectives are Specific, Measurable, Acceptable, Realistic objectives, defined in Time.



5.1.3 Tasks, responsibilities and authorities

The food business operator shall establish clear job descriptions 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 organization chart and the organization's reporting structure shall be documented.

Where the assistance of an external expert is required for the development, implementation, execution or review of the food safety system a written agreement in which the responsibilities and authorities of this external expert are described shall be included.

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 organization 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 coordinator 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 HACCP verification (5.11) shall be used as input for this review.

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 (including allergens), 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 shall 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, allergens, 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 organization. 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.

Specific food safety requirements are detailed in legislation, hygiene codes and customer or consumer specifications. Where specific requirements do not exist, the appropriate pre-requisite programs will be applied (see Annex I). The Codex General Principles of Food Hygiene lay a firm foundation for ensuring food safety and suitability.



HACCP Certification Scheme
Requirements for a HACCP based Food Safety System, June 2016

The food business operator shall decide which food hygiene principles, good manufacturing practices and food legislation must be included in the PRP of the organization 8.

Purchase programs shall result in a classification of food safety risks of suppliers and their products (5.5.1) as well as the controlled method of assessment and reassessment.

Dependent of the importance of food safety (see 5.6), the relevant basic prerequisite monitoring procedures must be introduced in which responsibilities, accountability and required records are set. The organization shall identify the causes of variations in the basic pre-requisite program to remove and to prevent recurrence. Corrective actions must be consistent with the effects of the deviations that occur.

The prerequisite program shall be verified in terms of implementation and effectiveness at pre-determined and regular intervals (Section 5.11).

The basic requirements related to the prerequisite program have been reviewed in annex I and are summarized in Figure 2.

Figure 2: Summary of the Codex General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4 (2009))

1 Primary production Environmental hygiene Hygienic production of food sources Handling, storage and transport 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 behavior 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 Labeling 7.4 Consumer education
4 Establishment: maintenance and sanitation 4.1 Maintenance and cleaning 4.2 Cleaning programs 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

⁸ 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 Analysis

The food business operator (HACCP team) shall identify, analyze 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 organizations (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
- Commodities;
- Process control within the chain;
- Characteristics of interim and end products (product specifications);
- Characteristics of used processes, including subcontracted services, etc.;

For each of the identified food safety hazards acceptable levels shall be determined and recorded for the food safety hazard in the end product. The level must meet the requirements with respect to food safety as laid down in laws and regulations and defined by customers.

5.5.2 HACCP - hazard analysis

The food business operator (HACCP team) shall conduct a HACCP hazard 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 hazard 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 development or the presence of contaminants including persistence of toxins, chemicals or physical contaminants in foods;
- cross contamination with allergens
- the conditions leading to the above.

The method used must be documented and the outcome of the hazard analysis must be recorded. The motivation / substantiation in the process of weighting/estimating the risks shall be clearly indicated.

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 hazard analysis, practical experiences, experimental data, professional literature, etc., shall be taken into account and be documented.



5.6 Specific Control Measures

The HACCP team shall identify and document all the control measures that are to be implemented when the hazard identification and hazard analysis concludes that the risk associated with each step in the process of an identified hazard is significant for controlling food safety. Identified management measures must be implemented effectively.

The HACCP team must conduct an assessment for each control measure, for example by means of a decision tree (see annex III), to determine whether it is a CCP. The substantiation must be registered. 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 related to CCP's shall be classified as specific control measures intended to avoid or eliminate hazards, or to reduce and control these hazards at an acceptable level. 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). Consideration shall be given that a certain part of the prerequisite program (e.g. cleaning of a production line between the production of allergen containing and allergen free products) also could be considered to be a specific control measure.

Control measures not classified as specific control measures are managed through the pre-requisite program (see 5.4).

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 shall establish and maintain an adequate practice with regard to the control and application of the relevant standards and critical limits. 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

5.8.1 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 means used to develop, establish and implement the measuring system must be described.

The means used to execute and track measuring requirements shall be recorded and include the following;

- surveillance tools that are used;
- frequency of monitoring;
- responsibilities and powers with regard to monitoring and assessment of the surveillance results.

The results of the monitoring shall be recorded including at least:

- monitoring reports (dated and signed);
- records of non conformities which have occurred (action limits and critical limits) and corrective actions taken.

The measuring equipment and methods used

- a) shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded,
- b) shall be adjusted or re-adjusted as necessary,
- c) shall be identified to enable the calibration status to be determined,
- d) shall be safeguarded from adjustments that would invalidate the measurement results, and
- e) shall be protected from damage and deterioration.

Registrations of the results of calibrations and authentication as well as the measures to process/product in the case of derogations shall be tracked (5.12.2).

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

5.8.2 Product release

Products can only be released when non conformities of products are absent and no corrective actions are necessary.

5.9 Corrective Actions

5.9.1 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 shall 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).



HACCP Certification Scheme Requirements for a HACCP based Food Safety System, June 2016

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.

5.9.2 Product Recall

The food business operator shall establish arrangements that provide procedures for recall of the products from the market place and/or from end consumers.

Actions and provisions with respect to product withdrawal and recall as defined in 5.9.1 en 5.9.2 shall be tested for effectiveness at a predetermined frequency but at least annually.

5.9.3 Tracking & Tracing

The Organization must ensure an effective tracking & tracing procedure. Products and parties must be registered and identified in order to assure that traceability and recall is possible ('General Principles of Food Hygiene, Codex Alimentarius', 7.1 – Annex 1 page 39).

5.10 Validation

5.10.1 General

Validation is not a part of verification, but a separate activity prior to authorizing the HACCP plan⁹.

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 and evaluated under the proposed plan.
- To provide evidence that selected specific control measures are appropriate to control food safety hazards for which these measures have been adopted and result in end products meeting customer and regulatory requirements with respect to food safety.

⁹ In the document "Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application" (Annex to CAC/RCP 1 –1969, Rev.4, 2009) 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.



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 specific control measures, the monitoring system and corrective actions.

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.

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 to validate. It is important to note that the data must be quantifiable and objective to be of any use.

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

5.10.2 Validation of the hazard identification and risk assessment

Validation of the identification and evaluation of risk to food safety shall be 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.

5.10.3 Validation of specific control measures

Validation is demonstrated by means of documented evidence that:

- all related, critical measurement and process equipment is properly installed and functioning properly;
- the installed process and measurement equipment is functioning properly under all circumstances permitted;
- for process indicators limits have been established within which the process is regarded as being controlled ("challenge" tests, worst case conditions);
- the control measures are effective and thus prevent unsafe product being released or provide evidence that the situation can be corrected immediately.

5.10.4 Modifications

The hazard identification and evaluation and thus the validation must be updated every time the organization introduces changes that could have a potential effect on food safety. Such changes could include changes in control measures, raw materials, processes, characteristics of the finished product or the intended use of the product.



5.11 Verification

5.11.1 General

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, non conformities and corrective actions taken to seek confirmation of implementation and effective control of CCP's;
- Compliance of the actual flow diagrams and layout with the documented situation;
- Evaluation of the implementation (practice) and effectiveness of the pre-requisites program (5.4);
- 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;
- Results of internal audits.

5.11.2 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.



5.11.3 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.

The food business operator shall collect and analyze 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. 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 and the functioning of other control measures. 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 shall include:

- 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 the management measures and the determination of the Specific Control Measures (CCPs);
- Monitoring reports (dated and signed) of the Specific Control Measures to demonstrate the control of the related CCP's;
- Records of non conformities occurred (exceeded action limits and critical action limits) of the Specific Control Measures and the corrective actions taken;
- Records of non conformities and actions taken in case of deviations of the prerequisite program.
- Records of the results of calibration and verification and measures to be taken to process/product in case of non conformities
- Records related to the verification program (including internal audits) and their evaluation;



HACCP Certification Scheme
Requirements for a HACCP based Food Safety System, June 2016

- Records that are relevant to ensure traceability of foodstuffs;
- Records regarding registration of complaints, handling of complaints and corrective actions undertaken.



6. ANNEX I: PRE-REQUISITE PROGRAM (PRP)

(Reference: Codex Alimentarius, "General Principles of Food Hygiene", CAC/RCP 1-1969, Rev. 4 2009)

The PRP has general requirements for food hygiene

Pre-requisite program (PRP)	
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 minimize 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, fertilizers (including natural fertilizers), 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 programs 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: <p>any necessary cleaning and maintenance is carried out effectively;</p> <p>an appropriate degree of personal hygiene is maintained.</p>
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.



HACCP Certification Scheme

Requirements for a HACCP based Food Safety System, June 2016

2.1.2 Equipment	<p>2.1.2.1 Equipment shall be located so that it:</p> <ul style="list-style-type: none"> • permits adequate maintenance and cleaning; • functions in accordance with its intended use; • facilitates good hygiene practices, including monitoring.
2.2 Premises and rooms	
2.2.1 Design and lay-out	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 minimize the build up of dirt and condensation and the shedding of particles.
	2.2.2.6 Windows shall be easy to clean, constructed to minimize 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 harboring 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.



HACCP Certification Scheme

Requirements for a HACCP based Food Safety System, June 2016

	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 disposal	2.4.2.1 Drainage and waste disposal systems shall be available, designed, 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"> • minimization 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.



HACCP Certification Scheme

Requirements for a HACCP based Food Safety System, June 2016

	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 minimize contamination, prevent damage and accommodate proper labeling.
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 Re-usable packaging	3.4.3.1 Re-usable packaging shall be suitably durable, easy to clean and, where necessary, disinfect.



HACCP Certification Scheme

Requirements for a HACCP based Food Safety System, June 2016

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: <ul style="list-style-type: none"> • 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 programs	
4.2.1 Specifications	4.2.1.1 Cleaning and disinfection programs shall ensure that all parts of the establishment are appropriately clean, and shall include the cleaning of cleaning equipment. Where documented cleaning programs 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, programs shall be drawn up in consultation with relevant expert advisors.
	4.2.2 Monitoring and verification
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 minimize 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 Preventing access	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 Harborage and infestation
4.3.3 Harborage 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.



HACCP Certification Scheme
Requirements for a HACCP based Food Safety System, June 2016

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: <ul style="list-style-type: none"> • jaundice • diarrhea • 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.



HACCP Certification Scheme

Requirements for a HACCP based Food Safety System, June 2016

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	<ul style="list-style-type: none"> • 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).



HACCP Certification Scheme
Requirements for a HACCP based Food Safety System, June 2016

7.4 Consumer education	7.4.1 Health education programs shall cover general food hygiene. Such programs 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: <ul style="list-style-type: none"> • 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 programs 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 non conformities (see section 3.5).
8.4 Refresher training	8.4.1 Training programs 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 Specific 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.

Parameters and limits

Critical process and product parameters

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.



5.8 Monitoring

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.

5.9 Corrective Actions

10. Establish corrective actions
 Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with non conformities 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.

5.10 Validation



HACCP Certification Scheme

Requirements for a HACCP based Food Safety System, June 2016

5.11 Verification

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 non conformities 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.

5.12 Documentation and Records

12 Establish Documentation and Records:

5.12.1 Documents, Document Control

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 operation.

5.12.2 Records

Documentation examples are:

- Hazard analysis
- CCP determination
- Critical limit determination

Record examples are:

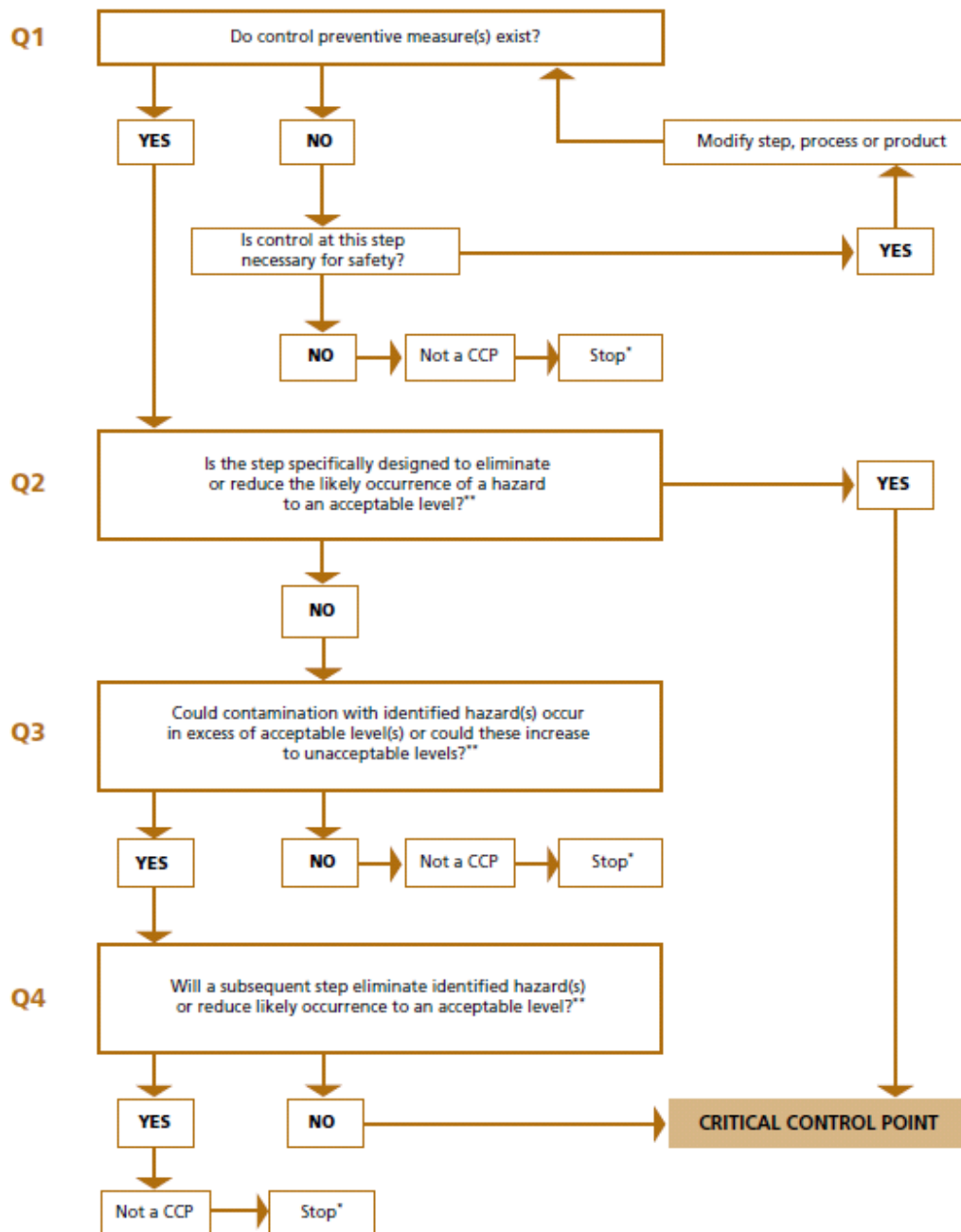
- CCP monitoring activities
- Non conformities and associated corrective actions
- Modifications of the HACCP system



8. ANNEX III EXAMPLE OF DECISION TREE

Example of decision tree to identify CCPs

(Answer questions in sequence)



* Proceed to the next identified hazard in the described process.

** Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.



HACCP CERTIFICATION REGULATIONS 2016

Article 1

These certification regulations apply to accredited certification bodies that have subscribed to the (Dutch) National Board of Experts HACCP (NBE-HACCP). In addition these regulations also apply to food processing businesses that receive assessment by these certification bodies in order to be granted a HACCP certificate. Certification bodies that are particularly accredited for this purpose issue HACCP certificates. The certificate provides buyers, consumers and other parties with justified assurance that the management and control of the safety of the food product meet the Requirements for a HACCP based Food Safety System and, in by doing so, the legislative/regulatory requirements with respect to HACCP. The overall basic requirements for hygiene, the GMP requirements, form part of these certification criteria. In most cases, these GMP requirements are mandatory by national legislation.

Article 2

The NBE-HACCP is authorized to decide on admitting certification bodies that are recognized by other accreditation bodies than the Dutch Council for Accreditation. Before admission is granted proof must be provided that this accreditation is comparable to the accreditation by the Dutch Council for Accreditation, at the discretion of the NBE-HACCP.

Article 3

The certification bodies are responsible for the full application of the certification scheme and have to observe the regulations and directives issued by the NBE-HACCP.

Article 4

Where these regulations do not stipulate any other requirements with respect to the HACCP certification process, the certification bodies have to apply the procedures set in force for the accredited certification of quality systems based on ISO/IEC 17021 and ISO/TS 22003.

Article 5

The certification bodies are obliged to apply the HACCP certification scheme as established by the NBE-HACCP. The scheme contains the certification criteria, methods of examination, the requirements for certification bodies with respect to the scope of activities, expertise and certification personnel (e.g. auditors and decision makers) and the procedures with regards to audits and their frequency. With regards to non conformities revealed, certification bodies are required to establish and maintain criteria for application of major and non-critical non conformities, in accordance with the specifications in the EA and/or IAF guidelines pertaining to ISO/IEC 17021. Only food operating businesses where no critical non conformities have been revealed in their HACCP system, can qualify for granting the HACCP certificate. HACCP certificates may only be issued on the basis of the actual status of the HACCP system of the food operating business and not on the basis of proposed or expected measures.



Article 6

The certification bodies must employ proven expertise and experience at three levels:

1. Audit team:

The requirements required in respect of auditors and the audit team are stipulated in the document Requirements for Certification Bodies concerning scope, expertise and certification personnel.

2. Staff:

The certification body is required to appoint at least one officer who is assigned the following duties:

- conduct of the contract review
- selection, training and informing/instruction (briefing) of audit teams
- participation in Harmonization Committee discussions carried out by certification bodies
- central point of contact for the NBE-HACCP.

The (collective) requirements demanded of this officer are that he/she must:

- be employed by the certification body (no on-the-job contracting; not necessarily full-time)
- meet the requirements with respect to 'HACCP auditor', as specified in the aforementioned Requirements for Certification Bodies concerning scope, expertise and certification personnel.
- have a minimum of five years' working experience in the relevant sector in one or more of the following sensitive subcategories:
 - primary animal products
 - cattle breeding
 - other primary sectors
 - egg-production and egg products
 - chopped fruit and vegetables
 - meat and meat products (unpacked and refrigerated)
 - fish and shellfish
 - dairy products.

For certification bodies which have only been accredited for 'other primary sectors', only the first three 'sensitive' sectors apply. In this case, other 'sensitive' sectors are not taken into consideration.

3. Decision maker(s):

The decision maker(s), responsible for granting, maintaining, extending, suspending and withdrawing HACCP certificates is/are required to satisfy each of the following criteria:

- be employed by the certification body (no on-the-job contracting) or be an independent panel of (wholly or partially external) experts, which is an integral part of the organizational structure of the certifying body;
- meet the requirements for 'HACCP auditor', as specified in the aforementioned;
- have a minimum of five years' working experience in the relevant sector in one or more of the following risk sensitive subcategories:
 - primary animal products
 - cattle breeding
 - other primary sectors
 - egg-production and egg products
 - chopped fruit and vegetables
 - meat and meat products (unpacked and refrigerated)
 - fish and shellfish
 - dairy products.

For certification bodies which have only been accredited for subcategories AI, AII, BI and BII, only the first three sensitive subcategories apply (primary animal produce, cattle breeding and other primary sectors). In this case the other sensitive subcategories are not taken into consideration.



ATT: The decision maker(s) and the staff officer ('HACCP co-coordinator') may be one and the same person, but may not participate in the audit team that has carried out the assessment in question.

Article 7

The period of the contract between the certification body and the food-processing organization shall last for 3 years. Reassessment, which takes place on expiration of these three years, is conducted in accordance with the initial assessment. By definition, during the initial certification period of three years a regime of semi-annual surveillance's will be in force.

The control frequency is dependent on the type of organization.

Category A and B (primary sector) and category FI, GI and GII (supporting industry) companies can be inspected each year when:

- at least two semi-annual surveillance's have been conducted following the initial certification audit;
- at control or re-assessments no major non conformities and a maximum of 3 minor non conformities are identified.

When these criteria are not satisfactory, the frequency of control is semi-annual.

The inspection frequency for category CI, CII, CIII, CIV, E and K (food manufacturing) companies is semi-annually.

Article 8

The certification body is required to apply the Calculation Model in the Rules for Time Allocation with respect to HACCP Audits, for determining the minimum auditor days for the initial certification audit, surveillance's and the re-assessment. The Calculation Model is enclosed as Appendix I to these HACCP certification regulations.

Article 9

During the initial assessment, the certification body is required to assess whether all Critical Control Points (CCPs) have been identified and are being monitored. A number of CCPs will be investigated with sufficient depth as much as possible at processes in action for implementation in practice. The initial investigation (on site certification audit) will be conducted in accordance with the two phase methodology as pointed out in ISO/IEC Guide 66/1998, article 5.3. Both phases are to be conducted at the company site. During Phase 1 the audit team will investigate the system documentation, especially the process, thoroughness and correctness of the hazard analysis and HACCP-analysis (risk), the HACCP-plan and the validation of this plan. The Phase I investigation will consist of a documentation investigation, a company survey and a planning of the Phase II investigation. The interval between Phase I and Phase II may not be longer than 6 months. The stage 1 audit should be repeated if a longer interval is needed.

4. The audit team will examine whether – seen the activities of the organization - all CCPs have been identified and whether all CCPs are being controlled as well as being monitored.
5. If the organization has defined an inordinate number of CCPs, the certification body is required to make a precise assessment of the level of expertise within the organization. In the event of an inordinate number of CCPs being identified, the HACCP analysis has most likely been carried out with an insufficient level of expertise and a major non-conformity is to be revealed. Before the start of the certification audit at-site, the organization is required to initiate a modified HACCP analysis with an acceptable number of CCPs and to make changes to the HACCP system (including the documentation).
6. After Phase I (if necessary, following any additional measures as indicated under 2), the audit team conducts a (risk) analysis of the CCPs identified by the organization and selects those CCPs (nature and number) for which a more in-depth assessment is necessary on site. On the basis of this in-depth assessment of the CCPs, a sound judgement shall be provided with respect to the conformity of the organization to the HACCP criteria.
7. As an integral part of the Phase I investigation the audit team will conduct an inspection at the site. During the on-site inspection the implementation of the 'Requirements' are assessed. Any non



conformities with regard to GMP/GHP and or the prerequisite program are to be reported specifically.

The report of the Phase 1 investigation must show which elements of the prerequisite program are assessed and to what extent the requirements are fulfilled.

8. Information or data of the hazard analysis and the HACCP-analysis, the validation and the companies HACCP-plan as well as the validation of the CCP's selected by the audit team are to be reported in a thorough and in-depth report.

During the following Phase-II-investigation the audit team will judge the implementation of the Food Safety System.

This assessment will also include a check if any non-conformities, reported in Phase I during the on-site inspection, are discontinued and arrangements to the Food Safety System to do so, are assessed. If necessary the HACCP analysis will be judged again whether it sufficiently encompasses the in practice occurring potential dangers.

During surveillance visits the implementation of the system and effective control of the processes/products will be reviewed by sampling. In the three year period ALL CCPs shall be assessed with full depth. However, by doing so, the certifying body must take into account new circumstances and new CCPs. The report with regard to any information or data of the hazard analysis and the HACCP-analysis which is drawn up during the initial investigation, as well as the CCPs assessed, has to be updated after every audit.

All sites of the certified legal entity shall be audited at least once during the three-year period, regardless of the absence of CCPs.

Article 10

During each assessment, the certification body is required to investigate the handling of complaints and any writings to relevant governmental inspection bodies that have been registered. Any complaints on the part of the authorities, related to the HACCP system can therefore provide a better insight into the functioning of the HACCP system.

Article 11

Organizations may not display the HACCP certification logo or mention possession of a HACCP certificate on their products.

Article 12

In the event of the relevant documents (certification scheme) being changed, organizations will be given 6 months' time of grace to adapt to the implementation of the new requirements, unless the legal regulations stipulate a different transition period.

Article 13

At least once per year, the certification bodies are obliged to provide the NBE-HACCP on request with all the information relating to the nature, the content and the functioning of the HACCP scheme. This information shall be made anonymous so that confidentiality with respect to organizations is assured.

Article 14

The certification bodies are required to ensure that the regulations, which are decided by the NBE-HACCP and accepted by the certification bodies, are established, authorized and included in their existing system documentation within a period of 2 months. Certification bodies are required to control these documents according to their own document control procedures.



Article 15

New information or changes with regards to the HACCP certification system are to be communicated by the certification bodies to those parties involved, such as certificate holders and HACCP auditors (auditors and experts) within a period of 2 months.

Article 16

If required by certification bodies or by organizations, the NBE-HACCP can be called to intervene in the event of different opinions in the interpretation of the certification scheme. The NBE-HACCP will however not make any judgements with regards to individual disputes or appeals. The appeal regulations of the certification body are applicable to these disputes or appeals.

Article 17

The audit report on the status of the HACCP system will comply with the extensive method which basics are set out in Appendix II. Application of this model is required for all assessments, including surveillance's. The report should show a faithful representation.

Article 18

The Dutch National Board of Experts HACCP approved these regulations on June 2016.

Appendix 1: 'Rules for Time Allocation with respect to HACCP Audits'

Appendix II: Basics for the audit report



APPENDIX 1 TO HACCP CERTIFICATION REGULATIONS 2016

Time allocation for HACCP Audits

The basis is formed by a table (Table 1) in which is indicated the minimum number of auditor-days, dependent on the total number of employees involved within the scope of the audit, together with four categories of activities of the company concerned. The total number of employees is the total number of employees on day shift plus the total number of employees in the largest shift (all expressed in full-time equivalents (FTEs)).

The number of auditor-days shown is applicable to initial audits. This basic table is applicable to the simple situation of a company with one group of products, one location and a low level of risk.

TABLE 1 - Minimum number of auditor-days

Number of employees (FTEs)	Initial audit - auditor-days			
	Company activities			
	A	B	C	D
1-19	2.5	2	1.5	1.5
20-29	3	2.5	2.0	1.5
30-59	4	3.5	2.5	2
60-100	5	4	3.5	3
100-250	6	5	4.5	4
250-500	8	7	6	5
500-1000	10	9	7	6

ATT. The time is shown in auditor-days; the minimum length of an auditor-day is 8 hours!

The table below links the food chain categories in accordance to ISO/TS 22003 and the company activities.

TABLE 1A

Company activities	ISO/TS 22003: 2007	ISO/TS 22003: 2013
A	A,B,C,D,E,G,L	A,B,C,E,K
B	A,B,C,D,E,G,L	A,B,C,E,K
C	H,J	F,G
D	H, J	F,G



Explanation:

Jobs

Calculated is the total number of employees that are involved within the scope of the audit of the organization. The total number of employees is the total number of employees on the day shift and the total number of employees in the largest team (all FTE's).

Considered as employees are not only those employed permanently, but also hired-in/temporary employees. The largest number of employees is the determining factor, taking into account any possible seasonal work.

The certification bodies are allowed to give a motivated discount if employees perform the same activities. The minimum audit duration as stated in ISO/TS 22003 is to be respected and should be based on the actual number of staff.

Company activities

A = preparation, processing, handling, packaging, transport, distribution and retailing

B = preparation, processing, handling and packaging

C = sorting, transport, distribution and retailing of unpackaged foodstuffs¹⁰

D = sorting, transport, distribution and retailing of packaged foodstuffs¹¹

The time indicated (auditor-days) is the estimated time for the phase 1 and phase 2 study, excluding preparation and reporting. Phase 1 and phase 2 study must be carried out on site.

Compensation should then be applied for exceptional circumstances, i.e. variations from the simple situation, for which the factors shown hereunder are to be used.

Outline risk level of the product and/or product group

Distinction is made between high and low risk. Used in calculating risk level are the product-inherent aspects, such as: number and origin of raw materials, microbiological-chemical-physical risks and technological aspects of production. In order to be able to establish the risk level, is made use of a list of product categories. To this end, Table 2 is applied. In the case of multiple product groups, the highest level of risk of the various product groups is taken as the basis.

TABLE 2 – Categorization of foodstuffs companies according to risk level

Product group	Risk level	
	Low	High
egg processing and egg products		X
dairy - chilled and frozen (dairy, milk products, ice cream and cheese (except hard cheese))		X
ready to eat or heat (chilled and frozen), including cooked meat and cooked fish products, salads, sandwiches		X
restaurants, hotel catering, canteens, kitchens		X

¹⁰ both the sorting en packing of unprocessed agricultural products derived directly from a farm

¹¹ both the sorting en packing of unprocessed agricultural products derived directly from a farm



other food categories	X	
-----------------------	---	--

The number of different product groups

In general within the company, different product groups will follow different production processes; as a consequence, the amount of time required for auditing will increase. As a definition is given that products belong to the same product group provided that there are no (significant) differences in the risk analysis in relation to the entire production process. In this, consideration should be given to the process and production characteristics. In almost all cases this can be derived from the scope that the company is required to provide; if this is not the case, the number of product groups can be established in consultation with the company or the risk analysis can be submitted in advance. The number of production lines is not taken into account further, as it is assumed that this is allowed for sufficiently by the number of employees.

Number of locations

In principle, each location of the company must be visited individually during all types of HACCP audit (initial assessment and follow-up audits). Each location is certified separately and receives its own certificate. Multisite is permitted in accordance with the requirements of ISO/TS 22003. The table is applied to each location, and the total is the total sum of the days needed for all the individual locations. If a main location and limited number of complementary sites have one central management system it is possible to issue not-autonomous certificates to the complementary sites. In each type of visit all locations should be visited, with the time spent per location calculated under the existing rules within the Certification Regulations.

In certain instances, (a well-founded and documented) reduction in the time can be given on the basis of the uniformity of multiple locations included in the study on the basis of proven uniformity, without the application of a multi-site approach. This cannot be covered in a table and will have to be substantiated on a case for case basis by the CB.

Time used for reporting

Typically, a minimum period of 4 hours will be necessary to cover making a report on an initial assessment or a reassessment, with 2 hours being necessary for a control audit. This time use should be added to the table.

The factors 'risk level' and 'number of product groups' have been incorporated in Table 3, in which is shown the number of days that would be added to the days in the basis table (Table 1) in a situation under consideration (Table 1).

TABLE 3 – Additional number of auditor-days

Number of product groups	Risk level	
	Low	High
1-2	0	1
3-4	0.5	1.5
5-7	1.5	3
8 or more	3	5

Follow-up audits and reassessments

The above refers to initial audits. The following instructions are applicable to follow-up audits and reassessments:

- In the case of follow-up audits, ca. 30% of the time is used for classification in groups A and B and ca. 20% of the time is used for classification in groups C and D.



- Approximately 80% of the initial audit time will be calculated for a complete reassessment. This initial audit time is the time as it is calculated for the situation prevalent at the time of reassessment (this can vary from the initial audit carried out).



APPENDIX II: BASICS FOR THE AUDIT REPORT

General objectives

- The report should contain information that primarily concerns the audited company.
- The Phase 1 and Phase II reports and the re-assessment report can differ.
- All below mentioned elements can be taken up in the report or added as an appendix.

Phase I Investigation

This report should at least contain the following elements:

- The requirements for a HACCP based Food Safety System, version 5.1, June 2016. Audit plan with date and place of execution. A description of the audited functions and processes;
- Description of the company (name legal entity and address);
- Scope;
- Description of the audit team members;
- Description of the representatives of the auditee;
- Conclusions (overview of agreed actions for Phase II investigation);
- Overview of Major and Minor NC's as well as remarks together with corresponding paragraph number and description;
- Documentation with an emphasis on the risk-analysis (general overview and in-depth description)
- Description of CCP's related to every process step;
- The auditor decides during the phase 1 audit which CCP's will at least be investigated thoroughly and registers this;
- Validation (general view / depth);
- PRP (General overview of the company survey and its results as well as a short checklist of the aspects of the PRP).

Phase II Investigation

This report should at least contain the following elements:

- The requirements for a HACCP based Food Safety System version 5.1, June 2016. Audit plan with date and place of execution. A description of the audited functions and processes;
- The Audit plan with date an place of execution and functions and processes that have been audited;
- Description of the company (name legal entity and address);
- Scope;
- Description of the audit team member;
- Description of the representatives of the auditee;
- Summary including conclusions and recommendations on certification;
- Overview of Major and Minor NC's as well as remarks together with corresponding paragraph number and description;
- Overview of relevant changes to documentation, processes and products;
- Description of CCP's reviewed. Indication of random sampling and result of this assessment.
- Verification (General overview / in-depth report);
- PRP (General overview of the company survey and its results as well as a short checklist of the aspects of the PRP);
- Registered complaints on Food Safety and reports to concerning government;
- Observation, evidence, conclusions, in accordance with regulations of the specific type of assessment.

Surveillance audit

This report should at least contain the following elements:

- Version of the Scheme;
- Audit plan with date an place of execution and functions and processes that have been audited;
- Description of the company (name legal entity and address);



- Scope;
- Description of the audit team member;
- Description of the representatives of the auditee;
- Summary including conclusions and recommendations on certification (recommendation);
- Overview of Major and Minor NC's as well as remarks together with corresponding paragraph, number and description;
- Overview of relevant changes to documentation, processes and products;
- Description of CCP's reviewed. Indication of random sampling and result of this assessment;
- Verification (General overview / in-depth report);
- PRP (General overview of the company survey and its results);
- Registered complaints on Food Safety and reports to concerning government;
- Observation, evidence, conclusions, in accordance with regulations of the specific type of assessment.



REQUIREMENTS FOR CERTIFICATION BODIES in respect of SCOPE OF ACTIVITIES, EXPERTISE and CERTIFICATION PERSONNEL

Introduction

This document stipulates the requirements for certification bodies and their personnel. These requirements have been drawn up by the (Dutch) National Board of Experts HACCP (NBE-HACCP) and apply to all certification bodies which are associated to the NBE-HACCP and are authorized to grant certificates in accordance with the 'Requirements for a HACCP based Food Safety System'.

These requirements are an explanation of the clauses in the accreditation standards ISO/IEC 17021, in particular the requirements relating to scope of activities and competence.

These requirements shall form an integral part of the internal rules and regulations of the certification body.

These requirements relate to the following aspects:

- the scope (field of work) of the accreditation
- the audit team and auditors
- staff personnel
- participate Harmonization Committee

1. Scope of the accreditation

The 'Requirements for a HACCP based Food Safety System' apply in the food preparation and food processing industries/organizations, including the primary sector and the transport and storage of foodstuffs and beverages.

The certification bodies are to be accredited on the basis of the standard ISO/IEC 17021:2011 and ISO/TS 22003:2013.

With regards to the scope, the certification body can be accredited for one or more categories (ISO/TS 22003:2013):

- AI Primary sector (cattle breeding);
- All Primary sector (fish, crustacean and shellfish farming);
- BI Primary sector (agricultural and horticultural produce);
- BII Primary sector (agricultural and horticultural produce);
- CI Food-processing industry (perishable animal products, including all processing and treatment activities after primary production e.g. slaughtering);
- CII Food-processing industry (perishable agricultural and horticultural produce);
- CIII Food-processing industry (perishable produce of mixed origin (animal and vegetal));
- CIV Food-processing industry (processing and treating products with a long shelf life at ambient temperature);
- E Catering;
- F Distribution;
- GI Transport and storage of perishable produce;
- GII Transport and storage of non-perishable produce;
- K (Bio)chemical manufacturing.

However mentioned in ISO/TS 22003:2013 Service activities; such as cleaning of processing equipment or supply companies (e.g. manufacturing packaging materials) do NOT fall under the scope of accreditation for HACCP certification.

When applying for accreditation as well as association with the (Dutch) National Board of Experts HACCP, the certification body must specify the required category and subcategories, related to its competence and experience. A certification body does not need expertise in all subcategories.



Note: a contract with the certification body will only be entered after it has been accredited for HACCP system certification in accordance with the requirements of the NBE-HACCP.

The applicant certification body will be given written authorization enabling it to use the 'Requirements for a HACCP based Food Safety System' for the accreditation procedure.

2. The requirements of HACCP auditors

As a general rule, where no additional requirements are specified, the requirements given in ISO/TS 22003:2013 shall be applied.

These requirements relate to the appointment of HACCP auditors and/or HACCP audit teams. With respect to the expertise in specific subcategories, the NBE-HACCP has made the following category and subcategories:

- AI Primary sector (cattle breeding)
 - cattle (game) breeding (meat);
 - primary animal produce (milk, honey and eggs);
- All Primary sector (fish, crustacean and shellfish farming)
 - fish, crustacean and shellfish farming;
- BI Primary sector (agricultural and horticultural produce)
 - agricultural produce (except for grains and legumes /pulses);
 - horticultural produce (including nuts, herbs and spices);
- BII Primary sector (agricultural and horticultural produce)
 - agricultural produce (grains and pulses);
- CI Food-processing industry (perishable animal products, including all processing and treatment activities after primary production e.g. slaughtering)
 - meat and meat products;
 - fish, crustaceans and shellfish;
 - dairy products, including ice-cream and desserts;
 - eggs and egg-based products;
- CII Food-processing industry (perishable agricultural and horticultural produce)
- CIII Food-processing industry (perishable produce of mixed origin (animal and vegetal))
- CIV Food-processing industry (processing and treating products with a long shelf life at ambient temperature)
- E Catering
 - catering, canteens, restaurants, kitchens (institution-related);
- FI Distribution
 - sales or trade;
 - distribution;
 - repacking/rewrapping (wrapping to hold the product combined, not to protect the product);
- GI Transport and storage of perishable products
- GII Transport and storage of non-perishable products
 - transport;
 - storage;
- K (Bio)chemical manufacturing
 - additives, including vitamins and flavourings.

Note: if an organization has been audited in a subcategory, but is included in the category, it is the responsibility of the certification body to consider an appropriate application.



Requirement of Notification:

For the time being, NBE-HACCP does not intend to set up or require a central register of HACCP auditors. It is up to the certification bodies themselves to register the competence levels of auditors per individual category and subcategories.

2.1 General requirements

The following underlying principles have been established for the selection and qualification of suitable HACCP auditors:

Subject matter related competence:

This relates to expertise of the subcategory, the products and production processes as well as an understanding of contamination aspects (chemical and physical).

Areas of expertise include:

- technology;
- microbiology;
- raw materials;
- knowledge of products.

Depending on the subcategory, one or more of the specified areas of expertise will be dominant with the qualification and assignment of the auditor. In general, the auditor should be capable of judging the hazards, which might arise within the specific subcategory with regards to the raw materials, products and processes used, and to have a sound understanding of the potential risks.

Experience, technical expertise and an analytical capacity are of vital importance. The auditor must have an understanding of any codes of practice which could be applicable within the sub-sector (Hygiene and GMP's).

The auditor shall be aware of the verification practices of these codes by third parties. The auditor shall consider the application and/or results of these verifications when conducting the HACCP audit. The auditor must demonstrate that the required knowledge and skills can also be applied.

2.2 Specific requirements with respect to the HACCP auditor

The HACCP auditor

- shall have knowledge of the certification scheme of his/her own body;
- the total demonstrable audit experience in accredited food safety management audits should contain:
 - at least 10 audits with a minimum total duration of 12 audit days;
 - within a minimum of 4 organizations;
 - of which 5 audits in this specific HACCP standard;
 - shall have relevant knowledge of the food-processing sector at minimum BSc level;
 - for the above-mentioned subcategories, at least 6 months' work experience within the subcategory is required or 4 food safety audits under the supervision of a qualified auditor.

2.3 Specific requirements for the HACCP audit team

With regards to the audit team, the following applies:

- at least half the participating HACCP-auditors must possess the relevant subcategory-specific expertise, obtained through minimally two years work experience in quality assurance/HACCP;
- if not all auditors have the relevant subcategory-specific expertise, the auditor must arrange for an oral briefing for the team prior to the audit;
- have documented knowledge of the applicable national legislation;
- the assessment and recommendations with regard to the classification of any deviations/non-conformities found by the auditor with the subcategory-specific expertise shall be communicated



to the certification decision-maker. This also applies to the review of the audit team's recommendations for certification made by the subcategory-specific expert.

The (subsector) expert

- shall have knowledge of the certification scheme;
- shall have relevant knowledge of the food-processing sector at minimum BSc level;
- knowledge of the relevant subcategory involves at least 6 months' work experience within the subcategory.

3. Requirements of staff personnel

The certification body shall include the following positions within their organization: (co-ordination) officer and decision maker(s). These can be one and the same individual, but the decision maker(s) shall not be part of the audit team that has conducted the assessment in question. Criteria have been established by the NBE-HACCP for each of these positions:

3.1 (Co-ordination) Officer

The certification body shall have at least one officer who has the following duties:

- execution of the contract review
- selection, training and briefing of audit teams
- participation in Harmonization Committee discussions
- contact person for the NBE-HACCP.

The (cumulative) requirements for this officer are:

- be employed by the certifying body (no on-the-job contracting; not necessarily full-time);
- meet the requirements with respect to 'HACCP auditor', as specified in section 2 of this document;
- have a minimum of five years' working experience in one or more of the following sensitive subcategories:
 - primary animal products;
 - cattle breeding;
 - other primary sectors;
 - egg-producing and egg products;
 - chopped fruit and vegetables;
 - meat and meat products (unpacked and refrigerated);
 - fish, crustaceans and shell fish;
 - dairy products.

For certification bodies, which have only been accredited for subcategories AI, AII, BI and BII, only the first three sensitive subcategories apply. In this case, other sensitive subcategories are not considered.

3.2 Decision maker(s)

The decision maker(s) responsible for granting, extending, maintaining, suspending and withdrawing HACCP certificates are required to satisfy each of the following criteria:

- be employed by a certifying body (no on-the-job contracting);
or
- an independent committee of (external) experts which is an integral part of the organizational structure of the certifying body;
- meet the requirements with respect to 'HACCP auditor', as specified in the section 2 of this document;



- have a minimum of five years working experience in one or more of the following sensitive subcategories:
 - primary animal products;
 - cattle breeding;
 - other primary sectors;
 - egg-producing and egg products;
 - chopped fruit and vegetables;
 - meat and meat products (unpacked and refrigerated);
 - fish, crustaceans and shell fish;
 - dairy products.

For certification bodies, which have only been accredited for subcategories AI, AII, BI and BII, only the first three sensitive subcategories apply.

The requirements for re-qualification (as mentioned below under 4) do not apply for the Decision maker. Exemption: the Decision maker shall participate in the internal harmonization activities.

4. Re-qualification of certification personnel

For re-qualification as auditor at least 5 or 10 audit days against a relevant accredited food safety standard shall be performed, of which at least 1 audit in this specific HACCP scheme.

At least one report (not older than three years) of attending an audit for the HACCP food safety system by the concerned auditor must be given. It is required that the witnessing auditor isn't part of the audit team and strictly observes.

Internal harmonization must take place at least once a year with all auditors and by all means the cases from the central harmonization session must be part of this internal harmonization.

5. Harmonization Committee

The certification body is obliged to participate in the Harmonization Committee. This committee must take place once every half year. In principle the co-ordination officer (see below 3.1) represents the certification body in this committee. In the Harmonization Committee cases will be brought in for discussion.

Each certification body in their own HACCP auditors/experts shall discuss the cases and the results of the Harmonization Committee

A regulation can be set up for the Harmonization Committee.

The Dutch National Board of Experts HACCP approved these requirements June 2016.



REGULATIONS for THE (DUTCH) NATIONAL BOARD OF EXPERTS HACCP (NBE-HACCP)

Article 1 Introduction

The (Dutch) National Board of Experts HACCP (NBE-HACCP) has been established to function as an advisory body - with discretionary powers – to the certification bodies, that have been authorized by the Dutch Council for Accreditation (RvA) or another accreditation body to conduct HACCP certification. The NBE HACCP is legally represented by the Foundation for Food Safety Certification. This Board provides parties with an interest in HACCP certification with the possibility to execute their participation in the development of the certification schemes that are managed by the NBE-HACCP. Additionally, they can participate in the co-ordination activities in the field of HACCP certification, as well as in the formulation and functioning of the HACCP scheme.

Article 2 Composition

The NBE-HACCP is composed by experts from consumer organizations, government, retail, trade, industry, certification bodies as well as by independent experts. The NBE-HACCP invites organizations concerned to make binding nominations. The NBE-HACCP itself appoints its members and ensures that the composition is balanced and manageable in size. The National Board can only reject an organizations nomination, based on the interests promoted by the National Board, stating the reasons. If the nomination is rejected, the organization involved is given the opportunity to make a new nomination. Members are appointed with consultation of the board of SCV. The board of SCV can reject a nomination if the rejection is based on interests which the foundation board looks after. Membership is terminated if the member relinquishes the capacity for which he or she was nominated, as well as if the organization concerned indicates a wish to terminate this membership. The National Board can appoint independent experts as members, as advisers or as temporary advisers. In doing so, the National Board can determine to what extent the adviser has voting powers.

The chairperson is appointed by the National Board in his or her capacity and is not an individual appointed from the ranks of National Board. In the absence of the chairperson the National Board will allocate a deputy chairperson. The (re) appointment of the chairperson and the independent experts takes place every three years. In the event of prolonged absences of a member the organization concerned will be asked to make a new appointment.

Article 3 Task

The National Board is responsible for the establishment of certification schemes. The Board organizes co-ordination activities in the field of HACCP certification and evaluates these in view of developments desired by interested parties, as well as with respect to other relevant (e.g. technical) developments. The National Board has the possibility to provide recommendations - on request or otherwise - to the associated certification bodies with respect to the HACCP certification scheme. The National Board can issue proposals to the relevant certification bodies for the contracting out of investigative work to third parties. The National Board is authorized to formulate the assignment and its constituent parts.

In any event, the National Board is required to provide advice in the following areas:

1. The nature, content and functioning of the HACCP scheme;
2. The scope of certification;
3. The establishment of requirements and the methods of investigation, which underpin the certification scheme, and establishment of the period of validity for the certification scheme;
4. To establish the frequency of surveillance assessments in order to ensure that stipulated requirements are continuously met;
5. The formulation of text on the HACCP certificate;
6. The competence of auditors involved in the scheme;
7. The full review of the “Requirements of a HACCP based Food Safety System” and the Dutch HACCP certification Scheme every 3 years.



Additionally, the National Board is authorized to provide recommendations - on request or otherwise - with regards to any aspect related to the management of certification schemes and to co-ordination activities in the field of HACCP certification.

With respect to all the aforementioned items, the associated certification bodies can accept or reject the recommendations of the National Board of Experts HACCP only in their entirety. In the event that (one or more of) the certification bodies do not accept the recommendations of the National Board, this needs to be notified to the National Board in writing, stating the reasons for this.

The National Board will reconvene and reach a decision on possible changes of the appealed recommendation. If this is not the case and the certification body in question continues to reject this decision with respect to the recommendations, no further appeal procedure is possible and the certification body will be excluded from further use of the services of the National Board. The services of the National Board of Experts can be called upon in the event of disagreements regarding the interpretation of the certification scheme, on the understanding that the Board does not rule on individual differences. The appeal board of the certification body is available for this purpose.

Article 4 Working order

1. In order to effectuate the responsibilities specified in article 3, the National Board convenes at least twice a year, and whenever the chairperson or three members of the board make a request to do so.
2. The secretarial work for the National Board is carried out by an agency or company or individual, which is nominated by the certification bodies and approved by the Board. The secretary or his or her deputy attends the meetings. He or she has an advisory vote in the meeting. The secretary provides the National Board with all the information (if required in coded form) which the National Board deems necessary for the effectuation of its responsibilities.
3. The chairperson can impose confidentiality on the National Board if the board receives confidential information necessary for carrying out its responsibilities.
4. In preparation for the tasks specified in items 2, 3 and 4 of clause 4, the secretary's office (possibly through work contracted out) is responsible for formulating drafts after consultation with the involved parties. Any opinions on the part of the involved parties that differ from the draft will be submitted to the National Board.

Article 5 Decision-making

The National Board aims to make decisions on the basis of consensus, including all participants, even those with no voting rights; in any event, two-thirds of the number of those members entitled to vote are required to be present or to have been balloted. Those entitled to vote are the members, with the exception of the representatives of the certification bodies.

Decisions can either be made in the meeting or by written consultation. Written consultation can be carried out by means of correspondence, i.e. by letter, fax or e-mail.

In the case of written consultation, those votes are counted which are received by the secretary's office within two weeks following a request to do so. In the event of the written procedure, all participants in the National Board can request verbal consultation in a meeting.

In the event of written consultation, decisions are made by consent: those opposing a motion can indicate whether to accept the majority position or remain opposed in principle. In case half or less vote for the motion, or if at least one person votes against the motion on principle, the proposal is required to be dealt with in a meeting or an amended motion is required to be submitted.

When decisions are made in a meeting, recommendations are accepted by a simple majority of votes. In the event of a tie, the issue is dealt with again and a vote taken. If a new vote is required, the final motion will be sent to the members entitled to vote within two weeks following the tie, to which a reply must be submitted within two weeks in writing. Split recommendations can be made in the event that the associated certification bodies are not required to integrally accept or reject the recommendations.



The National Board of Experts HACCP shall validate changes preceding their implementation with regards to the following aspects:

- Feasibility
- Effectiveness (with regards to the intended effect)
- Compliance with the relevant standards which apply to the Scheme.

Article 6 Harmonization Committee

The National Board receives advice from the Harmonization Committee.

The Harmonization Committee consists of representatives of the associated certification bodies.

Expertise requirements can be stipulated for these representatives.

The Harmonization Committee appoints three representatives from their number who participate in the meetings of the National Board.

The Harmonization Committee tasks includes the following:

- co-ordination and harmonization with respect to the commercial ownership of the technical specification 'Requirements for a HACCP based Food Safety System';
- proposals for items on the agenda for meetings of the National Board;
- preparing recommendations for the National Board;
- evaluating practical cases with respect to HACCP certification;
- organization of harmonization workshops for HACCP auditors;
- allocating the secretary's office for the National Board as referred to in article 4, paragraph 2.

The reports of the meetings of the Harmonization Committee are dealt with at the meeting of the National Board.

Article 7 Recording the content of meetings and resolutions

The secretary is responsible for recording the minutes of the meetings of the National Board. The draft minutes, including a list of draft resolutions, is sent to the members of the Board within three weeks following the meeting. If applicable, members are required to submit their comments with respect to the minutes and the list of resolutions to the secretary in writing within 14 days.

If no comments are received, the chairperson authorizes the minutes and list of resolutions to be finalized. The minutes as well as the list of resolutions is sent to the associated certification bodies.

The list is also published on the website. If recommendations or decisions imply an alterations of one of the relevant documents, the list will state the alteration and be valid as long as the alteration has not been processed and published. All associated certification bodies will be informed of the publication. For the subsequent meeting, the list of resolutions is sent out again as a "document received". In case the secretary receives comments, the draft report will be dealt with and finalized at the subsequent meeting.

Article 8 HACCP certificate

The design of the HACCP certificate will be similar to the certificates that are issued by the awarding certification body in question.

Notwithstanding this, the certificates shall include the following information:

- name and address of the food business organization receiving the certificate;
- period of validity;
- relevant signatures and positions of signatories;
- scope, expressed in terms of activities, products and sites;
- logo of the Accreditation Body.

Furthermore, the certificate shall contain the following standard text, as required and will be maintained by the National Board of Experts:

The food safety system is evaluated by(name certification body) and is in accordance with 'The Requirements for a HACCP based Food Safety System' [date of most recent version], as published by the National Board of Experts HACCP.



Certificates that do not fall within the scope of HACCP certification may not make any reference to the National Board of Experts HACCP.

Article 9 Exchange of Information

The secretary shall draw up reports of the National Board's activities.

These reports are made available to the participants and the advisers on the National Board and to the associated certification bodies who are not represented on the Board. In addition, the Accreditation Body is entitled to have access to the reports. The National Board will notify all associated certification bodies with regards to all binding recommendations that have been issued and provide the necessary documents. The certification bodies are required to respond to the recommendations issued within two months.

In order to fulfill its responsibilities, the National Board is required to receive information on request at least once a year from the Secretary and the associated certification bodies.

This information must relate to the nature, content and functioning of the HACCP scheme and shall include at least the following;

- the frequency and the results of the surveillance's (if necessary, in code) conducted by the associated certification bodies;
- complaints in respect of the HACCP certification, received by the Secretary, Accreditation Body and the certification bodies and information on how these have been dealt with;
- the number and nature of appeal procedures with respect to HACCP certification with the Accreditation body and the certification bodies;
- reports on the periodic assessments by the Accreditation Body with regards to those sections which are important for the functioning of the HACCP scheme;
- applications and contracts for HACCP certification as well as certificates granted, suspended or withdrawn.

The mentioned information may provide a source of discussion for the National Board in respect of possible changes to the HACCP scheme.

All information made available will be treated in confidentiality by the National Board.

The Secretary, in order to ascertain that the duties of the National Board are conducted correctly, will be responsible to ensure that the documents and information provided to the National Board do not contain any commercially sensitive information.

Article 10 Ratification and amendments

The National Board of Experts HACCP is entitled to ratify and amend these Regulations. This requires the approval of all the members of the National Board. Ratification and amendments also require the approval of the associated certification bodies.

Article 11 Concluding provision

In cases not covered by these Regulations, the HACCP National Board of Experts will make the final decision.

The Dutch National Board of Experts HACCP approved these requirements June 2016.