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பொதுசனக் கருத்துரைக்கான கட்டளை வரைவு
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Draft Sri Lanka Standard
REQUIREMENTS FOR A HACCP BASED FOOD SAFETY MANAGEMENT SYSTEM
(DSLS 1266 : .....) (SECOND REVISION)

HACCP මත පදනම් වූ ආහාර සුරක්ෂිතතා කළමනාකරණ ප්‍රද්ධතියක් සඳහා වන අවශ්‍යතා ඇතුළත්
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(ශ්‍රීලංප්‍ර කෙටුම්පත 1266 : .....) (දෙවන ප්‍රතිශෝධනය)

මෙම කෙටුම්පත ශ්‍රී ලංකා ප්‍රමිතියක් ලෙස නොසැලකිය යුතු මෙන් ම භාවිතා නොකළ යුතු ද වේ.
இவ்வரைவு இலங்கைக் கட்டளையெனக் கருதப்படவோ அன்றிப் பிரயோகிக்கப்படவோ கூடாது
This draft should not be regarded or used as a Sri Lanka Standard.

අදහස් එවිය යුත්තේ : ශ්‍රී ලංකා ප්‍රමිති ආයතනය, 17, වික්ටෝරියා පෙදෙස, ඇල්විටිගල මාවත, කොළඹ 08.

Comments to be sent to: SRI LANKA STANDARDS INSTITUTION, 17, VICTORIA PLACE, ELVITIGALA MAWATHA, COLOMBO 08.

හැඳින්වීම

මෙම ශ්‍රී ලංකා ප්‍රමිති කෙටුම්පත , ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සකසන ලදුව, සියලුම උද්‍යෝගී අංශ වලට තාක්ෂණික විවේචනය සඳහා යවනු ලැබේ.

අදාල අංශ භාර කමිටු මාර්ගයෙන් ආයතනයේ මහා මණ්ඩල වෙත ඉදිරිපත් කිරීමට පෙර , ලැබෙන සියලුම විවේචන ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සලකා බලා අවශ්‍ය වෙතොත් කෙටුම්පත සංශෝධනය කරනු ලැබේ.

මෙම කෙටුම්පතට අදාල යෝජනා හා විවේචන නියමිත දිනට පෙර ලැබෙන්නට සැලැස්වුවහොත් අගය කොට සලකමු. තවද, මෙම කෙටුම්පත පිළිගත හැකි බැව් හැගෙන අය ඒ බව දන්වන්නේ නම් එය ආයතනයට උපකාරී වනු ඇත.

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ඇල්විටිගල මාවත,
කොළඹ 08.

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Introduction

This Draft Sri Lanka Standard has been prepared by the Sri Lanka Standards Institution and is now being circulated for technical comments to all interested parties.

All comments received will be considered by the SLSI and the draft if necessary, before submission to the Council of the Institution through the relevant Divisional Committee for final approval.

The Institution would appreciate any views on this draft which should be sent before the specified date. It would also be helpful if those who find the draft generally acceptable could kindly notify us accordingly.

All Communications should be addressed to:

The Director General
Sri Lanka Standards Institution,
17, Victoria Place,
Elvitigala Mawatha,
Colombo 08.

Draft Sri Lanka Standard

REQUIREMENTS FOR A HACCP BASED FOOD SAFETY MANAGEMENT SYSTEM

(Second Revision)

DSLS 1266:

Gr.

SRI LANKA STANDARDS INSTITUTION
No, 17 , Victoria Place
Elvitigala Mawatha
Colombo 08
Sri Lanka

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Draft Sri Lanka Standard
REQUIREMENTS FOR A HACCP BASED FOOD SAFETY MANAGEMENT SYSTEM
(Second Revision)

FOREWORD

This Sri Lanka Standard was approved by the Sectoral Committee on Food Products and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on ……

Food safety is a global concern. Not only because of the continuous importance of public health, but also of its impact on international trade. Therefore, effective food safety systems shall manage and ensure the safety and suitability of foodstuffs. The 7 principles and the guidelines for the application of HACCP have been combined in this Standard with basic elements of quality management systems (ISO 9000) to establish this Standard.

The requirements in this Standard provide a basis for compliance of processes with national legislation and codes of practice.

This Standard was first published in 2005 and revised in 2011. This second revision has been taken up in order to update the Standard by amending the clauses regard to tasks, responsibilities and authorities, specific control measures, monitoring and measuring, product recall, tracking and tracing, validation, verification and records.

In the preparation of this Standard, valuable assistance derived from the following publication is gratefully acknowledged.

HACCP 2012 Requirements for a HACCP based food safety system (published by National Board of Experts – HACCP, the Netherlands.

1 SCOPE

In this Standard, 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.

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, such as suppliers of packaging materials, food equipment, industrial cleaning services, etc.

2 REFERENCES

SLS	143	Code of practice for general principles of food hygiene
SLS	1173	Guidelines for the application of Hazard Analysis Critical Control Point (HACCP) System
SLS ISO	22003-1	Requirements for bodies providing audit and certification of food safety management systems
SLS ISO	22003-2	Requirements for bodies providing evaluation and certification of products, processes and services, including an audit of the food safety system
SLS ISO	17020	Conformity assessment-Requirements for bodies providing audit and certification of management systems-requirements
SLS ISO	17025	General requirements for the competence of testing and calibration laboratories

3 DEFINITIONS

3.1 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.

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

3.3 category: Food categories according to **SLS ISO 22003-1** and **SLS ISO 22003-2**.

3.4 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.

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

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

3.7 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.

3.8 control measure, specific: A measure to control a CCP. A certain part of the pre-requisite 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.

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

3.10 corrective measure: Measure with respect to food safety which will be taken to eliminate the cause of a detected deviation (not complaint to a specified requirement), defect (not complaint to a requirement or reasonable expectation regarding the use, including those applicable to food safety) or other undesirable situation to avoid reoccurrence.

3.11 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).

3.12 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).

3.13 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.

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

3.15 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.

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

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

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

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

3.20 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.

3.21 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.

3.22 HACCP based food safety system/ HACCP system: The organizational structure, procedures, processes and resources needed to execute the HACCP plan(s) and meet its objectives.

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

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

3.25 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.

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

3.27 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.

3.28 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.

3.29 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.

3.30 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.

3.31 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.

3.32 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.

3.33 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.

3.34 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.

3.35 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.

3.36 (sub) sector: Specific industry subdivision by category (for example: category A Farming (animals) has three subsectors: (1) animals (wildlife) farming (meat), (2) primary animal products (milk, eggs and honey), and (3) fish)

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

3.38 validation: Obtaining evidence (in advance) that the control measures of the HACCP plan are effective.

3.39 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.

4 HACCP SYSTEM REQUIREMENTS

4.1 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.

4.1.1 *Policy*

The food business operator shall define and document (in writing) the policy of the organization with regard 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***** (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.

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

4.1.2 *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:

a) 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;
b) 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;
c) All products which are supplied to the market by the food business, whether processed or handled, shall be properly specified; and

d) All subcontracted activities (outsourced services, such as 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:

a) Specific differences between individual end products have been critically evaluated;
b) Manufacturing and storage conditions are comparable; and
c) 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.

The HACCP System shall be established in accordance with **SLS 1173**.

4.1.3 *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.

4.1.4 *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 co-ordinator shall be appointed to coordinate the development, implementation and maintenance of the HACCP system.

4.1.5 *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.

4.1.6 *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 (*see* clause **4.11**) 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.

4.2 Product information

4.2.1 *Product characteristics*

Each product (or a group of similar products: *see* clause **4.1.2**) 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) A general product description;
b) Raw materials and ingredients used (composition);
c) General product specifications such as appearance, weight, etc.;
d) Specific product specifications such as chemical (including allergens); microbiological and physical characteristics;
e) Specific requirements such as appropriate legislation, customer requirements;
f) General control of (chemical, microbiological and physical) safety;
g) Packaging, storage conditions, labelling (shelf life, product identification); and
h) Identification of potential mishandling of the product.

4.2.2 *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:

a) Additional preparation methods (e.g. heating) before consumption; and/ or
b) Cooling and storage at specific temperatures; and/or
c) An indication of the ultimate day of use, especially after breaking the packaging; and/ or
d) 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.

4.3 Process information

4.3.1 *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 such as:

a) Buffer and interim storage;

b) Transport pipes, distribution valves, etc.;
c) Loops for reworking and recycling;
d) Facilities for cleaning and disinfection of equipment and tools, including cleaning -in-place; and
e) Provision for start-up/ shut down/ emergency stops, etc.

4.3.2 *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:

a) The routing of products, personnel and air flows (in the case of 'high care' rooms);
b) 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; and
c) The areas and facilities for personnel use.

4.3.3 *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.

4.4 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.

Specified food safety requirements are detailed in legislation, hygiene codes and customer or consumer specifications. Where specific requirements do not exist, the appropriate pre-requisite programmes will be applied (**SLS 143**). The Codex General Principles of Food Hygiene lay a firm foundation for ensuring food safety and suitability.

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

***** *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."

The pre-requisite program shall be verified in terms of implementation and effectiveness at pre-determined and regular intervals (*see* clause **4.11**).

Purchase programmes shall result in a classification of food safety risk of suppliers and their products (*see* Clause **4.5.1**) as well as the controlled method of assessment and reassessment. Dependent on the importance of food safety (*see* Clause **4.6**), the relevant basic pre-requisite monitoring procedures must be introduced in which responsibilities, accountability and required records are set. The organization shall identify the cause 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 basic requirements related to the pre-requisite programme have been prescribed in **SLS 143** and are summarized in Figure **1**.

1 Primary production **1.1** Environmental hygiene **1.2** Hygienic production of food sources **1.3** Handling, storage and transport **1.4** Cleaning, maintenance and personal hygiene	**5 Establishment: personal hygiene** **5.1** Health status **5.2** Illness and injuries **5.3** Personal cleanliness **5.4** Personal behaviour **5.5** Visitors
2 Establishment: design and facilities **2.1** Location **2.2** Premises and rooms **2.3** Equipment **2.4** Facilities	**6 Transportation** **6.1** General **6.2** Requirements **6.3** Use and maintenance
3 Control of operation **3.1** Control of food hazards **3.2** Key aspects of hygiene control systems **3.3** Incoming materials requirements **3.4** Packaging **3.5** Water **3.6** Management and supervision **3.7** Documentation and records **3.8** Recall procedures	**7 Product information and consumer awareness** **7.1** Batch identification **7.2** Product information **7.3** Labelling **7.4** Consumer education

4 Establishment: maintenance and sanitation **4.1** Maintenance and cleaning **4.2** Cleaning programmes **4.3** Pest control **4.4** Waste management **4.5** Sanitation systems	**8 Training** **8.1** Awareness and responsibilities **8.2** Training programs **8.3** Instruction and supervision **8.4** Refresher training

FIGURE 1 – Pre-Requisite Programme (PRP)

Like the products and the processes, (the procedures belonging to) the PRP shall be subjected to the hazard analysis (*see* Clause **4.5**) in order to identify potential hazards and to decide in which way the hazards (risks) need to be controlled (*see* Clause **4.6**).

4.5 Hazard analysis

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

Whenever the food business operation changes in a manner that could adversely affect food safety all relevant steps of the hazard analysis shall be updated.

4.5.1 *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 such as:

a) Raw materials and ingredients;
b) Commodities;
c) Process control within the chain;
d) Characteristics of interim and end products (Product specifications); and
e) 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.

4.5.2 *HACCP – hazard analysis*

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

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

a) the likely occurrence of hazards and severity of their adverse health effects;
b) the qualitative and/ or quantitative evaluation of the presence of hazards;
c) the survival or multiplication of micro-organisms of concern;
d) the development or the presence of contaminants including persistence of toxins, chemicals or physical contaminants in foods;
e) cross contamination with allergens; and
f) 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 analysis, practical experiences, experimental data, professional literature, etc., shall be taken into account and be documented.

4.6 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* **Appendix I**), 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, water activity, 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. Consideration shall be given that a certain part of the pre-requisite 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 programme (*see* Clause **4.4**).

4.7 Parameters and critical limits

4.7.1 *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.

4.7.2 *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* Clause **4.8**) and the corrective actions (*see* Clause **4.9**) to be executed whenever the critical limits are exceeded.

In addition, the effectiveness of the established parameters and operational values shall be validated (*see* Clause **4.10**) to ensure food safety.

4.8 Monitoring and measuring

4.8.1 *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.

a) Surveillance tools that are used;
b) Frequency of monitoring; and
c) Responsibilities and powers with regard to monitoring and assessment of the surveillance results.

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

a) Monitoring reports (dated and signed); and
b) 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.

Registration of the results of calibrations and authentication as well as the measures to process/ product in the case of derogations shall be tracked (*see* Clause **4.12.2**).

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.

4.8.2 *Product release*

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

4.9 Corrective actions, product recall, tracking and tracing

4.9.1 *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* Clause **4.11**).

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 nonconforming products. The corrective actions may include:

a) 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; and
   - Disposal/ destruction of the product/ batch.

b) With respect to the process:
   - Adjusting the process; and
   - Adjustment/ correction of process conditions.

4.9.2 *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 **4.9.1** and **4.9.2** shall be tested for effectiveness at a predetermined frequency but at least annually.

4.9.3 *Tracking and tracing*

The organization must ensure an effective tracking and tracing procedure. Products and parties must be registered and identified in order to assure that traceability and recall is possible (**Clause 11** of **SLS 143**).

4.10 Validation

4.10.1 *General*

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

The objective of validation is:

a) 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; and

b) To provide evidence that selected specific controls 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.

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.

The composition of the validation team and the activities undertaken shall be clearly documented.

The food business operator shall demonstrate satisfactory completion of validation.

4.10.2 *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;

a) The established list of potential hazards is based on sound scientific data and has included all hazards; and
b) The questions used to assess the significance are answered using sound scientific and technical knowledge.

4.10.3 *Validation of specific control measures*

Validation is demonstrated by means of documented evidence that:
a) All related, critical measurement and process equipment is properly installed and functioning properly;
b) The installed process and measurement equipment is functioning properly under all circumstances permitted;
c) For process indicators limits have been established within which the process is regarded as being controlled ("challenge" tests, worst case conditions); and
d) The control measures are effective and thus prevent unsafe product being released or provide evidence that the situation can be corrected immediately.

4.10.4 *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.

4.11 Verification

4.11.1 *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* Clause **4.8**).

Procedures for verification shall be documented and shall include as a minimum:
a) Purpose;
b) Methods, standard operating procedures or tests applied;
c) Tasks and responsibilities;
d) Frequency; and
e) Records.

The verification procedure shall address, as a minimum, the following topics:
a) Review of the HACCP system and its corresponding records;
b) Analysis of (near) recalls and product dispositions;

c) Assessment of all specific control measures, non-conformities and corrective actions taken to seek confirmation of implementation and effective control of CCP's;
d) Compliance of the actual flow diagrams and layout with the documented situation;
e) Evaluation of the implementation (practice) and effectiveness of the pre-requisite program (*see* Clause **5.4**);
f) Analysis of customer and consumer complaints related to hygiene and food safety;
g) Review of analytical outcome of random sampling and analysis of products;
h) 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;
j) 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;
k) Consistency of the current documentation; and
m) Results of internal audits.

4.11.2 *Internal audit*

The food business operator shall determine whether the HACCP system;
a) 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.
b) 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.

4.11.3 *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 clause 4.1.6). 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 clause 4.9) 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.

4.12 Documentation and records

4.12.1 *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:

a) The policy of the food business operator with respect to food safety (*see* clause **4.1.1**) and the scope of the HACCP-based Food Safety System (*see* clause **4.1.2**);
b) The documented specifications, procedures and instructions established for the HACCP-based Food Safety System, or reference to them; and
c) 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:

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

4.12.2 *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:

a) Records to demonstrate that the members of the HACCP team have adequate knowledge, expertise and different disciplines available;
b) Records concerning management reviews and, if needed, related actions;
c) 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;
d) Records of the assessment of the management measures and the determination of the Specific Control Measures (CCPs);
e) Monitoring reports (dated and signed) of the Specific Control Measures to demonstrate the control of the related CCP's;
f) Records of non-conformities occurred (exceeded action limits and critical action limits) of the Specific Control Measures and the corrective actions taken;
g) Records of non-conformities and actions taken in case of deviations of the prerequisite program;
h) Records of the results of calibration and verification and measures to be taken to process/ product in case of non-conformities;
j) Records related to the verification program (including internal audits) and their evaluation;
k) Records that are relevant to ensure traceability of food stuffs;
m) Records regarding registration of complaints, handling of complaints and corrective actions undertaken.

APPENDIX 1