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QUALITY Guide

An ABC Guide on
Food Safety Management Systems

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An ABC Guide on Food Safety Management Systems

This is the second in a series of booklets produced by the Quality Programme, as a guide to understanding the role and importance of relevant food safety and quality issues.

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on Food Safety Management Systems

1 - LIST OF ABBREVIATIONS

• **BRC**	British Retail Consortium
• **CIES**	Global Food Business Forum
• **EHEDG**	European Hygienic & Engineering Design Group
• **Eurepgap**	European Retailer Produce working group – Good Agricultural Practice
• **FAO**	Food & Agriculture Organisation
• **GAP**	Good Agriculture Practices
• **GMP**	Good Manufacturing Practices
• **GFSI**	Global Food Safety Initiative
• **HACCP**	Hazard Analysis Critical Control Points
• **IFS**	International Food Standard
• **IFIC**	International Food Information Council
• **RASFF**	Rapid Alert System for Food and Feed (European Union)
• **WHO**	World Health Organisation
• **WTO**	World Trade Organisation
• **IAF**	International Accreditation Forum
• **ISO**	International Organisation for Standardisation
• **PRP's**	Pre-Requisite Programmes
• **OPRP's**	Operational Pre-Requisite Programmes
• **SPS**	Sanitary and Phytosanitary Measures
• **SQF**	Safe Quality Food
• **UNIDO**	United Nations Industrial Development Organisation
• **WFSO**	World Food Safety Organisation

2 - REFERENCES TO TERMINOLOGY

- **Allergens 3-A** - Allergens are identified as food safety hazards and must be considered in the Hazard Analysis. Sanitary Standards, Inc. (3-A SSI) is a non-profit association (US based) representing equipment manufacturers, processors, regulatory sanitarians and other public health professionals. Through many decades of co-operation, these groups have established a comprehensive inventory of 3-A Sanitary Standards and 3-A Accepted Practices, now known around the world for dairy and food processing equipment and systems

- **Benchmark** - Benchmarked Food Safety Standards by CIES . The CIES has 4 benchmarked standards (BRC, IFS , the Dutch Standard and the SQF 2000), along with an additional standard for primary producers

- **BRC** - British Retail Consortium - The British Retail Consortium has developed the Technical Standard, which is a Checklist, for those companies supplying Retailer branded food products. The Standard has been developed to assist Retailers in the fulfillment of their legal obligations and protection of the consumer, by providing a common basis for the inspection of companies supplying retailer branded food products. (www.brc.org.uk)

- **CE** - Conformité Européenne, a marking on products indicating compliance with European Directives

- **CBI** - Centre for the promotion of imports from developing countries into the EU. Through the access guide (www.cbi.nl/accesguide), the CBI provides the most recent EU information on legislation regarding imports into the EU

- **CIAA** - Confederation of the food and drinks industries in the EU

- **Codex Alimentarius** - A code of food standards for all nations, developed by the FAO and WHO. The Codex Alimentarius Commission was created in 1963 to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are the protection and health of consumers and ensuring fair trade practices in the food trade and promoting co-ordination of all food standards work undertaken by international governmental and non-governmental organisations

- **CIES** - The Global Food Business Forum is the only independent global food business network. It serves the CEOs and senior management of 175 retail and 175 supplier member companies in addition to their subsidiaries in over 150 countries

- **Certification** - ISO Definition of certification
  Definition 1
  "With certification, a company gives notice, with justified confidence, by means of a formal statement that a system or a product is in conformance with, respectively, a predefined standard or specification"
  Definition 2
  "A procedure by which accredited certification bodies, based on an audit provide written or equivalent assurance that food control systems conform to requirements"

- **Eurepgap** - The objective of EUREP, which is made up of leading European food-retailers, is to raise standards for the production of fresh fruit and vegetables. The prepared document (Checklist) sets out a framework for Good Agricultural Practice (GAP) on farms, which defines essential elements for the development of best-practice for the global production of horticultural products (e.g. fruits, vegetables, potatoes, salads, cut flowers and nursery stock)

- **EFSA - The European Food Safety Authority (EFSA)** is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks

- **EC** - European Commission

- **EHEDG - European Hygienic Engineering & Design Group**
  Faults in hygienic engineering could have a negative impact on food safety at the point of consumption - EHEDG provides guidance on the hygienic engineering aspects of manufacturing of safe and wholesome food. EHEDG's scope of work focuses on hygienic engineering for food manufacturing establishments such as equipment and building design and clean ability

- **EU Guidance document** The guidance document explains the implementation of procedures based on HACCP and facilitation of the implementation of HACCP principles in the retail food business, as required by EU regulation 852/2004 hygiene of food stuff
  http://europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

- **EU** - European Union, made of 27 countries, 490 million people, is a family of democratic countries commited to working together for peace and prosperity

- **FAO** - Food & Agriculture Organisation

- **FMI - The Food Marketing Institute (FMI)** The SQF Programme is owned by the Food Marketing Institute (FMI) in Washington,DC, USA . At the request of its retail members, FMI acquired SQF so they could utilise one programme that meets their requirements and at the same time provides efficiencies for suppliers. SQF is recognised by the Global Food Safety Initiative (GFSI) as conforming to the highest international standards and utilises protocols recognised by the International Accreditation Forum

- **GFSI - Global Food Safety Initiative (GFSI)** CIES has facilitated the initiative to enhance food safety, ensure consumer protection, strengthen consumer confidence and set requirements for food safety schemes and improve cost efficiency throughout the food supply chain. Following their lead, the Global Food Safety Initiative (GFSI) was launched in May 2000. It is based on the principle that food safety is a non-competitive issue, as any potential problem arising may cause repercussions in the whole sector

- **HACCP** - Hazard Analysis & Critical Control Points

- **Hazards** - HACCP identifies 3 types of food safety hazards with the potential to cause an adverse health affect: micro biological, physical and chemical

- **GMP - Good Manufacturing Practice** is a set of regulations, codes, and guidelines for the control and management of manufacturing and quality control testing of ingredients and products, especially in the areas of food, pharmaceutical and medical devices

- **IFS - The International Food Standard** (IFS) was created by the Federations of German Distributors (after which it was supplemented by French distributors) to make possible a systematic and uniform evaluation of food product suppliers. The IFS standard is based on the philosophy of the ISO 9001:2000 standard. The IFS standard (a Checklist similar to BRC) is primarily concerned with the setting up of the HACCP system

- **IFIC - The International Food Information Council** - IFIC Foundation is the educational arm of IFIC. IFIC's mission is to communicate science-based information on food safety and nutrition to health and nutrition professionals, educators, journalists, government officials and others providing information to consumers. IFIC is supported primarily by the broad-based food, beverage and agricultural industries

- **ITC - The technical co-operation** agency of UNCTAD and WTO for operational, enterprise-oriented aspects of trade

- **IQ Net - International certification network** - IQNet – The International Certification Network is an Association composed of 38 certification/registration bodies, with registered offices in Bern/Switzerland

- **RASFF - Rapid Alert System for Food and Feed**
  http://ec.europa.eu/comm/food/food/rapidalert

- **Rapid Alert -** Rapid Alert (EU) is a system supporting the work of RASFF, to provide the control authorities with an effective tool for exchange of information, on measures taken to ensure food safety. Information is classified under 2 headings of alert and information notifications

- **Risk -** The function of the probability or chance on an adverse health affect and the severity of that affect (e.g.: discomfort, hospitalised or even death)

- **Traceability -** Identification of incoming material from the immediate supplier and the initial distribution route of the end product to the final consumer

- **PORTAL** International Portal on Food Safety, Animal & Plant Health facilitates

trade in food and agriculture products and supports the implementation of the Sanitary and Phytosanitary (SPS) Agreement by providing a single access point for authorised official international and national information across the sectors of food safety, animal and plant health

- **SQF 1000 - SQF (Safe Quality Food) 1000 code** provides the primary producer with a food safety and quality management certification programme, tailored to the needs of the primary producer. The Food Marketing Institute (FMI) in Washington, DC, acquired the rights to the SQF programme

- **SQF 2000 - SQF (Safe Quality Food) 2000 code** provides the food sector (primary producers, food manufacturers, retailers, agents and exporters) with a food safety and quality management certification programme tailored to requirements which enables suppliers to meet regulatory, food safety and commercial quality criteria in a cost effective manner. The Food Marketing Institute (FMI) in Washington, DC, has acquired the rights to the SQF programme

- **Validation** - Validation concerns obtaining evidence that the elements of the HACCP system are effective. Validation ensures that the information supporting the HACCP system is correct and is useful in the design stage. Micro biological results can be used as validation to ensure that the control measures are properly implemented

- **Verification** - Methods, procedures, tests, reviews and other evaluations, additional to those in monitoring, to determine compliance with the HACCP system. Verification is carried out at planned intervals and the frequency of verification varies from a few days to monthly or even yearly activities

3 - ABC GUIDE ON FOOD SAFETY MANAGEMENT SYSTEMS

PART 1 SUMMARY OF HACCP
(HAZARD ANALYSIS CRITICAL CONTROL POINTS)

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1) INTRODUCTION

This document provides general background, a reference guide and practical information about HACCP (Hazard Analysis Critical Control Points).

2) BACKGROUND

HACCP was developed for the space programme of NASA, to prevent any hazards, that could cause illness or injury during space flights. In 1971, the HACCP system was presented to the public for the first time and was implemented in the food industry in the United States.

During the 70's and early 80's, the HACCP system was implemented by a number of companies in the food industry. From these initial experiences, it was concluded that the HACCP system is an approach which helps to prevent micro-biological, chemical and physical hazards and was therefore recommended by the Codex Alimentarius.

3) LEGALISATION IN EUROPE

In 1993, the EC-council established the EC-Directive 93/43/EC, in which the member states commited to implementing Food Regulations, where-by companies in the food industry are obligated to implement the HACCP system in their organisations.

In subsequent years, the regulations have becme obligatory in European Countries, in conformance with the EC Directive 93/43/EC, which was replaced by the Regulation 852/2004 of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs. Today all European companies within the food industry are obliged to have a quality system based on the HACCP principles.

4) FIELD OF APPLICATION

The objective of the HACCP system is to guarantee food safety, by implementation of a quality system, which covers the complete food production chain, from the primary producer up to the final consumer of the product. This means that the Food Manufacturer is not only responsible for Good Manufacturing Practices within his organisation, but must also deal with possible hazards which can occur before and/or after this step. For example, if there is a possibility that the raw materials are exposed to certain hazards, then the manufacturer is responsible to check if and how the supplier of the raw materials controls these hazards.

On the other side of the chain, the manufacturer must supply the consumer with sufficient information about handling of the product, to avoid hazards which can occur during cooking and/or storage of the product. The HACCP system is principally focused on food safety, but through this system, other important aspects such as controlling quality and financial features of the product/process, can be monitored very effectively.

5) THE HAZARDS

Regarding Food Safety, hazards can be defined in the following categories:

- **Microbiological hazards**
- **Chemical hazards**
- **Physical hazards**

Below are several examples for each hazard category, to explain and understand the wide range of hazards, which can occur during the manufacturing of a food product.

Microbiological hazards

Food can be infected by toxic pathogenic or infectious pathogenic micro-organisms, in all stages of the food chain. Whether the contamination of micro-organism will become a hazard depends on several circumstances during the production of product/material. These can be related to:

- Hygiene circumstances during production
- Presence of killing-step during production
- Conditions in the product/material regarding possible micro-biological growth
- Other biological hazards

Other possible hazards of biological origin are insects, rodents and other vermin, which can contaminate the raw material and/or product during cultivation, harvesting, storing and/or processing of the material and /or product

Chemical hazards

The chemical hazards can be divided into 3 categories:

- Intrinsic chemicals, which are already naturally in the food,

e.g. Haemaglutinins in red kidney beans, poisonous mushrooms, Japanese Fu-gu fish

- Added materials which might cause hazards for the consumer due to overdoses or reactions with other materials, e.g. Sodium nitrite (curing agent nitrosamins), coloring agents, preservatives, pesticides and fungicides
- Technical faults during cultivation, harvesting, transportation and/or processing might contaminate the food with chemicals, e.g. due to packaging materials containing poisonous material in contact with food, cleaning agents, metals dissolving in product and maintenance materials

Physical hazards

Physical hazards are divided into two basic categories:

- Intrinsic physical hazards which are in the food by nature, e.g. bones in fish or meat
- Technical faults during cultivation, harvesting, transportation and processing might cause contamination with physical material like foreign bodies (metal, glass, plastic) in raw materials, faulty packaging, engineering problems (nuts, bolts, etc.)

NOTE:

The food products belonging to the group of allergens (peanuts, cereals containing gluten, nuts, eggs, milk, crustaceans, fish, soybeans, celerey, mustrad, sesame seeds, sulphurdioxide and sulphites and products theroff) must be considered as part of the Hazard Analysis.

6) FACTORS TO BE CONSIDERED

6.1 Motivation

The implementation of a HACCP system in the EU is mandatory under Food Regulations, but if this is the only motivation to start implemetating HACCP, a company will not get the best results from the HACCP system. Other reasons for implementation include:

- Company policy on continuous quality improvement
- Total Commitment
- Customer requirements
- Guarantees regarding product liability
- Cost reduction and efficient management by a preventive approach

Important Note: It is essential to see the implementation of HACCP as a tool rather than an objective.

6.2 Preparation

To follow the sequence of implementation, firstly implement the Pre Requisites Programmes (PRP's), also called hygiene measures and Good Manufacturing Practice, prior to starting with HACCP. The Pre Requisite programme covers the following topics:

Personnel hygiene

- Layout of premises, including workspace and employee facilities
- Construction and layout of buildings and associated facilities
- Supplies of utilities like water, energy, air etc.
- Supporting services, including waste and waste disposal
- Suitability of equipment and its accessibility, maintenance and preventive maintenance
- Management of purchased raw materials, ingredients, chemical utilities or supplies, like steam, water and ice, disposal of waste and sewage along with handling of products (like storage and transportation)
- Measures to prevent cross contamination
- Cleaning and sanitising
- Pest Control

Some aspects of PRP's and HACCP can be implemented simultaniously (a gasoline forklift does not need to be replaced by a forklift on batteries before continuation in implementing HACCP.

6.3 Commitment

To get the best results from the HACCP system, commitment has to be demanded of all people within the organisation. Accordingly, each person has to be trained in HACCP.

6.4 Management

Company management must establish a policy, which supports the implementation and maintenance of the HACCP system.

Management is responsible for emphasising the importance of the system. Accordingly, management should draw up a formal 'Declaration of Intent', in which the commitment of the management is stated. This 'Declaration of Intent' is inserted in the HACCP manual and communicated clearly to the employees. Company management

is also responsible for the allocation of tasks related to the HACCP system and for the availability of people and the relevant funding and resources.

6.5 Training

All employees must be trained on hygiene issues and GMP (the PRP's) and HACCP (make use of photographs showing Conformance and Non Conformance hygiene and GMP situations with effective examples and training material.)

It is important to ensure that the company has one or more competent people to set-up such training programmes and to conduct the training on the PRP's, and where necessary to appoint a training officer, ensuring the participaion of Human Resources.

7) IMPLEMENTING A HACCP SYSTEM

The Codex Alimentarius, is an implementing system to be considered, which consists of 12 stages:

CODEX ALIMENTARIUS

1 • Assemble the HACCP team
2 • Describe product
3 • Identify the intended use
4 • Construct the flow chart
5 • Verify the Flow-Chart
6 • Conduct Hazard Analysis and Hazard Assessment
7 • Apply HACCP decision tree
8 • Establish target levels, tolerances and critical limits for each CCP
9 • Establish a monitoring system for each CCP
10 • Establish corrective actions
11 • Complete verification of the system
12 • Establish record keeping and documentation system

Comment: the steps from 6 to 12 are the so called 7 principles of the HACCP system. Steps 1 to 5 are the preliminary steps of the Hazard Analysis.

7.1 Assemble the HACCP team

The Codex Alimentarius, for implementing the HACCP system, recommends the use of multi disciplinary teams where knowledge is pooled and practicable, helping to create commitment from all members of the group

The HACCP team has the following responsibilities:

- Processing the implementation project
- Co-ordination between the different groups
- Implementation of the HACCP system
- On-going maintenance of the system
- Keeping consistent records of discussions and decisions agreed
- Providing the necessary information for all employees

'Quality starts with production': production managers, production supervisors and key operators should be fully involved in the development and implementation of HACCP, along wih the subteams.

Step 1 however, includes more: Terms of Reference and the Scope of the System are included in the very first step.

For practical reasons, it is better to complete a simple HACCP system first, rather than trying to be over ambitious. A simple system can be expanded later, instead of starting with a complex system, which may be never implemented or completed. The terms of reference should be outlined clearly from the start.

Example: Company A is producing dairy products (pasteurised milk, sour cream butter, yogurt and sour cream). The company receives raw milk from farmers and distributes the products to various outlets in the country and the company decides to implement HACCP. The HACCP team decides to implement HACCP in the milk-reception, processing and filling departments. At a later stage, it will be implemented in the butter, yogurt and sour-cream manufacturing departments. The Terms of Reference or Scope of the Plan is Milk-reception, the manufacturing of Pasteurised milk up to Cold Storage stage.

7.2 Describe product

A fully detailed description is required e.g.: composition, processing, packaging, technological details (pH, Aw, Salt %, etc.), method of distribution, storage (internal/external), shelf-life, etc.. This product analysis is needed to better understand the characterisicts of the products, in order to carry out the Hazard Analysis and preparation of technical information to be communicated to the customers.

7.3 Identify the intended use

Consumer usage and methodolgy must be analysed to determine if there are any abuses during preparation/consumption by the consumer. Target groups must be identified, so as to identify particularly vulnerable consumers, like children or eldery persons.

7.4 Construct the Flow Chart

To visualise the Flow of the production process and to make the process transparent, it is recommended to construct one or more Flow Charts and a floorplan. The flow chart should include all processing steps, starting with raw materials, up to and including the preparation/product consumption, depending on the Terms of Reference or Scope of the Plan.

Each step of the process should be determined, identifying which conditions are important in relation to possible hazards. The Flow of the product will be illustrated in a factory floor plan with an equipment layout.

7.5 Verify the Flow-Chart

After the construction of the flow chart, every processing step, within the control of the organisation, must be checked in practice, so non-conformances of the chart and/or conditions are determined. It is essential to pay attention to material inputs and outputs and to pay attention to auxiliaries, rework, waste and even downtime.

Remark: It is necessary to make a small description of each process step, including existing control measures and parameters applied and at least explain the objective of the process-step. This information has to be agreed upon in the HACCP team. At a later stage, while applying the decision tree, the objective of the process step is already laid down and this prevents unnecessary discussions.

7.6 List all hazards, carry out Risk Assessment and take preventive measures (principle 1)

All reasonable hazards must be determined at this step. To determine a complete list of the relevant hazards, a brainstorming session should be organised. It is important that all hazards are precisely stated - making reference to pathogenic bacteria is not sufficient, though the specific pathogenic bacteria has to be noted. The HACCP team conducts a Hazard Analysis, which includes the Hazard Assessment, (to identify the hazards which must be eliminated or reduced to acceptable levels, for the production of a safe food. Next to every hazard, all control measures are identified within the process, to prevent, eliminate or reduce hazards to an acceptable level. These control measures belong to the so called Operational Pre Requisite Programme (OPRP's), according to ISO 22000. Validation objective evidence is obtained, to ensure that the elements of the HACCP system are effective - using time/temperature charts for processing and/or with microbiological results.

7.7 Apply HACCP decision tree (principle 2)

To identify the CCP's, the so-called CCP Decision Tree is used. All hazards, as determined at step 6, must be evaluated by this CCP decision tree. Common sense and a discussion amongst the HACCP team members will eventually decide whether or not the process-step is a CCP. Make sure that the arguments in the discussion around the CCP are recorded and documented.

7.8 Establish target levels, tolerances and critical limits for each CCP (principle 3)

It is essential to set values, targets or norms, target levels, tolerances, control limits, warning levels or action limits and critical limits, appropriate for the effective elimination of the hazard. These must be formally established and specified. This may require some investigations including quantifying the targets, target levels and critical limits, which is not always so easily achieved e.g., how to quantify the effectiveness of cleaning operations.

7.9 Establish a monitoring system for each CCP (principle 4)

The HACCP plan includes monitoring, corrections and corrective action. Monitoring requires observations and whenever possible,

measurements made at each CCP, to ensure that critical limits are not infringed and targets are maintained. Continuous monitoring is advised and this process should be monitored closely at the most likely point of infringement.

7.10 Establish corrective actions (principle 5)

Correction and corrective actions must be identified for each CCP. Correction systems must be developed to deal with the affected product, should critical limits be infringed.

Corrective actions, preferably adjustments through indicating tolerance limits, should take place before critical limits are reached, to bring the process back under control. Each correction and corrective action should state: who/when/how should act and last but not least, what actions will be taken with the effected product. To register the non conformance incident, please apply the procedure relating to 'Production Non Conformance Report'.

7.11 Complete verification of the system (principle 6)

It is important to verify that the procedures put into effect as part of the HACCP process, are achieving the desired results or if not, that the necessary actions are taken to correct the situation. These verification activities may involve reviewing finished product testing, results on various audits, review of consumer complaints and non conformance reports after categorisation, review of sanitising results, validation of target levels and critical limits. These verification activities must be carried out periodically in a planned manner to ensure that the HACCP system is maintained and effective.

The review of the HACCP system, as part of verification, is used to determine whether the system is still appropriate to the process of verification. Changes in the process, routing, layout and modification to process equipment should be adapted in the HACCP system. The frequency of review is laid down in the procedure of Verification.

7.12 Establish record keeping and documentation system (principle 7)

The Codex Alimentarius recommends that all HACCP documentation and procedures are organised in a manual. The manual makes reference to other manuals such as, the manual for product

specifications. This will require proper documentation control and an appropriate procedure to ensure that the data remains up-to-date. The manual contains, next to information of each implementation step, a Time & Event schedule for the subjects to be implemented. Documentation is a firm requirement by ISO 22000. The table of contents of the HACCP manual is based on ISO 22000.

8) PROBLEMS OCCURRING DURING IMPLEMENTATION

Potential problems during the implementation include:

- HACCP is introduced before the PRP's are in place. If requirements related to PRP's are not attained at a sufficient level, then it will be impossible to control all hazards which may occur because of the inadequate situation
- HACCP has not sufficient commitment from top management
- HACCP is set up without the involvement and training of personnel
- Inappropriate person appointed as chairman of the HACCP team
- Under-estimation of required time to implement HACCP, lack of resources and/or knowledge
- HACCP concepts are not fully understood
- Changes in processing conditions are ignored
- Unimportant hazards are identified and too many CCP's are introduced

9) CONCLUSION

HACCP is a very effective system to visualise the processing of the product, to identify potential hazards, to implement control and preventive measures on these hazards and to have a plan of corrective action for the identified CCP's. Most important of all is the documentation, necessary for the entire process.

10) RECOMMENDATIONS

- Management Commitment is a firm requirement which must be in place
- Staff and employees must be trained on time, especially on the Pre Requisite Programmes, Hygiene measures and GMPs
- PRP's must be implemented and operational prior to starting with HACCP - certain elements can be implemented simultaniously

- Apply more than one Flow Chart, if necessary, by making use of the connectors, rather than making complex Flow Charts
- Control and/or preventive measures have to be taken from the cause of the hazard and not from the hazard itself - the Hazard Analysis must include the column for causes
- Make use of multidisciplinary groups rather than one permanent HACCP team
- Establish a time & event schedule and use this document as a tool throughout the implementation
- Have procedures, working instructions and checklists developed in an effective and user friendly way, according to ISO standards
- Make the production employees accountable and responsible for what they are doing, giving them the necessary authorisation
- Encourage and/or implement the process control to be carried out by the production employees
- Pay specific attention to downtime, rework and waste material
- Appoint the appropriate person as chairman of the HACCP team

11) REFERENCE LITERATURE

- Codex Alimentarius CAC/RCP 1-1969, Rev. 4-2003
- Food Hygiene Basic Texts. ISBN 92-5-104619-0 FAO and WHO 2001
- EC Regulation No 852/2004 of 29 April 2004 on the Hygiene of Foodstuffs
- ISO 22000 Food safety management systems – Requirements for any organisation in the Food Chain

4 - ABC GUIDE ON FOOD SAFETY MANAGEMENT SYSTEMS

PART 2 SUMMARY OF ISO 22000 FOOD SAFETY MANAGEMENT SYSTEMS

REQUIREMENTS FOR ORGANISATIONS IN THE FOOD CHAIN

1) INTRODUCTION

2) WHY ISO 22000

3) REQUIREMENTS OF ISO 22000

4) WHAT ISO 22000 DELIVERS

5) PRE-REQUISITE PROGRAMMES (PRP's)

6) ISO 22000 CLAUSES

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9) REQUIRED DOCUMENTS AND PROCEDURES

10) OTHER ISO DOCUMENTS RELATED TO THE FOOD INDUSTRY

11) DEVELOPMENT OF ISO STANDARDS

1) INTRODUCTION

Over the years, many countries have developed HACCP standards with different certification levels, subsequently implemented as HACCP systems, based on these standards. Accordingly, standards differ from country to country. However ISO 22000 Food Safety Management requirements for organisations in the Food Chain, have been developed specifically to harmonise with all the individual standards.

ISO 22000 is the combined output of working group WG 8 food safety management systems, ISO technical committee ISO/TC 34 food products, which was formally launched in September 2005.

Experts from 23 countries participated in the working group, together with international organisations with liaison status. In addition to the Codex Alimentarius Commission, these included the Confederation of the Food and Drink Industries of the European Union (CIAA), the CIES/Global Food Safety Initiative and the World Food Safety Organisation (WFSO). They were joined for the development of ISO/TS 22003 by experts from the ISO committee on conformity assessment, ISO/CASCO, the International Accreditation Forum (IAF) and the IQ Net international certification network.

The ISO 22000 standard emphasises the certification requirements for HACCP and will further contribute to the standardisation and harmonisation of the HACCP systems worldwide. The standard incorporates three requisite components:

- Requirements for pre requisites programmes including GMP
- Requirements for HACCP
- Requirements for implementing a management system with a strong component of interactive communication along the Food Chain

This ABC Guide on Food Safety Management Systems provides background information on the reasons for the development of ISO 22000 and more precise details are provided in the ISO standard.

2) WHY ISO 22000

Many HACCP standards have been developed internationally, for example:

- India uses the Indian Standard - Food hygiene – Hazard Analysis and Critical Control Points (HACCP) System and guidelines for its application: ISO 15000 : 1998
- Singapore applies the Singapore Standard 444
- South Africa uses SABS 0330: Code of Practice for the implementation of a HACCP system
- The Netherlands is using Requirements for a HACCP based Food Safety System version September 2002
- Ukraine uses the 'National Standard of Ukraine 4161-2003' Food Safety Management Systems
- Turkey uses the Turkish Standard TS 13001 (March 2003)
- Additionally, the FAO/WHO Codex Alimentarius HACCP Code of Practice CAC/RCP 1-1969, Rev. 4-2003 has been applied for certification

HACCP standards and certificates based on these standards, differ substantially from one country to another. ISO 22000 has been specifically developed to harmonise all of these individual standards.

It is applicable to all organisations, regardless of size, which are involved in any aspect of the food chain and who want to implement systems that consistently provide safe products. This means meeting any requirements of ISO 22000 can be accomplished through the use of internal and/or external resources.

3) REQUIREMENTS OF ISO 22000

ISO 22000 specifies requirements for a food safety management system, where-by an organisation in the food chain needs to demonstrate its ability, in controlling food safety hazards, in order to ensure that food is safe at the time of consumption.

ISO 22000 specifies requirements to enable an organisation:

- To plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer

- To demonstrate compliance with applicable statutory and regulatory food safety requirements
- To evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction
- To effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain
- To ensure that the organisation conforms to its stated food safety policy, to demonstrate such conformity to relevant interested parties
- To seek certification or registration of its food safety management system by an external organisation, or make a self-assessment or self-declaration of conformity to ISO 22000

4) WHAT ISO 22000 DELIVERS

ISO 22000 delivers the following:

- The standard can be used as the basis of any food safety management system, with or without 3rd party certification
- The standard includes requirements for addressing (assessing and implementing) food safety concerns of customers (e.g. retailers) and regulators
- The standard includes Prerequisite programmes (Hygiene and GMP)
- HACCP (Hazard Analysis) is included
- System management (ISO 9000 approach)
- Interactive communication along the food chains

5) PRE-REQUISITE PROGRAMMES (PRP's)

The following pre-requisites must be considered:

- Personnel hygiene
- Layout of premises, including workspace and employee facilities
- Construction and layout of buildings and associated facilities
- Supplies of utilities like water, energy, air, etc.
- Supporting services, including waste and waste disposal
- The suitability of equipment and its accessibility, maintenance and preventive maintenance

- The management of purchased raw materials, ingredients, chemical, utilities or supplies like steam water and ice, disposal of waste and sewage and handling of products (like storage and transportation)
- Measures to prevent cross contamination
- Cleaning and sanitising
- Pest control

Pre-requisites should be documented and the documentation of the pre-requisites depends largely on the size of the companies. The ISO 22000 is designed for both large companies but also for small enterprises. Large companies are highly recommended to document PRP's to facilitate verification purposes.

6) ISO 22000 CLAUSES

The main clauses of ISO 22000 are:

- Documentation requirements
- Management responsibility
- Resource management
- Planning and realisation of safe products
- Verification, validation and improvement of the Food Safety Management system

7) MANDATORY PROCEDURES

ISO 22000 identifies the following procedures which must be documented:

- Documentation
- Records
- Corrections
- Corrective actions
- Recall (which includes traceability)
- Internal auditing

8) DETAILS OF THE CLAUSES AND MANDATORY PROCEDURES

The following is some of the more detailed information and clauses for ISO 22000, where mandatory procedures are relevant:

8.1 Documentation requirements

Documents required by the food safety management system must be controlled to ensure that all proposed changes are reviewed, prior to implementation. This will help to determine the impact on food safety and food safety management system. A documented procedure (No.1) shall be established to define the controls needed.

Records must be established and maintained to provide evidence of conformity to requirements and of the effective operation of the food safety management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure (No. 2) shall be established to define the controls needed for the correction, identification storage protection, retrieval, retention time and disposition of records.

8.2 Management responsibility

Company top management shall provide evidence of their commitment to the development and implementation of the food safety management system and towards continually improving its effectiveness.

Management responsibilities include the following:

- Management commitment
- Food safety policy
- Food safety management planning responsibility and authority
- Appointment of food safety team leader
- Communications which include:
    - * External communication
    - * Internal communication
- Emergency preparedness and response
- Management review
    - * Review input
    - * Review output

8.3 Resource management

The organisation shall provide adequate resources for the establishment, implementation, maintenance and updating of the food safety management system. Resource management includes the following subparagraphs:

- Human resources - training is a major component of resource management
- Infrastructure
- Work environment

8.4 Planning and realisation of safe product

This clause refers more specifically to HACCP, details of which are not covered in this booklet - see Guidance Document on HACCP principles (EU) http://europa.eu.int/comm/food/biosafety/hygienelegislation/guidancedochaccpen.pdf

The ISO 22000 standard is an audible standard and the HACCP system has to comply with the information specified.

The company must plan and develop the processes needed, for the production of safe products. The company must implement, operate and ensure the effectiveness of the planned activities and any changes to those activities. These actions include the prerequisites as well as the operational pre-requisites.

The planning and production of safe products covers the following sub paragraphs:

- Pre-requisite programmes
- Preliminary steps to develop the hazard analysis include:
    - The Food Safety team
    - Raw materials and final product specifications and their intended use
    - Flow diagrams and description of the process steps and control measures
- Hazard analysis
- Operational pre-requisite programmes
- The HACCP plan which includes:
    - The critical control points (CCPs)
    - Determination of critical limits for the CCPs

    * Monitoring system
    * Actions to be implemented when monitoring results exceeding critical limits
- Updating preliminary information and documents specifying the pre-requisite programmes and the HACCP plan
- Verification planning
- Traceability system
- Control of non-conformities
    * Corrections

      The organisation must ensure that when critical limits for the CCPs are exceeded, or there is a loss of control of operational PRPs, the end products are identified and controlled with regard to their use and delivery. A documented procedure (No. 3) shall be established and maintained
    * Corrective actions
- The organisation shall establish and maintain a documented procedure (No. 4) that specifies appropriate actions to identify and eliminate the cause of the detected non conformities, to prevent a recurrence and to bring the process or system back into control after non-conformity is encountered
    * Handling of unsafe products
    * Withdrawal or product recall
- To enable the complete and timely withdrawal of implicated lots of end products that have been identified as unsafe, the organisation must establish and maintain a documented procedure (No. 5) for notification to the relevant interested parties (regulatory authorities, customers and/or consumers)

8.5 Validation, verification and improvement of the Food Safety Management Systems

The food safety team must plan and implement the processes needed to validate control measure combinations and to verify and improve the food safety management systems. Validation, verification and improvement of the food safety management systems covers the following sub paragraphs:

- Validation of control measure combinations
- Control of monitoring and measuring
- Food safety management system verification/internal audit
- The organisation shall conduct internal audits at planned intervals
- The responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records shall be defined in a documented procedure (No.6)
- Improvement
- Continual Improvement
- Food safety management updating

9) REQUIRED DOCUMENTS AND PROCEDURES

Next to mandatory procedures, the final ISO 22000 system contains the following documents and records:

- Management of the pre-requisite programmes
- Characteristics and intended use of the end product
- The HACCP plan
- Product/process flow diagram
- Hazard identification
- Hazard analysis
- Selection of control measures
- Critical limits
- Corrective action records
- Correction records
- Internal audit records
- Calibration records
- Traceability records
- Raw material and ingredient records
- Evaluation and handling of potentially unsafe products or nonconforming product
- Internal and external communication
- Management review
- Monitoring records for operational pre-requisite programmes and HACCP plan
- Product withdrawal records
- Verification
- Training and knowledge records
- Agreements with external food safety experts

10) OTHER ISO DOCUMENTS RELATED TO THE FOOD INDUSTRY

The ISO 9001:2000 standard can be applied for the Food Industry however this is not a common practice as a single system for the Food Industry. If used, it is recommended to be used together with and after HACCP implementation to have a complete Quality Management System.

Nowadays a single HACCP certificate or a single ISO 9001:2000 certificate is not enough. It is essential to have components of both. For this reason, ISO 22000 becomes the ideal standard, as ISO 22000 includes both the ISO 9001:2000 and HACCP requirements.

The ISO 15161:2001 standard provides guidelines on the application of ISO 9001:2000 for the food and drink industry. This guideline is based on the ISO 9001:2000 guideline and includes HACCP. However this standard is not designed for certification, it is not an auditable standard but rather a tool for the Food Industry to implement ISO 9001:2000 in combination with HACCP.

11) DEVELOPMENT OF ISO STANDARDS

ISO 22000 is one of a series of ISO documents. Presently, ISO is working under TC 34 Food Products, for various new documents. These standards will be known as the ISO 22000 family of standards. Others include:

- **ISO 22001** - Guidelines on the application of ISO 9001:2000 for the food and drink industry, which is a revision of ISO 15161:2001

- **ISO 22002** - Quality management systems - Guidance on the application of ISO 9002:2000 for crop production

- **ISO/TS 22003** - Food safety management systems - Requirements for bodies providing audit and certification of food safety management systems, will give harmonised guidance for the accreditation (approval) of ISO 22000 certification bodies and define the rules for auditing a food safety management system as conforming to the standard

- **ISO/TS 22004** - Food safety management systems - Guidance on the application of ISO 22000:2005 was published in November 2005 and provides information to assist organisations including SMEs around the world

- **ISO 22005** - Traceability in the feed and food chain - General principles and guidance for system design and development, will be circulated as a draft international standard

- **ISO 22000** - Fitness Checker: this is a practical, easy-to-use checklist designed to help SMEs to assess their readiness for ISO 22000 certification, in being prepared in partnership, with the International Trade Center (ITC)

5 - RELATED WEBSITES

CIAA	www.ciaa.be
Codex alimentarius	www.codexalimentarius.net
CBI	www.cbi.nl
CIES	www.ciesnet.com
GFSI	www.ciesnet.com
International Organization for Standardization (ISO)	www.iso.org
Food and agricultural Organization (FAO)	www.fao.org
World Health Organization (WHO)	www.who.int
RASSF	http://europa.eu.int/comm/food/food/rapidalert
EHEDG	www.ehedg.org
EUREPGAP	www.eurep.org
EFSA	www.efsa.eu.int
IPCS	www.who.int/pcs/
IQ net	www.iqnet-certification.com
IARC	www.iarc.fr
IFIC	www.ific.org
IFS	www.food-care.info
Portal	www.ipfsaph.org/En/default.jsp
SQF	www.sqfi.com
WFSO	www.worldfoodsafety.org
British Retail Consortium	www.brc.org.uk

ADDITIONAL USEFUL E-MAIL ADDRESSES

EU Basic Facts
http://europa.eu.int/comm/publications/booklets/eu_glance/51/index_en.html

EU DG SANCO (Directorate General for Health and Consumer safety)
http://europa.eu.int/comm/index_en.html

EU Legal Documents
http://europa.eu.int/eur-lex/RECH_menu.do?ihmlang=en

Healthy Food for Europe's Citizens
http://europa.eu.int/comm/publications/booklets/move/20txt_en.pdf

From Farm to Fork – Safe Food for Europe's Consumers
http://europe.eu.int/comm/publications/booklets/move/46/en.pdf

Food Rejected by FDA (US Food & Drugs Administration)
http://www.fda.gov/ora/import/default.html

Good Agricultural Practices (GAP)
http://www.fao.org/ag/magazine/GAP-V2-June02.pdf

EU Food Safety
http://europa.eu.int/comm/dgs/health_consumer/library/pub/cv/cv001/cv001-03_en.html

World Trade Organisation (WTO)
www.wto.org

EU White Paper on Food Safety (2000)
http://europa.eu.int/comm/dgs.health consumer /library /pub/pub06 en.pdf

EU Food Safety Training
http://europa.eu.int/comm/food/training/whitepaper en.html

General Food Regulations (UK)
http://hmso.gov.uk/si/si2004/200443279.html

Food Safety Authority (UK)
www.food,gov.uk/foodindustry/regulation/foodlawguidebranch

Food Safety (EU)
http://europa.eu.int/scadplus/leg/en/s80000.html

Food Safety (EU) Product Labeling and Packaging
www.europa.eu.int/scadplus/leg/en/s16600.html

Veterinary checks, Animal health rules, Hygiene of Food
http://europa.eu.int/scadplus/leg/en/s84000.html

Animal Health (EU)
http://europa.eu.int/scadplus/leg/en/s83000.html

Contamination and Environmental Factors (EU)
http://europa.eu.int/scapplus/leg/en/s86000.html

Organically Grown Agricultural Products and Foodstuffs
http://europa.eu.int/scadplus/leg/en/lvb/121097.html

Veterinary and Phytosanitary Inspections (EU)
http://europa.eu.int/scadplus/leg/en/lvb/132038.html

Prepacked Products (EU)
http://europa.eu.int/scadplus/leg/en/lvb/132029.html

Active and Intelligent Packaging (EU)
http://europa.eu.int/scadplus/leg/en/lvb/121082a.html

Identification of Foodstuffs by Lot (EU)
http://europa.eu.int/scadplus/leg/en/lvb/121091.html

Foodstuffs treated with Ionising Radiation
http://europa.eu.int/scadplus/leg/en/lvb/121117.html

Guidance Document on HACCP Principles (EU)
http://europa.eu.int/comm/food/biosafety/hygienelegislation/guidancedochaccpen.pdf

Codex Food Hygiene Text
ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene2003e.pdf

Recommended International Code of Practice of General Principles of Food Hygiene
www.codexalimentarius.net/download/standards/23/expooi.pdf

Example of an EU Inspection Report (Greece)
http://europa.eu.int/comm/food/fs/inspections/vi/reports/greece/virepgree9257-2003en.pdf

Guidance Document on the Hygiene of Foodstuffs (EU)
http://europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidancedoc852-2004en.pdf

Guidance Document: Key Questions related to Import Requirements and the New Rules on Food Hygiene and Official Food Products (EU)
http://europa.eu.int/comm/food/international/trade/interpretationimports.pdf

Other relevant Guidance Documents (EU)
http://europa.eu.int/comm/food/food/foodlaw/guidance/indexen.html

Guidelines on the Implementation of the main General Food Law requirements
http://europa.eu.int/comm/food/food/foodlaw/guidance/indexen.html

Benchmarked Standards for the Food Industry

- BRC Standard (British Retail Consortium)
  http://www.brc.org.uk/standards/indix.html
- IFS (International Food Standard, France & Germany)
  http://www.food-care.info
- SQF 2000 (Safe Quality Food)
  www.sqfi.com
- Dutch HACCP Code (The Netherlands)
  www.foodsafetymanagement.info

Food Nutrition Labelling (EU) Useful Information sources:

- Product Labelling and Packaging
  http://europa.eu.int/scadplus/leg/en/s16600.html
- Labelling, Presentation and Advertising of Foodstuffs
  http://europa.eu.int/scadplus/leg/en/lvb/121090.html
- Labelling Requirements
  www.fas.usda.gov/GainFiles/200508/146130611.pdf
  http://useu.usmission.gov/agri/label.html
- Canadian Exporters guide to Food Labelling &
- Packaging Requirements of the EU
  http://ats-sea.agr.ca/europe/e1429.htm (Note: 2000 Publication)

Nutrition Labelling (EU)
http://europa.eu.int/scadplus/leg/en/lvb/121092.html

Ingredient and Allergen Labelling
http://portal.wko.at/wk/dok_detail_file.wk?AngID=1&DocID=435488&StID=215710

McDonalds list of Allergens
http://www.mcdonalds.com/app_controller.nutrition.categories.allergens.index.html

EU on-line Customs data base
http://europa.eu.int/comm/taxation_customs/dds/en/tarhome.html

List of EU Customs Authorities
http://europa.eu.int/comm/taxation_customs/databases/bti_en.html