FOOD SAFETY MANAGEMENT SYSTEMS

WORD COUNT 20840
TIME SUBMITTED 05-NOV-2017 01:01PM
PAPER ID 32668181

FOOD SAFETY MANAGEMENT SYSTEMS

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JANUARY 2018

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Index

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INTRODUCTION

All actors in a food chain have a responsibility to ensure the safety of food products at the stages of intervention, irrespective of the nature of the activities they carry out. Food safety systems should be designed to control the production process and be based on preventive principles and concepts. With this type of systems, it is intended to implement measures that ensure efficient control by identifying points or stages where the health hazards of consumers can be controlled. The Hazard Analysis and Critical Control Points (HACCP) methodology is currently the internationally accepted benchmark for the implementation of food safety systems. This methodology has a scientific basis, and is based on a systematic approach. The implementation of a HACCP System facilitates compliance with legal requirements, and allows the most efficient use of resources in the immediate response to food safety issues. The increasing globalization of the food trade has also led to the need to harmonize international food security control measures. In 1993 the Codex Alimentarius Commission published the HACCP code, which was transposed into Community law by Council Directive no. 93/43/EEC of 14 June 1993. However, since 1986 this Commission has recommended that food application of self-monitoring systems based on HACCP principles. The growing number of legal diplomas and controls linked to food safety, as well as the increasing demands of consumers, have created strong and growing pressures on food businesses and on the development of food safety standards to help them meet those requirements. To this end, they have standardization bodies which, as in some countries (e.g. Denmark, the Netherlands, Ireland, Australia), have developed national standards specifying requirements for food safety management systems.

It is within this framework that, with this book, it is intended to present in a systematic way the main relevant elements for an

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adequate understanding of the HACCP methodology. Thus, it is intended to transmit a set of technical information that can facilitate the implementation of a food safety management system capable of satisfying legal requirements and meeting the HACCP certification requirements, thus constituting a reference manual implementation of HACCP Systems.
This book is organized in four sections:

- European legislation in food safety;
- Codex Alimentarius;
- HACCP system;
- Food safety standards.

Through these themes, the general objectives are:

- Introduce the Codex Alimentarius, highlighting in particular the set of codes of good practice and general principles of food hygiene available and discussing the relevance of the implementation of good manufacturing practices (GMP) as a prerequisite for the implementation of a food safety system.
- Explain the current legal framework as regards general hygiene standards for foodstuffs, listing the main legal requirements that an establishment engaged in the preparation, processing, manufacture, packaging, storage, transport, distribution, handling, sale or placing of foodstuffs is subject.
- Present the concept and principles and discuss the methodology of implementation of a HACCP System, describing and illustrating in detail the steps inherent in this process.
- To present the certification requirements associated with the implementation of a HACCP System according to certification standards such as IFS and BRC.

Paulo Baptista

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1

EUROPEAN LEGISLATION IN FOOD SAFETY

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Chapter Objectives

- Present the key European Legislation concerning the General Food Law.
- Present the key European Legislation regarding labelling and nutrition and its importance for food safety.
- Present the key European Legislation regarding the control of biological and chemical in food products.
- Present the key European Legislation concerning the use of additives and flavourings in food products.

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1.1
GENERAL FOOD LAW

1.1.1. PRINCIPLES

The general principles of food and feed law are outlined in the General Food Law Regulation (Regulation no. 178/2002 Articles 5 to 10). They form an horizontal framework underpinning all Union and national measures relating to food and feed. They cover all stages of the production, processing and distribution of food.

The general objectives of food law are:

- Guarantee a high level of protection of human life and health and the protection of consumer's interests. Also guarantee fair practices in food trade, taking into account animal health and welfare, plant health and the environment,
- Ensure free movement of food and feed manufactured and marketed in the European Union, in accordance with the General Food Law Regulation
- Facilitate global trade of safe food by taking into account international standards and agreements when developing European Union legislation, except where this might undermine the high level of consumer protection pursued by the European Union.

RISK ANALYSIS PRINCIPLE

The General Food Law Regulation establishes the principle of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations, which are undertaken by the European Food Safety Authority (EFSA).

Depending on the nature of the measure to be used, food law, and in particular measures relating to food safety must be

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supported by scientific information. The European Union has been at the forefront of the development of risk analysis principles and their subsequent international acceptance. Food law is based on the three inter-related components of risk analysis:

- risk assessment,
- risk management,
- risk communication.

Risk assessment must be undertaken in an independent, objective and transparent manner based on the best available knowledge.

Risk management is the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk. In the risk management phase, the decision makers need to consider a range of other information in addition to the scientific risk assessment, such as:

- most effective risk reduction actions depending on the part of the food supply chain where the problem occurs,
- feasibility of controlling a risk,
- socio-economic effects,
- environmental impact.

Risk communication is the interactive exchange of information and opinion throughout the risk analysis process among risk assessors, risk managers, consumers, food businesses, academics, other interested parties.

PRECAUTIONARY PRINCIPLE

The precautionary principle (Article no. 7 of the General Food Law – Regulation no. 178/2002) refers to specific situations where:

there are reasonable grounds for concern that an unacceptable level of risk to health exists

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the available supporting information and data are not sufficiently complete to enable a comprehensive risk assessment to be made.

When faced with these specific circumstances, decision makers or risk managers may take measures or other actions based on the precautionary principle, while seeking more complete scientific data. Such measures have to comply with the principles of non-discrimination and proportionality and should be provisional until the time when more comprehensive information concerning the risk can be gathered and analyzed.

1.1.2. REQUIREMENTS

SAFETY REQUIREMENTS

The safety of food is of critical importance. Consumers must have confidence and assurance that the food they buy will do them no harm or have an adverse effect.

The General Food Law Regulation establishes that only safe food can be placed on the European Union market or fed to food-producing animals. It also establishes basic criteria for establishing whether a food is safe.

TRACEABILITY

Food traceability throughout the food chain is very important for the protection of consumers, particularly when food are found to be faulty. The General Food Law Regulation defines traceability as the "ability to trace and follow food, feed, and ingredients through all stages of production, processing and distribution". Traceability should:

- facilitate withdrawal of unsafe food from the market,
- provide consumers with targeted and accurate information on specific products,
- cover all food and all food business operators, without prejudice to existing legislation on specific sectors,
- affect importers who are required to be able to identify from whom the product was exported in the country of origin,

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- oblige businesses to be able to identify at least the immediate supplier of the product in question and the immediate subsequent customers, with the exemption of retailers to final consumers - one step back-one step forward.

More detailed traceability requirements in the context of the General Food Law Regulation are laid down for certain specific sectors, namely:

- Foods of animal origin: Regulation no. 931/2011,
- Sprouts and sprout seeds: Regulation no. 208/2013.

OPERATORS RESPONSIBILITIES

Primary responsibility for ensuring compliance with food law - and in particular the safety of the food business operators. When food is unsafe, business operators are obliged to withdraw or recall it. They are also obliged to notify the competent national authorities so as to be able to monitor whether the appropriate measures have been taken or require that additional measures be taken for reducing or eliminating a food safety risk.

1.1.3. PROCEDURES

The General Food Law Regulation sets out certain procedures related to food safety. In particular, it provides for 4 measures:

- the establishment of the Rapid Alert System for Food and Feed (RASFF),
- the establishment of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee),
- the adoption of emergency measures,
- the establishment of a general plan for crisis management.

RAPID ALERT SYSTEM FOR FOOD AND FEED

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The primary focus of the European Union (EU) is on maintaining a high level of safety and ensuring quick responses to any threats that do arise. One key tool used to react rapidly to food and feed safety emergencies and incidents is the Rapid Alert System for Food and Feed. RASFF enables information to be shared efficiently between its members (EU-28 national food safety authorities, European Commission, EFSA, Norway, Liechtenstein, Iceland and Switzerland). RASFF members have to notify the RASFF if they take such measures as withdrawing or recalling food or feed products from the market in order to protect consumers health and if rapid action is required.

STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED

The PAFF Committee plays a key role in ensuring that European Union measures on food and feed safety, animal health & welfare as well as plant health are practical and effective. It delivers opinions on draft measures that the Commission intends to adopt. The PAFF Committee is composed by representatives of all Member States and presided by a European Commission representative. The PAFF Committee's mandate covers the entire food supply chain - from animal health issues on the farm to the product on the consumers table - helping the European Union to deal effectively with health risks at every stage of the production chain.

EMERGENCY MEASURES

Where food, including those imported from a non-EU country presents a serious risk to human health, the European Commission can put in place protective measures, following an opinion from the PAFF Committee and:

- suspend the placing on the market or use of products originating from the EU,
- suspend imports of products originating from non-EU countries.

Such action can be initiated by the European Commission itself, or requested by a Member State. However, if the European

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Commission does not act after having been informed of the existence of a risk, the EU country concerned may take interim protective measures. Within a period of 10 working days, the Commission must refer the matter to the PAFF Committee with a view to extending, amending or revoking the national measures.

CRISIS MANAGEMENT

Sometimes, incidents related to food that pose potential serious risks to human health cannot be managed properly within routine procedures. In such cases, the European Commission, the EFSA and the affected European Union countries shall follow the general crisis-management plan as adopted by Decision no. 2004/478/EC.

In the case of a serious risk, the European Commission must immediately set up a crisis unit, with scientific and technical support from EFSA. This crisis unit is responsible for collecting and evaluating all relevant information and identifying the options available for preventing, eliminating or reducing the risk to human health. Management procedures are lay down in Decision no. 2004/478/EC. In order to allow the application of the general plan for crisis management, Member States are also required to draw up their own contingency plans to apply in emergency situations. According to Article no. 13 of Regulation no. 882/2004, these contingency plans must outline the national administrative authorities to be engaged in crisis management, and their respective responsibilities and authorities, as well as the channels and procedures for communication between the relevant players.

1.2
LABELLING AND NUTRITION

1.2.1. FOOD LABELLING

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LEGISLATION

The Regulation no. 1169/2011 on the provision of food information to consumers entered into application on 13 December 2014. This law combines 2 Directives into one legislation:

- Directive no. 2000/13/EC - Labelling, presentation and advertising of foodstuffs,
- Directive no. 90/496/EEC - Nutrition labelling for foodstuffs.

KEY ELEMENTS

The key elements contained in the Regulation no. 1169/2011 that are mandatory in terms of labelling are:

- The name of the food;
- The list of ingredients;
- Any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;
- The quantity of certain ingredients or categories of ingredients;
- The net quantity of the food;
- The date of minimum durability or the 'use by' date;
- Any special storage conditions and/or conditions of use;
- The name or business name and address of the food business operator;
- The country of origin or place of provenance where provided;
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions;

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- With respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume;
- A nutrition declaration.

Some exceptions or specific rules are detailed in specific articles (Articles 17 to 28).

NUTRITION DECLARATION

Rules for application of a nutrition declaration are detailed in Section 3 – Artic 29 to 35 – of Regulation no. 1169/2011. The mandatory nutrition declaration shall include the following: i) energy value, and ii) the amounts of fat, saturates carbohydrate, sugars, protein and salt. Where appropriate, a statement indicating that the salt content is exclusively due to the presence of naturally occurring sodium may appear in close proximity to the nutrition declaration.

The content of the mandatory nutrition declaration may be supplemented with an indication of the amounts of one or more of the following:

- Mono-unsaturated fats;
- Polyunsaturated fats;
- Polyols;
- Starch;
- Fiber;
- Any of the vitamins or minerals listed in point 1 of Part A of Annex XIII, and present in significant amounts as defined in point 2 of Part A of Annex XIII of Regulation no. 1169/2011.

ORIGIN LABELLING

For fresh, chilled and frozen meat of swine, sheep, goats and poultry it is mandatory the indication of country of origin or place of provenance for fresh chilled and frozen meat of swine, sheep, goats and poultry after an impact assessment.

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1.2.2. NUTRITION AND HEALTH CLAIMS

European Union rules on nutrition and health claims have been established by Regulation no. 1924/2006. This regulation is the legal framework used by food business operators when they want to highlight the particular beneficial effects of their products, in relation to health and nutrition, on the product label or in its advertising.

The rules of this Regulation apply to nutrition claims and to health claims. The nutritional claims that can be used are:

- Low energy;
- Energy reduced;
- Energy-free;
- Low fat;
- Fat-free;
- Low saturated fat;
- Saturated fat-free;
- Low sugars;
- Sugars-free;
- With no sugars added;
- Low sodium/salt;
- Very low sodium/salt;
- Sodium-free or salt-free;
- No added sodium/salt;
- Source of fiber;
- High fiber;
- Source of protein;
- High protein;

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- Source of [name of vitamin/s] and/or [name of mineral/s];
- High [name of vitamin/s] and/or [name of mineral/s];
- Contains [name of the nutrient or other substance];
- Increased [name of the nutrient];
- Reduced [name of the nutrient];
- Light/Lite;
- Naturally/Natural;
- Source of Omega-3 fatty acids;
- High Omega-3 fatty acids;
- High Monounsaturated fat;
- High Polyunsaturated fat;
- High unsaturated fat.

The conditions for its use are described in the Annex of Regulation no. 1924/2006. The objective of those rules is to ensure that any claim made on foods labelling, presentation or advertising in the European Union is clear, accurate and based on scientific evidence and to prevent the use of claims that could mislead consumers on the EU market. The rules ensure the free circulation of foods bearing claims, as any food company may use the same claims on its products anywhere in the European Union.

1.2.3. FOOD SUPPLEMENTS

As an addition to a normal diet, food business operators market food supplements, which are concentrated sources of nutrients (or other substances) with a nutritional or physiological effect. Such food supplements can be marketed in "dose" form, such as pills, tablets, capsules, liquids in measured doses, etc.

The objective of the harmonized rules on those products in Directive no. 2002/46/EC is to protect consumers against potential health risks from those products and to ensure that they are not provided with misleading information.

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With respect to the safety of food supplements, the Directive lays down a harmonized list of vitamins and minerals that may be added for nutritional purposes in food supplements (in Annex I to the Directive no. 2002/46/EC and following amendments). The Annex II of the Directive contains a list of permitted sources (vitamin and mineral substances) from which those vitamins and minerals may be manufactured. The trade of products containing vitamins and minerals not listed in Annex II is prohibited.

Member States may, for monitoring purposes, request notification to their competent authority of the placing on the market in their territory of a food supplement product in accordance with Article 10 of the Directive no. 2002/46/EC.

1.2.4. ADDITION OF VITAMINS AND MINERALS

A wide range of nutrients and other ingredients are used in food manufacturing, such as):

- Vitamins,
- Minerals including trace elements,
- Amino acids,
- Essential fatty acids,
- Fiber,
- Various plants and herbal extracts.

Such nutrients or ingredients are added to food in order to "enrich" or "fortify" the food in question, so as to add or emphasize particular nutritional characteristics.

Regulation no. 1925/2006 harmonizes the provisions regarding the addition of vitamins and minerals and of certain other substances to foods. This Regulation ensures the effective functioning of the internal market whilst providing a high level of consumer protection.

In Annex I of the Regulation no. 1925/2006 it is presented the list of vitamins and minerals which may be added to foods. In Annex II presents a list of the sources of vitamins and minerals which may be added to foods. Annex I and Annex II have been

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amended later on by three Commission Regulations to include additional substances:

- Regulation no. 2017/1203,
- Regulation no. 119/2014,
- Regulation no. 1161/2011
- Regulation no. 1170/2009.

Annex III presents a list of substances other than vitamins or minerals whose use in foods is prohibited, restricted or under Community scrutiny. Annex III has been amended by Commission Regulation no. 2015/403.

Vitamin and mineral substances may be considered for inclusion in the lists following the evaluation of an appropriate scientific dossier concerning the safety and bioavailability of the individual substance by EFSA.

The Regulation provides for the setting of maximum amounts of vitamins and minerals in these products via the procedure of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). Minimum amounts are linked to the notion of significant amount, where this is defined according to Annex XIII to Regulation (EU) No 1169/2011.

The Commission, on its own initiative or at the request of a Member State, may initiate the procedure under Article 8 of the Regulation to prohibit, restrict or put under Union scrutiny a substance other than vitamins or minerals or an ingredient containing such a substance that is added to foods or used in the manufacture of foods. This could happen where the use of such substances in foods would result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

1.2.5. NATURAL MINERAL WATERS

There are different categories of waters intended for human consumption such as natural mineral waters and spring waters. Natural mineral waters may be distinguished from ordinary drinking water by their purity at source and their constant level

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of minerals. Spring waters are intended for human consumption in their natural state and are bottled at source.

The Directive no. 2009/54/EC regulates the marketing and exploitation of natural mineral waters. Certain provisions of this Directive are also applicable to spring waters such as the microbiological requirements and labelling requirements.

The Directive no. 2003/40/EC establishes the list, concentration limits and labelling requirements for the natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.

Natural mineral waters and spring waters may be treated at source to remove unstable elements and some undesirable constituents in compliance with the provisions laid down in Article 4 of the Directive no. 2009/54/EC. Treatments other than filtration or decanting with possible oxygenation have to be assessed and authorized at EU level prior to their use by industry. Regulation no. 115/2010 lays down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters.

Natural mineral waters are subject to an authorization procedure carried out by the competent authorities of the EU Member States or by European Economic Area (EEA) countries. The lists of natural mineral waters officially recognized by the Member States of the EU and of the EEA (Iceland and Norway) are published by the European Commission in the Official Journal of the European Union. These lists are regularly updated.

1.2.6. FOOD FOR SPECIFIC GROUPS

The Regulation no. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ('Food for Specific Groups') entered in force from 20th July 2016. This Regulation aims to protect specific vulnerable groups of consumers (infants and young children, people with specific medical conditions and people undertaking energy-restricted diets to lose weight) by regulating the content and marketing of food products specifically created for and marketed to them. It also aims to increase legal clarity for business and to facilitate correct application of the rules. This Regulation:

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- Strengthens provisions on foods for vulnerable population groups to ensure their protection,
- Sets general compositional and labelling rules and require the Commission to adopt, through delegated acts, specific compositional and labelling rules for:
  - Infant and follow-on formula,
  - Processed-cereal based food and other baby food,
  - Food for special medical purposes,
  - Total diet replacement for weight control,
- Simplifies the regulatory framework, by eliminating those rules that are unnecessary and contradictory and by replacing them with a new Framework which takes into account the developments on the market and in EU food law,
- Establishes a single European Union list of substances that can be added to these foods including minerals and vitamins,
- Requires the European Commission to transfer rules on gluten-free foods and very low gluten under Regulation no. 1169/2011 on food information to consumers in order to ensure clarity and consistency,
- Establishes that meal replacement products for weight control should be regulated solely under Regulation no. 1924/2006 on nutrition and health claims in order to ensure legal certainty.

1.3 BIOLOGICAL SAFETY

1.3.1. ANTIMICROBIAL RESISTANCE

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Antimicrobial resistance is the ability of microorganisms to resist antimicrobial treatments, especially antibiotics. Antimicrobial resistance is a natural phenomenon but an accumulation of factors, including excessive and inappropriate use of antimicrobial medicines on humans and animals and poor hygiene or infection control practices, transformed antimicrobial resistance into a serious threat to public health worldwide. Antimicrobial resistance is already responsible for an estimated 25,000 deaths per year in the European Union. Current worldwide mortality from Antimicrobial Resistance is estimated at 700,000 deaths per year.

It also has wide impacts on the economy, with higher costs of treatments and economic losses due to reduced productivity caused by sickness. In the EU alone it is estimated that antimicrobial resistance annually costs EUR 1.5 billion in healthcare costs and productivity losses. The World Bank warns that, by 2050, drug-resistant infections could cause global economic damage on a par with the 2008 financial crisis.

1.3.2. CRISIS PREPAREDNESS AND MANAGEMENT

EU legislation is built in accordance with the prevention principle. It thus aims at preventing outbreaks of food-borne disease through a set of comprehensive standards, such as good hygiene, limits of residues of substances used in the food chain, own-checks, official controls.

Nevertheless crises occasionally occur. Past food and feed safety crises (such as BSE - - bovine spongiform encephalopathy - in the 90's, dioxin in 1999, verotoxin-producing *Escherichia coli* (VTEC) in sprouts in 2011) caused human suffering and even deaths. In addition they had a tremendous impact on the European economy.

Preparedness and management of crisis related to food and feed safety aims to avoid or minimize the health and economic impact of possible future crisis.

The basic requirements are set-up on the Regulation no. 178/2002 (in Articles no. 55 to 57). The Commission Decision no. 2004/478/EC addresses a general plan for food crisis management.

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In order to support action by the EU agencies, the European Union is equipped with rapid alert systems allowing real-time exchange of information on:

- distribution and investigations of affected food and feed batches (RASFF)
- and real-time exchange of information on human cases (Early Warning Response System - EWRS).

The EU coordinates investigations both on the public health side (information from human cases) and towards the food source in different Member States by organizing, if needed daily, meetings of the responsible national coordinators. It also tries to streamline the communication to citizens and trade partners, for instance on advice to travelers. EFSA and the European Centre for Prevention and Control of Diseases (ECDC) provide at a very early stage joint rapid outbreak assessments supporting investigations by the public health and food safety authorities.

1.3.3. FOOD HYGIENE

Rules on hygiene of foodstuffs were adopted by the European Union in April 2004 through the Regulation no. 852/2004, 853/2004 and 854/2004. The 2004 rules merged, harmonized and simplified detailed and complex hygiene requirements previously contained in a number of Directives covering the hygiene of foodstuffs and the production and placing on the market of products of animal origin. These rules are in place since 2006, applicable to all food and all food operators right through the food chain ("from farm to fork").

1.3.4. FOOD-BORNE DISEASES (ZOONOSES)

Some infections in animals, the so-called zoonoses, such as brucellosis, salmonellosis and listeriosis, can be transmitted to humans in particular through contaminated food and in some cases, by contact with the live or slaughtered animal.

Specific measures against zoonoses exist in EU legislation relating to Veterinary Public Health. For instance, rules

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concerning BSE are laid down in Regulation no. 999/2001 and measures to inspect meat for the presence of parasites, such as *Cysticercus* and *Trichinella*, are included in the legislation concerning meat hygiene (Regulations no. 853/2004, 854/2004 and 2015/1375).

As a follow up of the 2000 White Paper on Food Safety and based on scientific advice, two Regulations were adopted to cut the incidence of food borne diseases such as Salmonella in the European Union:

- Regulation no. 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents,
- Directive no. 2003/99/EC on the monitoring of zoonoses and zoonotic agents.

1.3.5. FOOD IRRADIATION

Irradiation is physical treatment of food with high-energy ionizing radiation to:

- Destroy micro-organisms, viruses, bacteria or insects,
- Prevent germination and sprouting of potatoes, onions and garlic,
- Slow down ripening and ageing of fruit and vegetables,
- Prolong the shelf life and prevent food-borne diseases in meat, poultry and seafood.

Its use is limited but authorized in many countries. Treating food with ionizing radiation may be authorized if:

- there is reasonable technological need,
- it poses no health hazard,
- it benefits consumers,
- it does not replace hygiene, health or good manufacturing or agricultural practice.

Irradiated food or one containing irradiated ingredients must be labelled. Food irradiation has nothing to do with radioactive contamination of food resulting from a spill or an accident.

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1.4
CHEMICAL SAFETY

1.4.1. CONTAMINANTS

Contaminants are substances that have not been intentionally added to food. These substances may be present in food as a result of the various stages of its production, packaging, transport or holding. They also might result from environmental contamination. Since contamination generally has a negative impact on the quality of food and may imply a risk to human health, the EU has taken measures to minimize contaminants in foodstuffs.

The EU established maximum levels for different contaminants. These maximum levels might be applicable to all or just to some type of food products. Maximum levels of the same contaminant might be different for different types of foods. The following basic principles of EU legislation on contaminants in food are laid down in Directive no. 315/93/EEC:

- food containing a contaminant to an amount unacceptable from the public health viewpoint and in particular at a toxicological level, shall not be placed on the market,
- contaminant levels shall be kept as low as can reasonably be achieved following recommended good working practices,
- maximum levels must be set for certain contaminants in order to protect public health.

Maximum levels for certain contaminants in food are set in Regulation no. 1881/2006. Maximum levels in certain foods are set for the following contaminants:

- nitrate,
- mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins and citrinine),

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- metals (lead, cadmium, mercury, inorganic tin, arsenic),
- 3-MCPD,
- dioxins,
- dioxin-like PCBs,
- non dioxin-like PCBs,
- polycyclic Aromatic Hydrocarbons (PAH) (benzo(a)pyrene) and sum of 4 PAHs),
- melamine,
- erucic acid.

1.4.2. RESIDUES OF VETERINARY MEDICINES

Food-producing animals may be treated with veterinary medicines to prevent or cure disease. These substances may leave residues in the food from treated animals. Food may also contain residues of pesticides and contaminants to which animals have been exposed to. In all cases, the levels of residues in food should not harm the consumer.

The EU countries must implement residue monitoring plans to detect the illegal use or misuse of authorized veterinary medicines in food producing animals and investigate the reasons for residue violations. The Non-EU countries exporting to the EU must implement a residue monitoring plan which guarantees an equivalent level of food safety as that of the EU.

The European Medicines Agency (EMA) is responsible for assessing Maximum Residue Limits for veterinary medicinal products marketed in the EU. Member States need to monitor food of animal origin for the presence of residues. The key legislation covering residues of veterinary medicinal products is the following:

- Directive no. 96/22/EC - Bans the use of certain substances in food producing animals,
- Directive no. 96/23/EC – Establishes residue monitoring plans, sampling frequency and range of substances to be

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tested for,

- Decision no. 97/747/EC – Includes additional sampling frequencies for milk, eggs, honey, rabbits and game meat,
- Decision no. 98/179/EC – Establishes rules for taking official samples and accreditation requirements for official laboratories,
- Directive no. 2001/82/EC - Establishes the rules for the authorization and use of veterinary medicinal products,
- Decision no. 2002/657/EC – Establishes rules for the validation of analytical methods used in the residue monitoring plan,
- Directive no. 2005/34/EC - Establishes Minimum Required Performance Limits (MRPLs) for residues of certain veterinary medicines not permitted to be used in the EU but which may present in imported food,
- Regulation no. 396/2005 - Establishes maximum residue limits for pesticides in food,
- Regulation no. 1881/2006 - Establishes maximum levels for contaminants in food,
- Regulation no. 470/2009 - Establishes procedures for the Setting of Maximum Residue Limits (MRLs) for veterinary medicines in food,
- Regulation no. 37/2010 - Establishes a list of MRLs for permitted substances.

1.4.3. HORMONES IN MEAT

In 1981, with Directive no. 81/602/EEC, the EU prohibited the use of substances having a hormonal action for growth promotion in farm animals such as oestradiol 17ß, testosterone, progesterone, zeranol, trenbolone acetate and melengestrol acetate. This prohibition applies to Member States and imports from third countries. The legal instrument in force is the Directive no. 96/22/EC as amended by Directive no.

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2003/74/EC. These Directives established the prohibition of the use in stock farming of certain substances having a hormonal or thyrostatic action and of ß-agonists.

1.4.4. PESTICIDE RESIDUES

The term pesticides includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematicides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides. Pesticide can be defined as something that prevents, destroys, or controls a harmful organism ('pest') or disease, or protects plants or plant products during production, storage and transport.

The most common use of pesticides is in the form of plant protection products (PPPs). The term 'pesticide' is often used interchangeably with 'plant protection product', however, pesticide is a broader term that also covers non plant/crop uses, for example biocides. Plant protection products are pesticides that protect crops or desirable or useful plants. They are primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. A plant protection product usually contains more than one component. The active component against pests/plant diseases is called 'active substance'. An active substance is any chemical, plant extract, pheromone or micro-organism (including viruses), that has action against pests or on plants, parts of plants or plant products. Active substances have one of the following functions:

- to protect plants or plant products against pests/diseases, before or after harvest,
- to influence the life processes of plants (such as substances influencing their growth, excluding nutrients),
- to preserve plant products,
- to destroy or prevent growth of undesired plants or parts of plants.

APPROVAL OF ACTIVE SUBSTANCES

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Before an active substance can be used within a plant protection product in the EU, it must be approved by the European Commission. Active substances undergo an intensive evaluation and peer-review by Member States and the European Food Safety Authority before a decision can be made on approval.

The main steps for the approval of an active substance in the EU are the following:

- Application to an EU country called Rapporteur Member State (RMS),
- RMS verifies if the application is admissible,
- RMS prepares a draft assessment report,
- EFSA issues its conclusions,
- Standing Committee for Food Chain and Animal Health votes on approval or non-approval,
- Adoption by the Commission,
- Publication of a Regulation in the EU Official Journal.

Normally it takes 2.5 to 3.5 years from the date of admissibility of the application to the publication of a Regulation approving a new active substance. This time varies depending on the degree of complexity and detail of the dossier.

MAXIMUM RESIDUE LIMITS

The traces pesticides leave in treated products are called 'residues'. A maximum residue limits (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly (GAP - Good Agricultural Practice). The amounts of residues found in food must be safe for consumers and must be as low as possible. The European Commission fixes MRLs for all food and animal feed products. These can be found in the database on the European Commission website (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN).

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1.4.5. FOOD CONTACT MATERIALS

Before being consumed, food products might come into contact with many materials during its production, processing, storage, preparation and serving. Such materials are called Food Contact Materials (FCMs). Food contact materials are either intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use. This includes direct or indirect contact. Examples include:

- packaging materials,
- containers for transporting food,
- equipments to process food,
- tools and utensils.

The term does not cover fixed public or private water supply equipment.

FCMs should be sufficiently inert so that their constituents neither adversely affect consumer health nor influence the quality of the food. To ensure the safety of FCMs, the EU law establishes rules that food business operators must comply with.

The EU rules on food contact materials can be of general scope, that means, apply to all FCMs or apply to specific materials only. EU law can be complemented with Member States national legislation if specific EU rules do not exist.

The safety of Food Contact Materials is tested by the business operators placing them on the market, and by the competent authorities of the Member States during official controls. Scientific knowledge and technical competence on testing methods is being maintained by the European Reference Laboratory for Food Contact Materials (EURL-FCM).

EU GENERAL LEGISLATION

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Regulation no. 1935/2004 provides a harmonized legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

The principles set out in Regulation no. 1935/2004 require that materials do not:

- release their constituents into food at levels harmful to human health,
- change food composition, taste and odor in an unacceptable way.

Moreover, the framework provides:

- special rules on active and intelligent materials (they are by their design not inert),
- power to enact additional EU measures for specific materials (e.g. for plastics),
- the procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority,
- the rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle, or a soup spoon) or by reproducing the appropriate symbol,
- Requirements for documentation compliance and traceability.

EU REGULATION ON GOOD MANUFACTURING PRACTICES

Regulation no. 2023/2006 ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- premises fit for purpose and staff awareness of critical production stages,
- documented quality assurance and quality control systems maintained at the premises, and

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- selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles.

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials.

EU LEGISLATION ON SPECIFIC MATERIALS

In addition to the general legislation, certain FCMs — ceramic materials, regenerated cellulose film, plastics, as well as active and intelligent materials — are covered by specific EU measures. There are also specific rules on some starting substances used to produce FCMs.

PLASTIC MATERIALS

The most comprehensive specific EU measure is Regulation no. 10/2011 on plastic materials. It sets out rules on the composition of plastic FCMs, and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles. This Regulation has been regularly amended (Regulations no. 1282/2011, no. 1183/2012, no. 202/2014, no. 865/2014, no. 174/2015, no. 1416/2016, no. 752/2017).

An important mechanism to ensure the safety of plastic materials is the use of migration limits. These limits specify the maximum amount of substances allowed to migrate to food. For the substances on the Union list the Regulation sets out Specific Migration Limits (SMLs). These are established by EFSA on the basis of toxicity data of each specific substance. To ensure the overall quality of the plastic, the overall migration to a food of all substances together may not exceed the Overall Migration Limit (OML) of 60mg/kg food, or 10 mg/dm2 of the contact material.

The Regulation sets out detailed migration testing rules. Although migration testing in the food prevails, migration is usually tested using simulants. These simulants are representative for a food category and are done under

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standardized time/temperature conditions, representative for a certain food use, and covers the maximum shelf life of packed food.

To ensure the safety, quality and compliance of plastic materials, adequate data on the composition of (intermediate) materials has to be communicated via the manufacturing chain, up to but not including the retail stage. For this purpose a 'Declaration of Compliance' (DoC) needs to be provided. The DoC is based on supporting documentation which documents the reasoning on the safety of a plastic food contact material, and which must be provided to enforcement Authorities on their request.

ACTIVE AND INTELLIGENT MATERIALS

Active and intelligent materials extend the shelf-life by maintaining or improving the condition of packaged food, by releasing or absorbing substances to or from the food or its surrounding environment. As a result they are exempted from the general inertness rule in Regulation no. 1935/2004. The specific rules are defined in the Regulation (EC) No 450/2009 addressing their specific purpose, such as:

- absorption of substances from food packaging interior such as liquid and oxygen,
- release of substances into the food such as preservatives,
- indicate expiry of food through labelling that changes Colour when maximum shelf life or storage temperature is exceeded.

Active materials do not include systems that absorb substances entering from the atmosphere, such as active oxygen barriers.

OTHER MATERIALS

Regulation no. 10/2011 sets out criteria for the composition of new plastic materials. However after these materials have been used, they do not comply anymore with this regulation as they may have been contaminated with other substances. Therefore, a separate Regulation exists to control the recycling processes:

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Regulation no. 282/2008 on recycled plastic materials and articles intended to come into contact with foods

Other specific regulations exists for ceramics: Directive no. 84/500/EEC – approximating EU countries laws on ceramic articles intended to come into contact with foods; regenerated cellulose film: Directive no. 2007/42/EC - materials and articles made of regenerated cellulose film intended to come into contact with foods.

Other legislation on specific substances also exists: Regulation no. 1895/2005 - restricting use of certain epoxy derivatives in materials and articles intended to come into contact with food; Directive no. 93/11/EEC – concerning the release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers. From the 1st July 2011 kitchenware made of melamine or polyamide originating or consigned from China or Hong Kong must comply with the import rules of Regulation no. 284/2011.

1.5

FOOD IMPROVEMENT AGENTS

Food additives, food enzymes and food Flavourings are also known as 'food improvement agents'. Food improvement agents are added to food for different reasons. Among others, food additives preserve, Colour and stabilize food during its production, packaging or storage. Enzymes have specific biochemical actions which serve technological purposes in a certain stage of the food chain. Flavourings give or change the odor or taste to food.

1.5.1. ADDITIVES

Additives are substances used for a variety of reasons - such as preservation, Colouring, sweetening - during the preparation of food. The European Union legislation defines additives as 'any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value'. Added to food for technological

Erasmus+

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purposes in its manufacture, processing, preparation, treatment, packaging, transport or storage, food additives become a component of the food.

Additives can be used for various purposes. EU legislation defines 26 functional classes of food additives in foods and of food additives in food additives and food enzymes:

- acidity regulators,
- acids,
- anti-caking agents,
- anti-foaming agents,
- antioxidants,
- bulking agents,
- carriers,
- Colours,
- emulsifiers,
- emulsifying salts,
- firming agents,
- flavour enhancers,
- flour treatment agents,
- foaming agents,
- gelling agents,
- glazing agents,
- humectants,
- modified starches,
- packaging gases,
- preservatives,
- propellants,
- raising agents,

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- sequestrants,
- stabilizers,
- sweeteners,
- thickeners.

EU RULES

The safety of all food additives that are currently authorized has been assessed by the Scientific Committee on Food (SCF) and/or the European Food Safety Authority. All additives in the EU must be authorized and listed with conditions of use in the EU's positive list based on:

- a safety assessment,
- the technological need,
- ensuring that use of the additive will not mislead consumers.

Regulation no. 1333/2008 sets the rules on food additives: definitions, conditions of use, labelling and procedures. It contains:

- Annex I - Technological functions of food additives,
- Annex II - EU list of food additives approved for use in food additives and conditions of use,
- Annex III – European Union list of food additives approved for use in food additives, food enzymes and food Flavourings, and their conditions of use,
- Annex IV - Traditional foods for which certain Member States may continue to prohibit the use of certain categories of food additives,
- Annex V - Additives labelling information for certain food Colours.

The list of authorized food additives approved for use in food additives, enzymes and flavourings can be found in the Annex of Commission Regulation no. 1130/2011 which amends Annex

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III to Regulation no. 1333/2008. The additives approved for use in flavourings can be found in part 4 of this Annex.

Food additives must comply with specifications which should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity. Regulation no. 231/2012 laid down specifications for food additives listed in Annexes II and III to Regulation no. 1333/2008.

An up-dated EU database concerning authorized additives it is available in the European Commission website (https://webgate.ec.europa.eu/foods_system/main/?sector=FAD&auth=SANCAS).

1.5.2. FLAVOURINGS

Flavourings are products added to food in order to impart or modify odor and/or taste. EU legislation defines several types of flavourings:

- flavouring substances,
- flavouring preparations,
- thermal process flavourings,
- smoke flavourings,
- flavour precursors,
- other flavourings.

The EU Rules on flavourings and certain food ingredients with flavouring properties are intended to ensure a high level of protection of human health and a high level of consumer protection. Regulation no. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in/on foods lays down general requirements for safe use of flavourings and provides definitions for different types of flavourings. The Regulation sets out substances for which an evaluation and approval is required. The Union list of flavouring substances, approved for use in and on foods, was adopted on 1 October 2012 and was introduced in Annex I of this Regulation. The Union list of flavourings has been amended several time in the following Regulations: no. 545/2013, no. 985/2013, no. 246/2014, no. 1098/2014, no. 648/2015, no.

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1102/2015, no. 1760/2015, no. 54/2016, no. 55/2016, no. 178/2016, no. 617/2016, no. 692/2016, no. 1244/2016, no. 378/2017. The Regulation prohibits the addition of certain natural undesirable substances as such to food and lays down maximum levels for certain substances, which are naturally present in flavourings and in food ingredients with flavourings properties, but which may raise concern for human health.

An up-dated EU database concerning authorized food additives that can be used as flavourings can be found in the European Commission website (https://webgate.ec.europa.eu/foods_system/main/?sector=FAD&auth=SANCAS). There is also a separate Union list of smoke flavouring primary products. Regulation no. 1321/2013 established the EU list of smoke flavouring primary products for use as such in foods and for the production of derived smoke flavourings.

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2

GOOD PRACTICE CODE/ CODEX ALIMENTARIUS

AUTHORS:

- **Paulo Baptista**

Chapter Objectives

- Introduce the Codex Alimentarius, highlighting in particular the set of codes of good practice and general principles of food hygiene available.
- Discuss the relevance of the implementation of good practices as a prerequisite for the implementation of a food safety system and the relevance of the Codex Alimentarius to support the conduct of hazard analysis when implementing such systems.
- Present good practices that should be included in most codes

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of good practice and which should be adequately ensured prior to the implementation of a food safety management system.

2.1

THE CODEX ALIMENTARIUS

The Codex Alimentarius Commission (CAC) was created in 1962 at a conference on legal standards for food organized by the Food and Agriculture Organization of the United Nations and the World Health Organization. The members of the Codex Alimentarius Commission are the Member States of Food And Agriculture Organization (FAO) and WHO that have notified their interest in participating in the group. The organization of the Codex Alimentarius Commission is structured in committees of three types:

- Horizontal, to address problems of a general nature;
- Vertical, organized in a product logic;
- Regional, structured around geographical areas: Africa, Asia, Europe and Latin America.

The Codex Alimentarius consists of a set of documents of various kinds, grouped into two main groups: food standards and advisory provisions. Food standards aim to protect consumer health and ensure uniform application of practices in international trade through their international acceptance. The provisions of a consultative nature come in the form of codes of practice, guidelines and other recommendations and are therefore not binding on the part of the Member States. These are intended to guide and promote the development and establishment of food requirements.

The provisions of the Codex Alimentarius include standards for the main processed, semi-processed or raw foods, raw materials and also include aspects related to the distribution of food products. Codex Alimentarius also addresses issues related to food hygiene, food additives, pesticide residues,

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contaminants, labeling and presentation, methods of analysis and sampling. The elaboration of these standards involves Committees of Experts and consultants of FAO and WHO, which provide the scientific considerations that support the recommendations of practices for the international trade of food products and of good practices in the generality of the questions related to food, for To ensure their safety when made available to the consumer.

Acceptance of Codex Alimentarius standards by a country shall be in accordance with its established legal and administrative procedures regarding the distribution of the product concerned within the territory under its jurisdiction, regardless of whether it is locally produced or imported. Acceptance of the standards can be total, scheduled or with specific restrictions. Full acceptance means that a country ensures that the product in question is distributed freely, in accordance with Codex Alimentarius standards, within the territory under its jurisdiction. In this way, it also ensures that products that do not conform to the standards are not distributed. Scheduled acceptance means that the country indicates its intention to accept the standard after a certain period of time. It also means that it will not impede the distribution of products within its area of jurisdiction, provided that they meet the requirements specified by the Codex Alimentarius. Acceptance with specific restrictions means that the country accepts the standard, except in certain respects, which must be detailed in its acceptance statement, explaining the reasons for these restrictions. A country which accepts a Codex Alimentarius standard in one of the ways provided shall be responsible for the uniform and impartial application of the provisions of that standard.

2.2 THE GENERAL PRINCIPLES OF FOOD HYGIENE OF THE CODEX ALIMENTARIUS

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2.2.1. CODEX STANDARDS

Since 1966, the Codex Alimentarius Commission has produced a set of nearly 250 standards covering all major processed, semi-processed or raw foods. This list has been extended permanently, with the concern of including new products that are being introduced in the market and are gaining expression.

2.2.2. RECOMMENDED CODES OF GOOD PRACTICES

The CAC / RCP-1 - International Code of Recommended Practice for General Principles of Food Hygiene (CAC, 1999a) has been published by the Codex Alimentarius Commission since 1969, which is still today The international reference in principles of food hygiene. The effort of the Codex Alimentarius Commission to update its documents incorporating the relevant elements arising from the development of technical and scientific knowledge will not be surprising. CAC / RCP-1 (CAC, 1999a), prepared in 1969, underwent three revisions and one amendment in 1999, at which the description of the HACCP methodology - Hazards Analysis and Critical Control Points (Hazard Analysis and Identification of Critical Control Points).

Based on this latest version of CAC / RCP-1 it is possible to enumerate as objectives of the General Principles of Food Hygiene of the Codex Alimentarius the following:

- Identification of basic food hygiene principles applicable throughout the food chain (from primary production to the final consumer) in order to achieve the objective of ensuring the supply of safe food to the final consumer;
- The recommendation of an approach based on the HACCP system as a means of increasing food safety;
- Definition of the methodology for implementing these principles;
- The provision of guidelines for specific codes, which may be necessary in certain sectors of the food chain, processes or products, in order to increase food safety in associated

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activities.

The General Principles of Food Hygiene apply to the entire food chain, from primary production to the final consumer, establishing hygienic conditions necessary to produce food that is safe for consumption.

The General Principles of Food Hygiene of the Codex Alimentarius considered in CAC / RCP-1 recommend hygiene practices at various levels and are structured in ten sections:

- Section I – Objectives
- Section II - Scope, use and definitions
- Section III - Primary production
- Section IV - Establishment: project and facilities
- Section V - Control of operations
- Section VI - Establishment: maintenance and sanitation
- Section VII - Establishment: personal hygiene
- Section VIII – Transport
- Section IX - Product Information and Consumer Communication
- Section X – Training

2.2.3. GENERAL GUIDELINES

Another set of relevant Codex Alimentarius documents are the General Guidelines. These guidelines are laid down for the implementation of a diverse set of procedures. As regards the implementation of food safety systems, CAC / GL-21 - Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC, 1997) and CAC / GL-30 - Principles and Guidelines for the Application and Microbiological Risk Assessment (CAC, 1999b) are probably the most important documents in that they establish some relevant guidelines for biological hazard analysis methodology (Baptista, P. and Venâncio, A., 2003).

The Codex Alimentarius also has Lists of Maximum Residue Limits (e.g. pesticides, veterinary drug residues) which are a

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very important source of information in the preparation of a HACCP Plan, namely in establishing critical limits associated with critical control points (see Chapter 3) for chemical hazards. The list of Codex Alimentarius standards, codes of good practice, general guidelines and maximum residue limits, are available at the Codex Alimentarius website (http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/).

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3.
THE HACCP SYSTEM

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- **Paulo Baptista**

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Chapter Objectives

- Present the concept and principles of the HACCP System.
- Present the methodology of implementation of a HACCP System, describing in detail the steps inherent in this process.
- Illustrate the implementation methodology of a HACCP System, pointing out, whenever possible, the main elements to be taken into account in each step of the implementation.
- Provide information to support the understanding of the HACCP methodology and to facilitate its implementation in a company, in particular in the steps related to hazard analysis, the determination of critical control points, the establishment of critical limits and the establishment of the monitoring system.

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3.1 INTRODUCTION

All actors in a food chain have a responsibility to ensure the safety of food products in the intervening stages, irrespective of the nature of the activities they carry out. Contrary to the commonly accepted idea that food safety is something that should only be ensured by the food industry, the existence of food safety systems is a requirement for all units, whether industrial or not, where the preparation, processing, manufacture , Packaging, storage, transport, distribution, handling and sale or making available to the consumer of foodstuffs.

The HACCP System is designed to control the production process and is based on principles and preventive concepts. It is intended to apply measures that guarantee an efficient control, through the identification points or stages where the hazards can be controlled, which can be of biological, chemical or physical nature (Baptista, P. and Venâncio, A., 2003).

This system is scientifically based and is based on a systematic approach that not only ensures food safety but also reduces operational costs by reducing the need for microbiological analysis and destruction or reprocessing for safety, Of the final product.

The implementation of the HACCP System reduces the need for inspection and analysis of the final product, thus increasing consumer confidence and safety. The implementation of a HACCP System facilitates compliance with legal requirements, and allows the most efficient use of resources in the immediate response to food safety issues.

The HACCP System can be applied in all stages of food processing and development, from primary production to the final consumer. However, a HACCP Plan is specific to each product / process, and the respective study and planning must be carried out on a case-by-case basis. A HACCP System must be able to adapt to changes such as innovations in equipment design, process procedures and technological developments. In the following sections the concept, principles and history of the HACCP System are presented in more detail and the respective implementation methodology is discussed.

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3.2 THE CONCEPT OF THE HACCP SYSTEM

The HACCP system is based on the identification of food safety hazards to the consumer that may occur along the food process chain, on the assessment of those hazards and on Control in order to ensure food safety.

The Hazard Analysis and Critical Control Points (HACCP) system is a systematic approach to biological, chemical and physical hazards, rather than inspection and testing of final products, and is therefore a preventive system through which, by identifying Of potential risks, preventive measures are taken to reduce the likelihood of occurrences that could jeopardize the safety of products and consequently of consumers.

HACCP is based on an engineering system known as Failure Mode and Effect Analysis (FMEA), which identifies, at each step of the process, the errors that can occur, Their probable causes and their effects, to establish the most adequate control mechanisms. Thus, the HACCP System is a management tool that establishes an effective methodology for controlling hazards. It is a rational, logical, integrated, continuous and systematic system. It is rational because it is based on recorded data on the causes of diseases transmitted by foodborne diseases. It is logical and integrated since it considers the raw materials, process and subsequent use of the product in the subsequent risk analysis. As a continuous system, it allows the detection of potential problems before they occur, or when they arise, facilitating the immediate application of corrective actions. Finally, it is systematic, leading to a comprehensive plan, resulting from an analysis methodology covering all operations, processes and control measures.

HACCP is compatible with other quality control systems. This means that safety, quality and productivity can be addressed together, resulting in benefits for consumers, which is expressed in the growing benefit to the health of consumers and the development of organizations and the economy in general.

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3.3

THE HISTORY OF THE HACCP SYSTEM

The first event that led to the establishment of the HACCP System is associated with W.E. Deming. In the 1950s, Deming developed the Total Quality Management (TQM) system, which is a production-oriented system, while aiming to improve quality and reduce costs.

However, it was a second event that proved decisive in the development of the HACCP System. In the 1960s, the National Aeronautics and Space Administration (NASA), following an assessment of the origins of diseases that could affect astronauts during a space mission, identified those resulting from food poisoning as the most important. The result led to the collaboration of the Pillsbury Company with the US Army and NASA to develop a program for the production of safe food for the American space program. Thus, the Pillsbury Company developed and adopted the HACCP System to ensure more safety while simultaneously reducing the number of inspections to the final product.

The HACCP System was first introduced by the Pillsbury Company in 1971 at a food safety conference and published the first document detailing the HACCP technique in 1973.

In the United States, this system served as a basis for the FDA to develop legal standards for the production of low-acid foods, and used as a reference for training of FDA inspectors.

The National Academy of Sciences in 1985, responding to food control and inspection agencies, recommended the use of the HACCP System in food safety programs, having in 1988 the International Commission for Microbiological Specifications in Foods (ICMSF - International Commission on Microbiological Specification for Foods) suggested the use of the HACCP System as the basis for quality control from a hygienic and microbiological point of view.

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The Codex Alimentarius Commission has incorporated the "Guidelines for the Implementation of the HACCP System" (ALINORM 93 / 13a, Appendix II) at its twentieth meeting in Geneva, Switzerland, from 28 June to 7 July 1993. The Recommended International Practices - General Principles of Food Hygiene [CAC / RCP 1-1969, Rev. 3, Amd.1 (1999a)] was last amended in 1999.

The European Union has harmonized the general rules for foodstuffs, incorporating the principles of the HACCP system, by adopting the Directive no. 93/43/EEC of 14 June 1993.

3.4
THE PRINCIPLES OF HACCP

The HACCP System is based on a set of 7 fundamental principles:

- Principle 1 - Hazard analysis;
- Principle 2 - Determination of critical control points (CCPs);
- Principle 3 - Establishment of critical limits;
- Principle 4 - Establishment of a monitoring system;
- Principle 5 - Establishment of corrective actions;
- Principle 6 - Establishment of verification procedures;
- Principle 7 - Establishment of documentation and registration.

For proper implementation of the HACCP System, it is very important to properly understand and interpret the exact meaning of these principles.

Principle 1 - Hazard analysis

Conducting a hazard analysis requires the identification of the potential hazards associated with all phases of the process, from raw materials to the final consumer. Inherent in this

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analysis of hazards is the assessment of the probability of occurrence and the severity of the hazard identified, as well as the analysis of possible preventive measures established for its control, in order to determine their significance.

Principle 2 - Determination of critical control points

s based on the determination of critical control points (CCPs) that can be controlled to eliminate the hazar r minimize the likelihood of its occurrence. A critical control point shall be a point, procedure, operation or stage at w n control shall be applied and shall be essential to prevent, reduce to acceptable levels or eliminate a hazard related to food safety.

Principle 3 - Establishment of critical limits

It consists in establishing the critical limits that must be ensured in order to ensure that each CCP is controlled. Critical limit means the value or criterion that differentiates acceptance from non-acceptance of the process.

Principle 4 - Establishment of the monitoring system

It consists in the establishment of a monitoring system to ensure systematic monitoring of CCPs. As a m itoring system is meant the observation or measurement of control parameters to assess whether a critical control point is within acceptable values.

Principle 5 - Establishment of corrective actions

It presupposes the establishment of corrective actions to be taken when m itoring indicates that a particular CCP is not under control. Loss of control means a deviation from the critical control limit of a CCP.

Principle 6 - Establishment of erification procedures

It is based on the establishment of verification p edures to confirm the effectiveness of the HACCP System. Verification means the application of methods, procedures, tests and other

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assessments to confirm compliance with the HACCP Plan and the effectiveness of the HACCP System.

Principle 7 – Documents and registers

It is based on the establishment of documentation on all procedures and records appropriate to these principles and their application. The records constitute the evidence of the performance of activities associated with the operation of the HACCP System.

3.5
THE HACCP METHODOLOGY

The practical implementation of a HACCP System normally follows a methodology consisting of 12 sequential steps, which is based on the 7 stated principles. In fact, the 7 steps of the implementation methodology of the HACCP System are directly related to the 7 HACCP Principles. To these are added 5 preliminary steps that correspond to the structuring of the team that will develop the study and planning of HACCP and the compilation of information of support relevant for conducting the analysis of hazards:

- Step 1 - Establishment of the HACCP Team;
- Step 2 - Description of the product;
- Step 3 - Identification of the intended use;
- Step 4 - Construction of the flowchart;
- Step 5 - Confirmation of the flowchart in the field;
- Step 6 - Hazard identification and analysis, analysis and identification of preventive measures to control identified hazards (principle 1);
- Step 7 - Determination of critical control points (principle 2);
- Step 8 - Establishment of critical control limits for each CCP (principle 3);

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- Step 9 - Establishment of the monitoring system for each CCP (principle 4);
- Step 10 - Establishment of corrective actions (principle 5);
- Step 11 - Establishment of verification procedures (principle 6);
- Step 12 - Establishment of control of documents and data (principle 7).

Figure 3.1 shows the sequence and interaction of the HACCP methodology steps, and the identification of the associated HACCP Principles.

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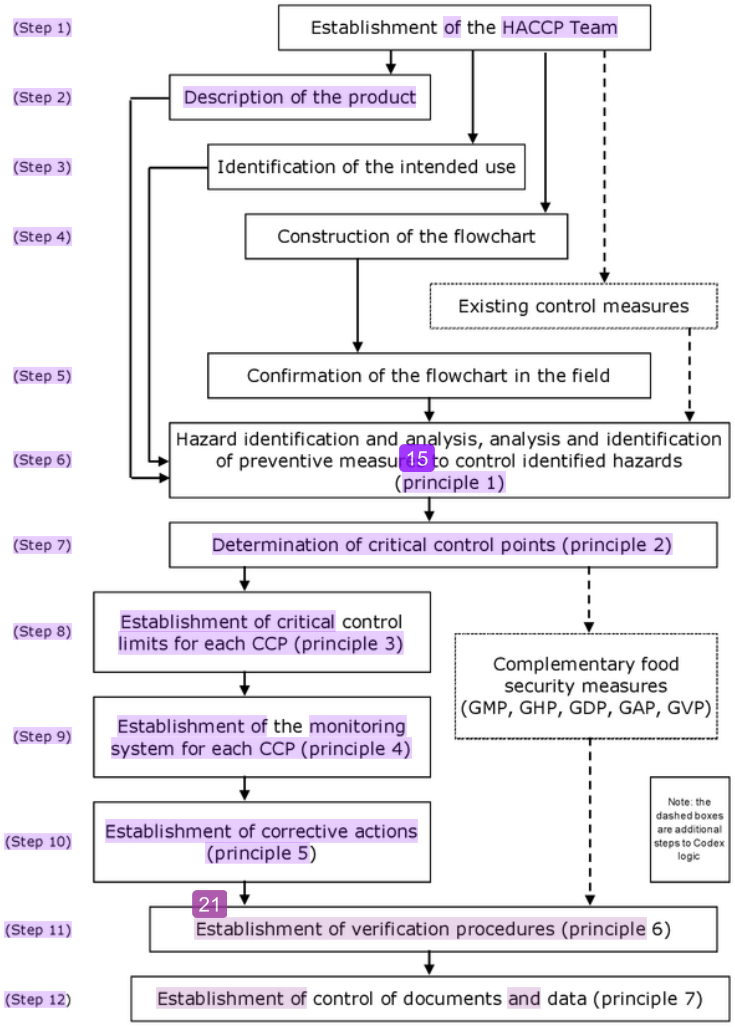

Figure 3.1 - The sequence and interaction of the steps of the HACCP methodology

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3.5.1. HACCP TEAM

THE HACCP TEAM

The HACCP study and planning should be performed by a multidisciplinary team - the HACCP Team - which should include people from various areas (e.g. quality, production, packaging) selected on the basis of criteria such as:

- Your responsibilities;
- Your knowledge and experience in the company;
- Your knowledge and experience regarding relevant products, processes and hazards within the scope of the HACCP study. The HACCP Team should, where necessary in certain phases of the study, be extended with elements from other areas whose knowledge and experience is relevant in those phases. The HACCP Team may, if necessary, include outside consultants who possess know-how and information, which do not exist in the company, which are indispensable for the conduct of the HACCP study.

HACCP TEAM COORDINATOR

The HACCP Team should have a coordinator. The HACCP Team should not be organized conditioned by the hierarchical structure of the company.

The HACCP Team Coordinator will be responsible for:

- Ensure that the composition of the HACCP Team is adequate for the needs of the HACCP study to be carried out;
- Suggest modifications in the HACCP Team whenever necessary;
- Coordinate the work of the HACCP Team;
- Ensure that the pre-established plan is followed;
- Distribute work and responsibilities to HACCP team members;
- Ensure the use of a systematic approach in conducting the

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HACCP study;

- Ensure that the scope of the HACCP study is fully considered;
- Coordinate the meetings of the HACCP Team, ensuring the conditions for unrestricted participation of all its elements;
- Ensure that deviations and / or conflicts between elements of the HACCP Team or their departments are avoided;
- Establish mechanisms for the decisions of the HACCP Team to be communicated to the organization;
- Represent the HACCP Team before the Directorate / Administration.
- Be thoroughly familiar with the HACCP study and have a thorough knowledge of the company's activities.

INITIAL TRAINING

The HACCP Team should receive initial training regarding the HACCP Principles, the implementation and application of the HACCP System.

Initial training shall ensure that:

- The HACCP Team work in groups with shared goals and using the same language;
- That the objectives of the HACCP study are adequately understood by all.

RESOURCES

The number of meetings will depend on the scope of the study, on the complexity of the company's activities of the means involved in carrying out the HACCP study. Meetings should be of limited duration, follow a pre-established agenda, and be held at a frequency that keeps the HACCP Team involved, but sufficiently spaced to allow the necessary information to be obtained at all times (e.g. bi-weekly). In between meetings HACCP Team members should carry out the work that the

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Coordinator will distribute in order to make the HACCP Team meetings more effective. It is suggested that the elements for discussion assembled or prepared by the various members of the HACCP Team be pre-distributed by the others so that they can analyze them in a timely manner. In this way, at the HACCP Team meeting, the discussion and decision-making phase can be more quickly entered.

The Board should demonstrate its involvement by ensuring the allocation of resources required for the HACCP study, namely:

- Time / people for the HACCP Team;
- The costs of initial training;
- The necessary documentation;
- Access to analytical laboratories;
- Access to sources of information (e.g. universities, research centers, official authorities, consultants, technical and scientific literature, databases, etc.).

3.5.2. PRODUCT DESCRIPTION

In the implementation of a HACCP System, the HACCP Team should begin by describing the food, which description should take into account both the raw materials used and the final product.

RAW MATERIAL

At the level of the description of the raw materials the HACCP Team should characterize:

- Type of raw materials, packaging materials, method of transportation and packaging, ...
- Percentage in the final product;
- Source;
- Physical-chemical characteristics (pH, water activity - w_a, viscosity, temperature, concentration in aqueous solution,

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...);

- Microbiological characteristics;
- Conservation conditions;
- Preparation / processing conditions before use.

FINAL PRODUCT

For the final product, the description should take into account the following elements:

- General characteristics (composition, volume, structure, ...);
- Physical-chemical characteristics (pH, water activity, type and concentration of additives, modified atmosphere, storage temperature, ...);
- Microbiological characteristics;
- Information at labeling level (product life, conservation instructions / preparation mode, ...);
- Storage and distribution conditions.

3.5.3. INTENDED USE FOR THE PRODUCT

After describing t18product, the HACCP Team should reflect the conditions of use of the product by the consumer. The HACCP Team should take into account the identification of the normal customer / consumer groups and the assessment of the existence of potentially sensitive consumer groups among them, in terms of ingredients (e.g. gluten, lactose), and in terms of level of microbiological contamination (e.g. infants, elderly, sick). The communication to the consumer of the presence of ingredients to which certain groups are intolerant and the conditions of preparation / processing of the product by the consumer are essential in order to avoid their misuse. This communication is made through the labeling, meeting the legal requirements at the level of food labeling established in Regulation no. 1169/2011.

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This evaluation of the intended use by the consumer, which is important in assessing the danger associated with improper use of the same, may even determine the recasting of the product and / or process to adapt it to the actual conditions of use of the consumer without such conditions There are more significant hazards.

3.5.4. CONSTRUCTION OF THE FLOWCHART

As important as an adequate description of the product and its intended use is the knowledge of all stages of the process, from the raw materials to the final product, given that it is this set of information that will support the realization of the HACCP study. The description of processes and their interactions can be described in a systematic way with the use of flowcharts. The construction of flowcharts should take into account:

- The sequence of all steps of the manufacturing process;
- The phases in which inputs of raw materials and intermediate products (including subcontracted products) occur;
- The phases where re-work or recycling of raw materials / products occurs;
- The phases where intermediate products, by-products or waste are removed;
- The time / temperature conditions throughout the process.

In addition to the flow charts, the plant layout should be taken into account with the layout of the equipment (Baptista, P. and Noronha, J., 2003). This information is relevant because it is the best way of facilitating the subsequent cross-contamination hazard analysis. Thus, on plant facilities and equipment layout should be marked:

- Personnel circuits;
- The circuits of raw materials, intermediate products and final products;
- Potential pathways of cross-contamination;

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- Areas of segregation.

3.5.5. VERIFICATION OF THE FLOWCHART

Since sometimes the construction of the flowchart is totally or partially carried out in the room, it is essential to ensure that the flowchart elaborated corresponds to the present situation. This step is very important because, in many cases, organizations already have process flowcharts, plant plans and equipment layouts, developed at a given moment, but do not have routines for updating these documents. In this situation, or in the absence of full flowcharts, it is recommended that the HACCP Team begin by collecting or initial confirmation of the information at the facility. At the end, after the construction of the flowchart, the HACCP Team must confirm it by following the process. This should be done several times throughout production, covering all operations, to ensure that processes are always conducted in the same way. The possibility of this not occurring increases when there is a greater turnover of process operators and when companies operate in turns, particularly when operators have a direct intervention in the control of operating conditions. Confirmation of the flowchart must also involve all elements of the HACCP Team, since the multi-disciplinarity of their competencies is relevant to an adequate confirmation of all the information supported in the flowcharts. This approach is also extendable to the confirmation of the facility plan and equipment layout.

3.5.6. HAZARD ANALYSIS

Hazard analysis is the key element in the development of the HACCP Plan. The hazard analysis consists of a process of collecting and evaluating the information on the hazards and the circumstances that result in their presence, in order to decide what are the significant ones for the safety of the food and which should therefore be addressed in the HACCP Plan (Baptista, P. and Venâncio, A., 2003).

HAZARD ANALYSIS

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Conducting hazard analy56 requires identifying the potential hazards associated with all stages of the process, from raw materials to final consumers. Inherent in this analysis of 39zards is the risk assessment according to the probability of occurrence and the severity of the hazard identified, in order to determine their signi40nce. Only the dangers considered significant are taken to the "decision tree" to identify critical control points. The analysis of hazards also presupposes the analysis of possible preventive measures established for the control of significant hazards.

2

Hazard analysis must be performed for each product or process type and for each new product. In addition, the hazard analysis of a product associated with any type of process should be reviewed whenever there is any change in the raw material, product formulation, processing or expected use of the product 18 the consumer. Hazard analysis must take into account biological, chemical and physical hazards (Baptista, P. and Venâncio, A., 2003).

In order to perform a duly sustained hazard analysis, it may be necessary to carry out some process parameter measurements in order to c2nfirm the actual operating conditions. Some examples of measurements that may be relevant depending on the product or type of process include:

- Time-temperature combinations of the product, in processes involving the transfer of heat - heating or cooling of products;
- pH and w_a (water activity) of the product during processing and at the end, preferably at room temperature or taking into account the corrections to be made at room temperature;
- Pressure in under-pressure processes such as sterilization processes (e.g. cans of preserves);
- Microbiological analyzes of samples, in process evaluation studies and determination of the life time for new products.

The data of the processes obtained with these measurements and other avail97e information related to the process data shall be analyzed in order to determine the implications of the operational conditions on the food safety of the products produced. Some examples include:

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- Comparison of the time-temperature registers of the processes with the data of optimal temperatures of growth of microorganisms and the temperature ranges in which they can be multiplied (Table 3.1);
- Comparison of aw and pH values of the product with the intervals in which growth or destruction of pathogenic microorganisms may occur (Table 3.1);
- The evaluation of product stability (AFNOR, 1998).

Table 3.1 - Main conditions for the occurrence of some of the main biological hazards

Biological Hazards	Parameters					
	$T_{mín}$ (ºC)	T_{Max} (ºC)	$pH_{mín}$	pH_{Max}	$w_{a\ mín}$	$NaCl_{Max}$ (%)
Bacillus cereus	4	55	4.3	9.3	0.92	10
Campylobacter jejuni	30	45	4.9	9.5	0.987	2
Clostridium botulinum	3.3	45	5	9	0.97	5
Clostridium botulinum	10	48	4.6	9.0	0.94	10
Clostridium perfringens	10	52	5.0	9.0	0.93	7
Escherichia coli	6.5	49.4	4.0	9.0	0.95	6.5
Enterotoxin staphylococcus	10	50	4.76	9.02	0.86	12
Listeria monocytogenes	-0.4	45	4.4	9.4	0.92	10
Salmonella spp.	5.2	46.2	3.7	9.5	0.94	8

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Shigella spp.	6.1	47.1	4.8	9.34	0.96	5.2
Staphylococcus aureus	7	50	4	10	0.83	20
Staphylococcus aureus – toxin	10	48	4	9.8	0.85	10
Vibrio parahaemolyticus	5	45.3	4.8	11	0.94	10
Vibrio cholerae	10	43	5	10	0.97	6
Vibrio vulnificus	8	43	5	10	0.96	5
Yersinia enterocolitica	-1.3	42	4.2	10	0.945	7

Source: (FDA, 2001)

Hazard analysis shall be performed in a systematic and sequential manner in order to minimize the likelihood of not identifying all significant hazards. Particular attention in this analysis should be given to the raw materials and the process, which are, directly or indirectly, the origin of most occurrences of dangerous situations that were not properly controlled and reflected to the consumer.

At the level of the analysis of hazards related to raw materials it is important to consider, when selecting and / or receiving various issues, such as:

- Are there pathogenic micro-organisms, toxins, chemicals or physical objects that may be present?
- Do the raw materials used incorporate preservatives or other additives in their formulation?
- Is any ingredient (e.g. additive) dangerous if used in excess or, if used in less than recommended amount, can result in a danger of allowing the growth of microorganisms or germination of sporulated cells?

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- How can the acidity and water activity of raw materials affect the growth of micro-organisms in the final product?
- At what temperature conditions should the raw materials be maintained during storage and transport?

When analyzing processing-related hazards, including aspects related to the flow of raw materials and product and the movement of operators, it is also possible to list some of the issues that may facilitate the identification of hazards:

- Contaminants can come in contact with the product during this process operation, through operators, equipment or utensils (Baptista, P. and Noronha, J., 2003)?
- Can any pathogenic microorganism multiply or survive during this stage of the process to the point of danger?
- The operations are performed by operators, respecting good manufacturing practices and good hygiene practices (Baptista, P. and Saraiva, J., 2003)?
- Are there later steps that eliminate or can reduce the identified hazards to acceptable levels (Baptista, P. and Venâncio, A., 2003)?

RISK ASSESSMENT

Risk assessment is generally qualitative, obtained by combining experimental data, epidemiological, local or regional data, and specific bibliographic information. Epidemiological data are an important tool for assessing risks by demonstrating products that are potentially hazardous to consumer health.

To carry out a risk assessment, the following elements must be taken into account:

- Review of customer complaints;
- Return of lots;
- Results of laboratory tests;
- Data from monitoring programs for foodborne disease

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agents;

- Information on the occurrence of animal diseases or other situations that may have implications for human health.

SEVERITY

Not all microorganisms are classified in the same way when assessing their potential to cause disease. This potential, or the type of danger that a microorganism represents, varies from zero to very serious. In hazard analysis a hazard classification by level can be established. One possibility is to classify the severity into three levels: high (3), medium (2) and low (1), which can be characterized as follows:

High: Serious effects on health, requiring hospitalization and even death;

Average: The pathogenicity is lower as well as the degree of contamination. The effects can be reversed by medical care, however they may include hospitalization;

Low: The most common cause of outbreaks, with rare or limited subsequent spread. Relevant when the food ingested contains a great amount of pathogens, being able to cause indisposition and malaise, being necessary medical attention.

Table 3.2 shows some examples of contaminations that are likely to fall into this classification.

Table 3.2 - Hazard classification examples for severity

Classification	Examples
HIGH	**Biological**: Clostridium botulinum toxin, Salmonella Typhi, S. Paratyphi A e B, Shigella senteriae, Vibrio cholerae O1, Vibrio vulnificus Brucella melitensis, Clostridium perfringens type C, hepatitis A and E viroses, Listeria monocytogenes (in some groups), Escherichia coli O157:H7, Trichinella spiralis, Taenia solium (in some cases).

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	Chemical: Direct contamination of foods by chemical products or indirect contamination such us as heavy metals, like mercury, that enter in the food chain or by used non-authorized additives or excessive concentrations of additives that can cause a serious food poisoning to a large number of persons or to a specific group of persons. **Physical**: foreign bodies and unwanted fragments that may cause injury or damage to the consumer, such as stones, glasses, needles, metals, sharp and perforating objects, constituting a risk to consumer life.
MEDIUM	**Biological**: outras Escherichia coli enteropatogénicas, Salmonella spp., Shigella spp., Streptococcus ß-hemolítico, Vibrio parahaemolyticus, Listeria monocytogenes, Streptococcus pyogenes, rotavírus, vírus (tipo) Norwalk, Entamoeba histolytica, Diphyllobothrium latum, Cryptosporidium parvum.
LOW	**Biological**: Bacillus cereus, Clostridium perfringens tipo A, Campylobacter jejuni, Yersinia enterocolitica, toxina do Staphylococcus aureus, the majority of parasites. **Chemical**: chemical substances allowed in foods that may cause mild reactions such as drowsiness or transient allergies.

PROBABILITY

Risk is also a function of the likelihood of a hazard occurring in a process and affecting the safety of the food. The probability assessment presupposes a statistical analysis. Although there

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are data on the quantitative risk assessment of some chemical and biological hazards, their numerical determination is not always available. Similar to what is done for severity assessment, levels should be established for the probability, and the respective limits should have an associated quantification (e.g. number of occurrences per year, based on the occurrences / history of the organization or based on Epidemiological data), even when expressed qualitatively. A possible classification, also with 3 levels: high (3), medium (2), low (1), may be considered. Sometimes a fourth level is used: null.

IDENTIFICATION OF SIGNIFICANT HAZARDS

Based on this classification for the severity and probability of occurrences, the severity versus probability map, presented in Figure 3.2, was constructed to define the combinations for which the risks are significant. These correspond to shaded combinations.

Figure 3.2 - Map of severity versus probability of occurrences - Identification of significant hazards (example)

In this case it is considered that, irrespective of frequency, a danger with a high severity should be considered as a significant hazard. The definition of severity - probability combinations that correspond to significant hazards should be made by each company taking into account the number of levels it considered and the limits it set for each level.

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Annex (Annex II) presents a form for recording a hazard analysis.

3.5.7. DETERMINATION OF CRITICAL CONTROL POINTS

In order to determine the points in the process where controls should be applied in order to prevent, eliminate or reduce hazards to acceptable levels - Critical Control Points - the so-called "decision tree" is used. The "decision tree" (Figure 3.3) is a protocol consisting of a sequence of structured questions, applied at each step of the process, to determine if a given control point at this stage of the process constitutes a Critical Control Point. The four questions used in the decision tree and their interpretation are presented here.

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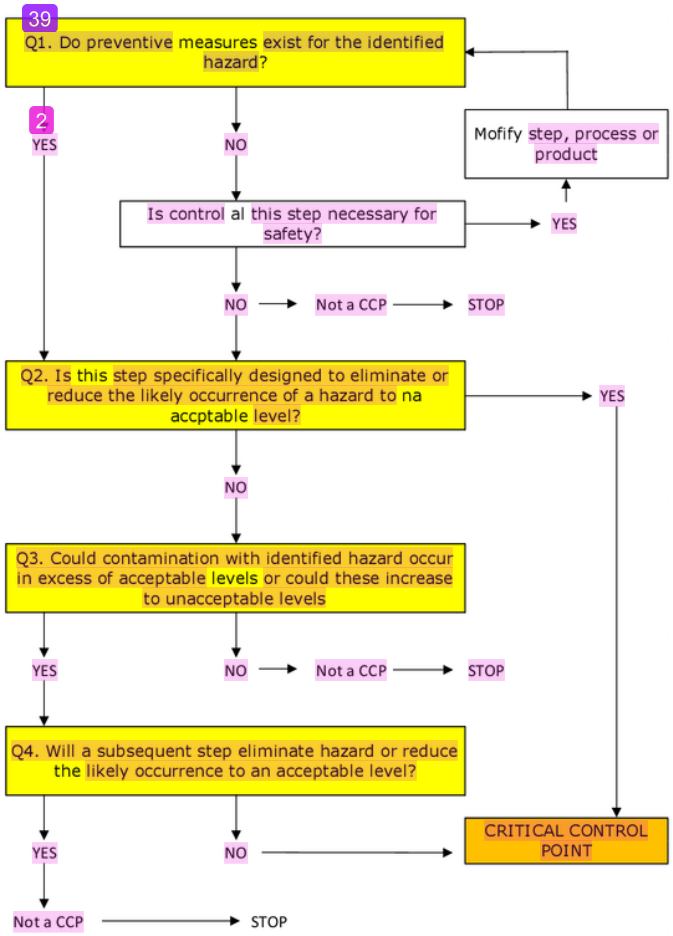

Figure 3.3 - Decision Tree

Q1. Are there preventive measures for the hazard identified?

Question Q1 should be interpreted as asking whether the operator could use a preventative measure for this operation to control the identified hazard (e.g. temperature control, visual inspection, metal detector). If the answer to Q1 is "yes" then the control measures that the operator could use and follow for Q2 of the decision tree should be described.

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If the answer is "no", i.e. no preventive measure, the manner in which the hazard identified will be controlled before or after the manufacturing process shall be indicated. If it is necessary to ensure food safety, the operation, process or product must be modified in such a way as to provide for a preventive measure. This means that, for all significant hazards implemented, preventive measures must be in place.

Q2. Has this step been specifically designed to eliminate the possible occurrence of the hazard or to reduce it to an acceptable level?

If the process or operation is designed for the specific purpose of eliminating the possible occurrence of the hazard or reducing it to an acceptable level the response shall be "yes" and shall be passed to Q4.

If the stage is not specifically designed, answer "no" and proceed to the next question (Q3).

Q3. Can contamination of identified hazard occur above acceptable levels, or may it increase to unacceptable levels?

Question Q3 is intended to verify that the hazard has an impact on the safety of the product, taking into account the likelihood and severity associated with it. Regardless of whether the answer is "yes" or "no", it should justify a response, for future reference. This is especially useful in dealing with certain dangers which may be controversial and where it is necessary to review the risk analysis, in particular as a result of changes in the process or the characteristics of the raw materials and the intended end product.

If the company's history or if the scientific literature suggests that the contamination with the identified hazard may increase to an unacceptable level and result in a health hazard, the answer should be "yes" and then move on to the next "tree" question Of decision ": question Q4.

If the contamination does not pose a significant threat to health or there is no possibility of occurrence, the answer should be "no", implying that this hazard is not a significant hazard. In this situation one should move to the application of the decision tree to the next significant danger identified in the process.

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Q4. Will a subsequent step eliminate the identified hazard or reduce the possible occurrence to an acceptable level?

The purpose of this question is to identify hazards which pose a threat to human health or which may increase to an unacceptable level and to assess whether these hazards will be controlled by a subsequent operation in the process.

If there is no subsequent step in the process to control the hazard, the response should be "no" and in this case the step under review becomes a CCP and should be identified as such. If there is any subsequent operation in the process that will eliminate the identified hazard or reduce it to an acceptable level, the response should be "yes", in which case the step does not constitute a CCP. However, the subsequent steps that control the hazard must be identified before proceeding to the next identified hazard.

The determination of CCPs concludes the HACCP study phase. The following steps, encompassing principles 3 to 7 of the HACCP System, lead to the development of the HACCP Plan. The HACCP Plan includes the establishment of: (i) critical limits, (ii) the monitoring system, (iii) corrective actions. The HACCP System is completed with the establishment of verification procedures and maintenance of HACCP.

3.5.8. ESTABLISHMENT OF CRITICAL LIMITS

CRITICAL LIMITS

For the critical control points identified in the previous step it is necessary to establish the respective critical limits, understood as the value or the criterion that differentiates the acceptability from the non-acceptability. Critical limits must be established for each parameter associated with a CCP. The parameters associated with each CCP must clearly demonstrate that it is controlled (e.g., temperature, time, flow rate, relative humidity, water activity, pH). The critical limits must comply with legally established requirements and be in conformity with existing scientific and technical knowledge. Whenever possible, critical limits should be supported by evidence. Critical limits based on subjective data (e.g. visual inspection) must be supported by

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clear specifications of what is considered acceptable or unacceptable.

The establishment of critical limits should be done within the scope of the HACCP Team. In establishing these limits, the HACCP Team may use various sources of information, including:

- Data from scientific publications or research;
- Legal requirements;
- Specialists (e.g. consultants, food engineers, microbiologists, equipment manufacturers, university professors and researchers);
- Experimental studies (e.g. internal, sub-contracted or performed by third parties).

If the information necessary to establish the critical limits is not available, a conservative value should be established, while relying on technical-scientific knowledge, in particular that associated with other products. The bibliographic references used in the reasoning of the decisions taken constitute the documentation supporting the HACCP System and should therefore be registered (e.g. Table 3.3).

Table 3.3 - Time / Temperature Guide to Control Growth of Pathogens and Formation of Toxins in Sea Foods

Potential hazards	Product temperature	Maximum accumulated time of exposition
Bacillus cereus toxins	4- 6º C	5 days
	7-10º C	17 hours*
	11- 21º C	6 hours*
	Above 21ºC	3 hours
Campylobacter jejuni	30-34ºC	48 hours
	Above 34ºC	12 hours

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Clostridium botulinum Tipo A, and proteolyptic B e F	10-21ºC Above 21ºC	11 hours* 2 hours*
Clostridium botulinum Tipo E, e non-proteolytic B e F	3.3-5ºC 6- 10º C 11-21ºC Above 21ºC	7 days > 2 days 11 hours 6 hours
Clostridium perfringens	10- 12º C 13- 14º C 15- 21º C Above 21ºC	21 days 1 day 6 hours* 2 hours*
Escherichia coli	7-10ºC 11-21ºC Above 21ºC	14 days 6 hours 3 hours
Listeria monocytogenes	-0.4-5C 6- 10º C 11-21ºC Above 21ºC	7days 2 days 12 hours* 3 hours*
Salmonella spp.	5.2-10ºC 11-21ºC Above 21ºC	14 days 6 hours 3 hours
Shigella spp.	6.1-10ºC 11-21ºC Above 21ºC	14 days* 12 hours* 3 hours*
Staphylococcus aureus toxins	7-10ºC 11-21ºC	14 days 12 hours*

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	Above 21ºC	3 hours
Vibrio cholerae	10ºC 11-21ºC Above 21ºC	21 days 6 hours* 2 hours*
Vibrio parahaemolyticus	5-10ºC 11-21ºC Above 21ºC	21 days 6 hours* 2 hours*
Vibrio vulnificus	8-10ºC 11-21ºC Above 21ºC	21 days 6 hours 2 hours
Yersenia enterocolitica	-1.3-10ºC 11-21ºC Above 21ºC	1 day 6 hours 2.5 hours

* Additional data needed

Source: FDA

Parte superior do formulário

OPERATIONAL LIMITS

In practice, in any processing, it is desirable that steps can be taken when monitoring processes indicate a tendency for loss of control, even before the critical threshold is reached. It is therefore appropriate to establish more restrictive limits, known as operational limits, which, once achieved, will give rise to the initiation of corrective actions without any violation of the critical limits.

This approach reduces the number of situations where critical limits are reached, with costs substantially lower than those that would inevitably be associated if critical limits were reached (e.g. acidification process: critical limit = 4.6 and operational limit = 4.4).

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3.5.9. ESTABLISHMENT OF MONITORING SYSTEM

MONITORING SYSTEM

The monitoring consists of carrying out a planned sequence of measurements of the control parameters to evaluate if their respective critical limits are respected. The monitoring should provide timely information to enable corrective action to be taken to keep the process under control before segregation and / or product rejection (e.g. time / temperature measurements, salt concentration, pH, water activity) should be undertaken. In practice, as has already been pointed out, it is often desirable for such monitoring to affect operational limits in order to provide a safety margin, allowing some time to adjust the process before the critical limit is exceeded.

In addition to measuring the level of process performance at the critical control point and, by trend analysis, to anticipate any loss of control, the monitoring also aims to record the level of system performance by To comply with the HACCP Plan.

In addition to measuring the level of process performance at the critical control point and, by trend analysis, to anticipate any loss of control, the monitoring also aims to record the level of system performance by To comply with the HACCP Plan.

MONITORING METHODOLOGY

The monitoring of a critical control point may be carried out continuously or batch by batch. Continuous monitoring is preferable since it allows, more reliably, to identify deviations from established values more quickly. However, this type of monitoring is not always possible, often because of the very nature of the measurement (e.g. it is not possible to do it in real time as it takes some time to perform the measurement / analysis) or associated costs. In such situations, sampling size and frequency should be defined taking account of the process variability itself, the distance between the critical limit and the operational limit, and the ability to intervene in order to correctly identify the potentially affected product and to trigger Corrective actions when deviations occur.

When problems are detected, the monitoring frequency should be increased until the root cause of the problem has been

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identified and effective corrective actions have been implemented.

Measurements of a physical-chemical nature (e.g. time, temperature, pH, moisture content) or visual observations are preferably used for the rapidity of their realization.
The monitoring plan for critical control points is what is commonly called the HACCP Plan. This should indicate which:

- Critical control points;
- The control parameters associated with each critical point (e.g. time, temperature, pH, w_a);
- Critical limits of control for each CCP;
- The method as parameters will be monitored (e.g. temperature probe, stopwatch, pH meters);
- The frequency of monitoring;
- Who is responsible for monitoring;
- Actions to be taken in case of deviation from the established critical limits;
- The location where the monitoring data is recorded.

Annex (Annex II) presents a model for the preparation of the HACCP Plan.

Monitoring should be performed by trained personnel with defined knowledge and authority to specify and implement corrective actions where necessary. Monitoring procedures and associated records shall provide operators with sufficient information to enable them to take decisions on the acceptance or rejection of a product and to support the initiation of appropriate corrective actions or the immediate communication of deviations to those having the authority to trigger such actions .

Persons with responsibility for monitoring critical points should:

- Know the process they are monitoring;
- Know the monitoring process and carry out the monitoring activities with the established frequency;

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- Record monitoring results;
- Interpret the results of monitoring and trigger, where necessary, corrective actions in accordance with the authority assigned to it in the HACCP Plan;
- Immediately report deviations within critical limits.

3.5.10. ESTABLISHMENT OF CORRECTIVE ACTIONS

Corrective action must be defined within a HACCP system as an action or procedure to be implemented when the results of CCP monitoring indicate a loss of control, i.e.: a deviation from the critical limit of a CCP. These procedures should detail:

- The actions to be taken to ensure that the CCP is brought back into control limits;
- The authority for the definition / implementation of corrective action;
- What actions to take to deal with the defective product.

When a deviation occurs it is expected that it will be identified if the monitoring system is properly implemented. The monitoring system should also allow action on the processes when monitoring results indicate a tendency to lose control of a CCP. In this latter situation, the corrective actions to be implemented should allow the process to be brought back to operational limits before a deviation beyond critical limits occurs.
In case of deviations from the critical limits, that is, if they are violated, the company must:

- Have a system to identify deviations when they occur;
- Have effective procedures for isolating, clearly identifying and controlling all product produced during the deviation period;
- Evaluate the product using a qualified person to ensure that: (i) the sampling is appropriate to identify the extent of the problem, as well as appropriate testing; (ii) the assessment is based on a logical and systematic analysis, and (iii) the

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product is not released until the assessment determines that there is no potential hazard.

Depending on the nature and extent of the diversion, the product may have diverse destinations ranging from its reprocessing or use in another type of process or product to disposal.

With the implementation of corrective actions it is intended:

- Determine the cause of the problem;
- Take action to avoid recurrence;
- Follow up through monitoring and reassessment to ensure the effectiveness of the implemented action.

Following the implementation of the corrective action, consideration should be given to the need to revise the HACCP system in order to prevent any recurrence.

The corrective actions implemented should be recorded to demonstrate the control of products affected by the diversion and to provide information regarding the corrective action taken that supports the management activity of the HACCP System.

3.5.11. ESTABLISHMENT OF VERIFICATION PROCEDURES

The purpose of the verification is to determine:

- If the HACCP System is implemented according to the HACCP Plan (correct determination of the PCC, correct definition of the parameters and respective critical limits of control, adequate monitoring) and that the necessary corrective measures have been implemented;
- If the current HACCP Plan is properly developed and implemented taking into account the current products and processes, that is, it proves to be effective.

Verification procedures shall clearly state the responsibility, frequency and methods used. Verification should be carried out by qualified personnel with knowledge of the HACCP Plan /

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System (e.g. elements of the HACCP Team) capable of detecting deficiencies in the plan or its implementation. This activity must be carried out:

- Upon completion of the HACCP study, for validation;
- Whenever there is a change that may affect hazard analysis (e.g. change of raw materials, product or process);
- When a deviation occurs;
- When scientific knowledge of new potential hazards or control measures;
- Due to unsatisfactory results in the scope of auditing;
- Faced with customer or consumer complaints;
- At regular intervals, according to a predetermined program.

The verification of the HACCP System involves the analysis of HACCP document documents and their records, the scientific evaluation of all the hazards considered, to ensure that all those that could be considered significant and the analysis of critical threshold deviations and actions Corrections taken for each deviation. Periodic verification should help to improve the HACCP Plan by exposing and strengthening weaknesses in the system and eliminating unnecessary or ineffective control measures. Key verification activities include:

- Validation of the HACCP plan;
- Audits to the HACCP System;
- Collection and analysis of samples.

VALIDATION OF THE HACCP PLAN

The validation of the HACCP Plan corresponds to the activity of assessing whether the HACCP Plan adequately identifies and controls all significant hazards to food safety or reduces them to an acceptable level. The evaluation should be supported in a review of the literature to ensure an adequate scientific and technical basis for decisions. Validation of the HACCP Plan should include:

- Review of hazard analysis;

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- Determination of CCPs;
- Justification for critical limits (e.g. legal requirements or available scientific data);
- Evaluation of monitoring results / records of the HACCP Plan;
- Analysis of corrective actions implemented and their effectiveness;
- Review of HACCP audit reports;
- Review of changes to the HACCP Plan;
- Review of previous validation reports;
- Review of diversion reports;
- Evaluation of the effectiveness of corrective actions implemented;
- Review of information on customer and consumer complaints;
- Review of the links between the HACCP Plan and the good manufacturing and hygiene practice programs (Baptista, P. and Saraiva, J., 2003).

AUDITS TO THE HACCP SYSTEM

Audits, as part of the verification, are performed to compare the actual practices and procedures of the HACCP System with those written in the HACCP Plan. Audits of the HACCP System are intended to carry out independent and systematic assessments through on-site observations, interviews and document and record analyzes to determine whether the procedures and activities set out in the HACCP Plan are effectively implemented and are complied with.

The on-site observation can be used to verify several elements of a HACCP Plan, of which the following stand out:

- Proper description of products and flowcharts;
- Compliance with PCC monitoring in accordance with the HACCP Plan;

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- The execution of the processes within the established critical limits;
- Records of HACCP activities (e.g. monitoring records as established in the HACCP Plan, corrective action records triggered against deviations from established critical limits, calibration records of inspection and measurement equipment).

Audits should be planned and carried out at appropriate frequency to ensure the maintenance of the effectiveness of the HACCP system, taking into account the specificities of the products in terms of risk and the variability of the processes. At the very least, a full audit of the HACCP System should be carried out once a year. Following failure situations of the HACCP System, the need to carry out extraordinary audits that were not initially planned should also be considered.

SAMPLE COLLECTION AND ANALYSIS

The verification may also include a sampling plan and analyzes. The sampling and analysis plan consists of the collection and analysis of product samples and raw materials to ensure that critical limits are adequate for product safety. Sampling of raw materials may be carried out to verify the supplier, in particular where the reception of the raw material constitutes a critical control point. This verification is even more critical when it is intended to change supplier of raw materials.

In general, sampling and microbiological analyzes are not adequate per se to ensure the safety of the food. Microbiological analyzes are rarely effective in monitoring CCP and cannot be used as a means of controlling the process due to delayed analytical procedures and the inability to deliver results in real time. However, microbiological analyzes are useful in checking the HACCP System when critical limits are established to eliminate or reduce pathogens to an acceptable level to verify the efficiency of the HACCP Plan and to ensure that the identified microbiological limits are not exceeded. The performance of microbiological analyzes is very useful in process validation (AFNOR, 1998).

Samples of products may also be collected at points of sale and analyzed for any problems not considered in the hazard

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analysis but which may arise along the food chain due to inadequate storage or handling of the product of customers. Microbiological analyzes shall be carried out in accordance with a pre-established program which shall take into account the nature of the processes and the level of risk associated with the raw materials and products (Table 3.4, Table 3.5).

Table 3.4 - Categories of risk for different product types

Food group	Product	Category
Meat	Steaks	1
	dried fish	2
	ham – raw (Parma/country style)	5
	kebabs	2
	meat meals (shepherds/cottage pie, casseroles)	2
	meat pies (steak and kidney, pasty)	1
	meat, sliced (cooked ham, tongue)	4
	meat, sliced (beef, haslet, pork, poultry)	3
	pork pies	1
	poultry (unsliced)	2
	salami and fermented meat products	5
	sausages (smoked)	5
	sausage roll	1
	scotch egg	1
	tripe and other offal	4
Seafood	crustaceans (crab, lobster, prawns)	3
	herring/roll mop and other raw pickled fish	1
	other fish (cooked)	3
	seafood meals	3

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	molluscs and other shellfish (cooked)	4
	smoked fish	4
Dessert	cakes, pastries, slices, and desserts - with dairy cream	3
	cakes, pastries, slices, and desserts - without dairy cream	2
	cheesecake	76 5
	mousse/dessert	1
	tarts, flans, and pies	2
Savoury	cheese-based bakery products	2
	fermented foods	5
	flan/quiche	2
	mayonnaise/dressings	2
	pâté (meat, seafood, or vegetable)	3
	Spring rolls	3
5 Vegetable	Coleslaw	3
	fruit and vegetables (dried)	3
	fruit and vegetables (fresh)	5
	prepared mixed salads and crudités	4
	rice	3
	vegetables and vegetable meals (cooked)	2
5 Dairy	Cheese 5	5
	ice cream, milk shakes (non-dairy) 2	2
	ice lollies, slush, and sorbet 2	2
	yoghurt/frozen yoghurt (natural)	5
Ready-to-eat meals	pasta/pizza	2
	meals (other)	2
Sandwiches and filled rolls	with salad	5
	without salad	4
	with cheese	5

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Source: Guidelines for the microbiological quality of some ready-to-eat foods sampled at the point of sale (adapted) (Gilbert, R.J. et al., 2000)

Table 3.5 - Microbiological quality criteria for ready-to-eat foods

Food category (see table 3.5)	Criterion	Microbiological quality (CFU per gram unless stated)			
		Satis-factory	Accepta-ble	Unsatis-factory	Unacceptable/ potentially hazardous*
	Aerobic colony count (a) 30°C/48h				
1		$<10^3$	10^3-$<10^4$	$\geq 10^4$	N/A
2		$<10^4$	10^4-$<10^5$	$\geq 10^5$	N/A
3		$<10^5$	10^5-$<10^6$	$\geq 10^6$	N/A
4		$<10^6$	10^6-$<10^7$	$\geq 10^7$	N/A
5		N/A	N/A	N/A	N/A
	Indicator organisms (b)				
1-5	Enterobacteriaceae (c)	<100	100-<100	$\geq 10^4$	N/A
1-5	*E. coli* (total)	<20	20-<100	≥ 100	N/A
1-5	Listeria spp (total)	<20	20-<100	≥ 100	N/A
	Pathogens				
1-5	Salmonella spp	(1)			(2)
1-5	Campylobacter spp	(1)			(2)
1-5	*E. coli* O157 & other VTEC	(1)			(2)
1-5	V. cholerae	(1)			(2)
1-5	V. parahaemolyticus (d)	<20	20-<100	100-$<10^3$	$\geq 10^3$
	L. monocytogenes	<20**	20-<100	N/A	≥ 100
1-5	S. aureus	<20	20-<100	100-$<10^4$	$\geq 10^4$
1-5	C. perfringens	<20	20-<100	100-$<10^4$	$\geq 10^4$
1-5	*B. cereus* and other pathogenic				

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1-5	Bacillus spp (e)	$<10^3$	10^3-$<10^4$	10^3-$<10^4$	$\geq 10^5$

(1) Not detected in 25 grams
(2) Detected in 25 grams
N / A: Not applicable
*: Based only on high colony counts and / or organism counts. In the absence of other criteria of unacceptability it is unlikely to s ed
**: not detected in 25 grams of certain long-lasting products in refrigerators
(a): colony counting guidelines may not apply to certain fermented foods, for example salami, soft cheese, and unpasteurized yogurts. These foods fall into category 5. Acceptability is based on the appearance, smell, texture and levels of absence of indicator f organisms or pathogens.
(b): in certain situations, the strains may be pathogenic.
(c): not applicable to fresh fruit, vegetables and vegetable salads.
(d): relevant only for fish.
(e): if the bacillus count exceeds 104 CFU / g, the micro- anism shall be identified.
The terms used to express the microbiological quality of ready-to-eat foods are:
Satisfactory - the test results indicate a good microbiological quality result.
Acceptable - a level indicating the microbiological quality threshold.
Unsatisfactory - the test results indicate that more samples will be needed and that officials from the official bodies may wish to carry out another inspection to check whether hygienic food oduction practices are appropriate.
Unacceptable / potentially dangerous - test results indicate that it is necessary to locate the source of the problem; A detailed risk alysis is recommended. Such results can lead to court action, especially if they occur in more than one sample.

Source: Guidelines for the microbiological quality of some ready-to-eat foods sampled at the point of sale (adapted) (Gilbert, R.J. et al., 2000)

They shall also be carried out where there is evidence that the food safety status may have changed, in particular where:

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- it is found that the critical control limits are violated;
- Records reviews indicate inadequate monitoring;
- Complaints or rejection of the product by customers or consumers;
- New scientific data will emerge.

VERIFICATION FREQUENCY

Verification procedures should be scheduled at a frequency that ensures that the HACCP Plan remains current and properly implemented and that the HACCP Plan is fully complied with. The frequency of verification activities can be modified over time. The changes shall take into account the history of the verification activities and the records of deviations. There may even be a reduction in the frequency of these activities, as long as this does not compromise the maintenance of the level of confidence in the implemented HACCP System.

The verification procedures of the HACCP System should be documented and the results from these activities should be recorded.

3.5.12. DOCUMENTS AND REGISTERS

The HACCP System is a documented system. An adequate establishment of documentation is essential for an effective implementation of the HACCP System. Figure 3.4 shows the hierarchy of documentation normally found in a HACCP management system.

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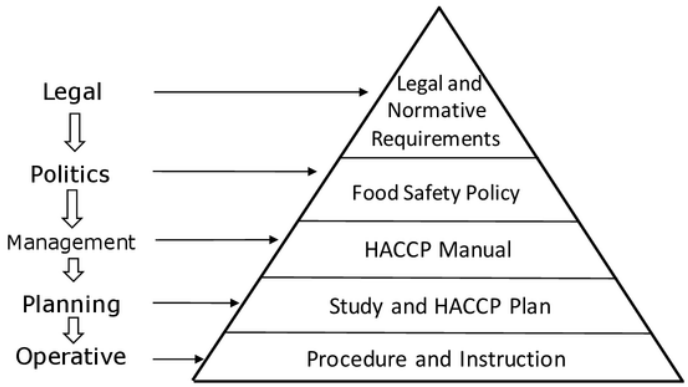

Figure 3.4 - Documentary structure of a HACCP system

The records are evidence of activities and constitute an important source of information to support an adequate implementation of a HACCP System and ensure its revision when necessary.

TYPES OF DOCUMENTS AND RECORDS

Among the documents and records to be considered in a HACCP System are the following:

- The procedures describing the HACCP System;
- Documents and data used in hazard analysis and establishment of the HACCP Plan (e.g. data used to define control measures and establishment of critical control limits; data obtained in process validation and product shelf-life);
- Descriptions of the products and their expected use;
- Flowcharts of production processes;
- Hazard analysis and the determination of critical points;
- The HACCP Plan, including the description of critical limits for each CCP and its monitoring;
- Records associated with CCP monitoring;

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- The reports / minutes / minutes produced at HACCP Team meetings;
- Deviations and associated corrective / preventive actions;
- HACCP audit reports;
- Product Technical Data Sheets;
- Technical Data Sheets of Raw Materials;
- Identification cards of the state of inspection and testing;
- Sanitation plan (Baptista, P., 2003);
- Pest control plan (Baptista, P., 2003);
- Training plan;
- Training records (e.g. program content, summaries, attendance list);
- Calibration Plan;
- Calibration records (e.g. calibration certificates);
- Maintenance plan;
- Maintenance records (e.g., equipment registration forms);
- Internal Audit Plan;
- Internal Audit Reports;
- HACCP Team Meeting Minutes;
- Registration Control Table;
- Document Control Table;
- Various procedures (e.g. Management review by the Management, Control of Documents and Data, Control of Inspection, Measurement and Monitoring Equipment, Treatment of Nonconformities, Corrective and Preventive Actions, Control of HACCP Records, Internal HACCP Audits, Training).

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Figure 3.5 identifies the link between the various document types and records with the structure of the HACCP System and associated activities.

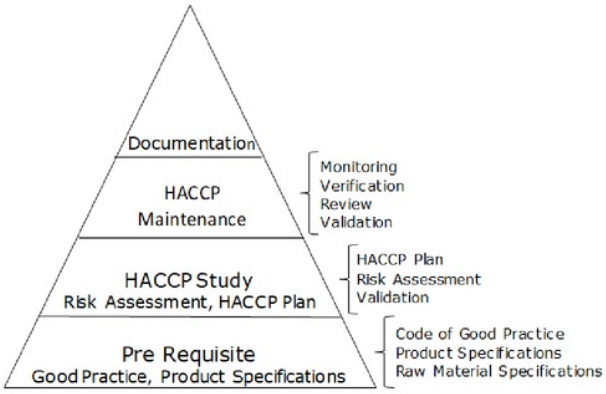

Figure 3.5 - Links between the various document types and records with the structure of the HACCP System and associated activities

MANAGEMENT OF DOCUMENTS AND RECORDS

Documents and records shall be managed in accordance with a specific procedure. They must:

- Find themselves indexed;
- Be available for consultation where needed for the activity;
- May be modified / updated (procedures and forms);
- Be maintained during pre-defined periods, established based on the life time of the product and other criteria, namely of a legal nature;
- Indicate the update status.

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An adequate archive of records makes it possible to prove, under any circumstances, that the HACCP Plan procedures a 52 being complied with in accordance with the requirements of the HACCP System. Thus, these records are used to demonstrate compliance with the specific critical limits established for each CCP in food processing. Records review can also be an instrument for identifying trends and making adjustments to operational limits.

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4

FOOD SAFETY STANDARDS FOR CERTIFICATION

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4.2.2.5. MEASUREMENT, ANALYSIS, IMPROVEMENT

4.2.2.6. FOOD DEFENSE AND EXTERNAL INSPECTIONS

4.2.3. COMPARISON BETWEEN BRC AND IFS STANDARDS

Chapter Objectives

- XXX
- XXX
- XXX

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Keywords (Index)

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Critical control point

D

Decision tree

Documents

- control
- types

E

Emulsifiers

Emulsifying salts

Equipments measuring

F

Facilities

69

Firming agents

Flavour enhancers

Flour treatment agents

Flowchart

- construction
- verification

Foaming agents

Food

Food Safety Policy

G

Gelling agents

Glazing agents

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Good manufacturing practices

H

HACCP

- communication
- concept
- history
- methodology
- principles
- resources
- review
- team
- team coordinator

HACCP Plan

Hazard

- identification
- potential
- relevant

Hygiene

- food (rules / general principles)

I

ISO 22000:2005

ISO 9001: 2015

L

Layout

Legislation

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Q

Quality management system

R

Raising agents

Raw material

Register

Risk assessment

S

Sanitation

Sequestrant

Severity

Stabilisers

Storage

Suppliers

Sweeteners

T

Thickeners

Toxins

Training

Transport

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Glossary

Acidity regulators - substances which alter or control the acidity or alkalinity of a foodstuff.

Acids - substances which increase the acidity of a foodstuff and/or impart a sour taste to it.

Action - Action taken when monitoring results demonstrate that critical limits have been exceeded or established procedures have not been met.

Anti-caking agents - substances which reduce the tendency of individual particles of a foodstuff to adhere to one another.

Anti-foaming agents - are substances which prevent or reduce foaming.

Antioxidants - substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes.

Audit (HACCP) - Systematic review to determine if the activities of the HACCP System and the associated results are in accordance with the established plan, and implemented effectively, and are adequate to ensure that the objectives are achieved.

Bacteria - a single-cell microorganism usually between 0.5 and 10 µm in length or diameter, with rigid walls that multiply by dividing into two.

Biological hazard - Any unacceptable growth or survival of bacteria in foods that may affect their safety or quality, or the production or persistence of substances such as toxins, enzymes or products resulting from microbial metabolism in food.

Bulking agents - substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value.

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Carriers - substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use.

Colours - substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Regulation.

Control measure - Activity necessary to prevent or eliminate hazards or reduce their presence to acceptable levels.

Critical control limit - Value or criterion that differentiates acceptance from non-acceptance of the process.

Critical control point (CCP) - Point, procedure, process step or element of the food chain in which control can be applied which is essential to prevent, reduce to acceptable levels or eliminate a food safety hazard.

Decision tree - Sequence of issues that can be applied at each stage of the process, to a relevant identified hazard, in order to determine whether it constitutes a critical control point.

Emulsifiers - substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff.

Emulsifying salts - substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components.

Firming agents - substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to

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produce or strengthen a gel.

Flavour enhancers - substances which enhance the existing taste and/or odour of a foodstuff.

Flour treatment agents - substances, other than emulsifiers, which are added to flour or dough to improve its baking quality.

Flowchart - Systematic representation of the sequence and interrelation between stages and operations used in the preparation of a given food product.

Foaming agents - substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff.

Food Safety - Guarantee that the product will not affect the consumer's health when processed and / or consumed according to its intended use.

Gelling agents - substances which give a foodstuff texture through formation of a gel.

Glazing agents - substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating.

Good hygienic practices (GHP) - Guidelines, methods and activities designed and monitoring to promote and maintain health through the use of sanitary conditions.

Good manufacturing practices (GMP) - Preventive measures related to internal and external conditions of the organization, with the aim of avoiding or reducing the likelihood of contamination of the product by sources of internal and external origin.

HACCP - A systematic analysis involving the application of methods, procedures, tests or other evaluations (eg audits, measurements) to confirm compliance with the HACCP Plan and verify its effectiveness.

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HACCP Plan - Document prepared in accordance with HACCP principles to ensure control of relevant hazards within the HACCP management system.

HACCP system - A system that controls the hazards that are relevant to food safety through critical control points.

Hazard (in food) - Any biological, physical and chemical property that can make a food harmful to consumption.

Hazard analysis - A process for collecting and evaluating information on potential hazards and the conditions that may lead to their presence in food, in order to decide which hazards are relevant to food safety and which should therefore be considered in the HACCP Plan .

Humectants - substances which prevent foods from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium.

Modified starches - substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached.

Mold - Microscopic plants - fungi - filamentous that develop in soil, air, water and food.

Monitoring - A planned sequence of observation or measurement of control parameters to assess whether (a critical control point) is within acceptable values.

Operational limit - Limit which, once achieved, will lead to the initiation of corrective action in order to avoid that the critical limit is reached.

Packaging gases - gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container.

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Parasites - Organisms that grow, nourish and protect themselves in a different organism and take what they need from it.

Pathogenic micro-organism - A micro-organism capable of causing disease.

Pesticide – Is a product/substance that prevents, destroys, or controls a harmful organism (pest) or disease, or protects plants or plant products during production, storage and transport.

pH - An index used to measure the acidity / alkalinity of a solution, represents the inverse of the logarithm of the concentration of the H_3O^+ ion.

Potential hazard - Hazard that, theoretically, can occur.

Preservatives - substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms.

Propellants - gases other than air which expel a foodstuff from a container.

Raising agents - substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter.

Register- Evidence of the accomplishment of the activities associated with the operability (of the HACCP System).

Relevant (or significant) hazard - Potential hazard requiring control according to hazard analysis.

Risk - Consequences of a given hazard occurring, measured by the probability and severity of the hazard.

Sequestrants - substances which form chemical complexes with metallic ions.

Stabilisers - substances which make it possible to maintain the physical-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous

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dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food.

Sweeteners - substances used to impart a sweet taste to foods or in table-top sweeteners.

Thickeners - substances which increase the viscosity of a foodstuff.

Toxins - Chemical substances produced by certain microorganisms present in food, which may develop in the food or in the body after consumption of contaminated food.

Validation (HACCP) - Confirmation, through objective evidence, that the HACCP management system ensures food safety.

Virus - Very small microorganisms, less than 0.1 µm in diameter. The viruses do not have cells, like the other microorganisms, being constituted by nucleic acid coated by a protein. They need a host to multiply in living cells.

Water activity (w_a) - Measurement of water available in food for micro-organisms, expressed as the quotient between the water vapor pressure of the food and the pure water vapor pressure.

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Abbreviations

AFNOR – Association Française de Normalisation

W_a – Water Activity

BRC – British Retail Consortium

BSE - Bovine spongiform encephalopathy

CAC – Codex Alimentarius Commission

CCP – Critical Control Point

CFU – Colony-forming unit

DoC – Declaration of Compliance

EC – European Community

ECDC – European Centre for Prevention and Control of Diseases

EEA – European Economic Area

EEC – European Economic Community

EFSA – European Food Safety Authority

EMA – European Medicines Agency

EU – European Union

EURL-FCM – European Reference Laboratory for Food Contact Materials

EWRS - Early Warning Response System

FAO – Food and Agriculture Organization

FCMs – Food Contact Materials

FDA – Food and Drug Administration

FMEA – Failure Mode and Effect Analysis

GAP – Good Agricultural Practices

GDP – Good Distribution Practices

GHP – Good Hygienic practices

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GL – Guidelines

GMP – Good Manufacturing Practices

GVP – Good Veterinary Practices

HACCP – Hazard Analysis and Critical Control Point

ICMSF – International Commission on Microbiological Specification in Foods

IFS – International Featured Standard

ISO – International Standards Organization

MRLs – Maximum Residues Limits

MRPLs – Minimum Required Performance Limits

NASA – National Aeronautics and Space Administration

OML –Overall Migration Limits

PAFF Committee – Standing Committee on Plants, Animals, Food and Feed

PPPs – Plant Protection Products

RASFF -Rapid Alert System for Food and Feed

RCP – Recommended Code of Practices

RMS - Rapporteur Member State

SCF – Scientific Committee on Food

SMLs – Specific Migration Limits

TQM – Total Quality Management

US – United States

VTEC – Verotoxin-producing *Escherichia coli*

WHO – World Health Organization

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