



Training activities on auditing general hygiene requirements and control procedures based on the HACCP principles developed by FBOs

Modules Description

Opening & welcome. BTSF initiative presentation (video).	15 min
Training objectives & presentation of the training programme	15 min
Presentation & expectations of each participant	15 min
Initial test of knowledge (ToK)	30 min

Topic 1: HACCP overview

Specific objectives of Topic 1:

The objective of this first topic is to refresh and harmonize the participants' knowledge of EU requirements with regard to HACCP, its importance, background and roots. The subject will be introduced by the "Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses" (CNHACCP) - as the most important reference for understanding HACCP, HACCP based principles and related flexibility. Information about quality and safety management of food and the relation between main food safety private standards and HACCP will be provided.

Module 1.1 Background to HACCP systems and EU legislation related to HACCP

Tutor(s):	DUO 1: Elizabeta Micovic / Lisa-Marie Hedberg
Duration:	30 minutes
Type of activity / methodology:	Theoretical presentation + Interactive discussion on the general perception and difficulties encountered by inspectors
Aids:	Infographics

Contents
<ul style="list-style-type: none"> • Overview of the background and timeline of HACCP: special attention to Codex Alimentarius. Importance of HACCP in international trade. Conclusions: benefits and constraints of the HACCP system; • Printed Infographic on the HACCP background timeline will be provided to the participants; • EU hygiene package and specific articles of the EU legislation related to HACCP containing requirements for Feed and Food Business Operators (FBOs); • Introduction to the "Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses", outline core elements and incl. emphasis on the concept of flexibility and simplified HACCP-based procedures; • Introduction to the main private food safety standards: ISO 22000, BRC and IFS; • Difficulties, constraints and challenges encountered by inspectors.
Reference documents: - Codex Alimentarius (CAC/RCP 1-1969, Rev.4- 2003)



- IFS vs 6.1, BRC Issue 7, ISO 22000:2005
- Regulations (EC) N° 852/2004 - 853/2004 - 854/2004 - 882/2004 resp. upcoming Reg. 625/2017 - 2073//2005 - 178/2002
- Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (CNHACCP)
- Final overview report. Report on the State of Implementation of HACCP in the EU and Areas for Improvement. European Commission. Directorate-General For Health And Food Safety. Directorate F - Food And Veterinary Office. 2015. (FVO Report on HACCP)

Topic 2: Prerequisites programmes

Specific objectives of Topic 2:

This second training topic, being a key element to the preparation and implementation of general measures contributing to manage Food Safety, aims to refresh, recall and deepen participants' knowledge on the prerequisites requirements and their importance in a food safety management system. Short information about the prerequisites in ISO 22000 and IFS standards will be included.

Module 2.1 General hygiene requirements: prerequisites

Tutor(s): DUO 1: Elizabeta Micovic / Lisa-Marie Hedberg

Duration: 45 minutes

Type of activity / methodology: Theoretical presentation
+ Q&As during the presentation and at the end

Contents
<ul style="list-style-type: none"> • Introduction: definitions and importance of prerequisites (PRPs) in food businesses for controlling hazards; • The concept of Food Safety Management System: prerequisites plus HACCP; • Links between FSMS, PRPs, GHP, GMP and HACCP; • Specific articles of the EU legislation related to prerequisites and their implementation; • Recommendations of CNHACCP about prerequisites: main features and examples; • Alternative methods for surfaces disinfection: steam, hot water, ozone, UVA rays; • Comparison of prerequisites stated with other food safety management standards and guidelines (Codex, and ISO 22000 & ISO/TS 22002-1); • Documentation on PRPs: legal framework, problems; • Flexibility on PRPs: specific contents included in the Commission Notice on HACCP.
<p>Reference documents:</p> <ul style="list-style-type: none"> - Regulation (EC) N° 852/2004 - Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption - Regulation (EU) N° 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products - Codex Alimentarius, CAC/RCP 1-1969, Rev. 4-2003 - CNHACCP - Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene - IFS 6.1



- ISO 22000:2005 and ISO/TS 22002-1:2009
- Directorate F - Food And Veterinary Office. 2015. (FVO Report on HACCP)

Module 2.2 Virtual visit to a Food Business Operator (FBO). Exercise on auditing prerequisites programmes.

Tutor(s):	TC DUO: Plinio Simon / Andreas Wunsch
Duration:	30 minutes
Type of activity / methodology:	Virtual field visit / Role play
Aids if any:	360° panorama pictures of the premises of a food business operator implementing HACCP system

Contents

A virtual visit to a factory of a food business operator by means of a sequence of interactive pictures will be carried out. The pictures give a 360° panorama of the premises, and are operated with the computer mouse. Later, by means of a role play, where participants act as inspectors/auditors, an on-site audit of prerequisites will be simulated. The tutor will act as the company's quality manager answering to questions from the participants as in a real audit of prerequisites. With the information obtained in the virtual tour, the participants will have to identify which aspects regarding prerequisites may be addressed and further investigated in order to assess the proper implementation of the prerequisites. Closing this first practical exercise, the tutor will summarise observations made, point out good/bad practices, and comment on questions raised by the participants.

Module 2.3 Case study on a prerequisite

Tutor(s):	DUO 1: Elizabeta Micovic / Lisa-Marie Hedberg
Duration:	45 minutes
Type of activity / methodology:	Case study in working groups

Contents

Two examples where hazards are controlled by PRPs, based on real cases, will be presented to the participants. The first one will be about the presence of an allergen, and the second one - on microbiological contamination in a specific process. The achieved results will be discussed within the working groups and in plenary, and the tutor will explain the correct answers.

Topic 3: HACCP method and plan

Specific objectives of Topic 3:

The main objective of Topic 3 is that participants obtain a deeper knowledge of the HACCP methodology, the necessary preparatory work and its different approaches focusing on Principle 1 (hazard analysis), Principle 2 (establishing CCP) and Principle 6 (verification) which seem to be the most difficult elements to understand, and generate more doubts according to the *Final Overview Report on the State of Implementation of HACCP in the EU and Areas for Improvement*. Theoretical and practical exercises for each principle will be used for a better understanding of the theory.

Module 3.1 Preparatory stages of HACCP

Tutor(s):	DUO 1: Elizabeta Micovic / Lisa-Marie Hedberg
Duration:	30 minutes



Type of activity / methodology: Theoretical presentation
+ Qs&As during the presentation and at the end

Contents
<ul style="list-style-type: none"> • Importance of the previous stages. Description of the goals and development of each stage: <ol style="list-style-type: none"> 1. Assembly of a multidisciplinary HACCP team; 2. Description of the product(s) at the end of the process; 3. Identification of the intended use; 4. Construction of a flow diagram (description of manufacturing process); 5. On-site verification of the flow diagram. <ul style="list-style-type: none"> • Special attention to the description of the product (including physical-chemical parameters) and flow diagram due to its importance in the latest HACCP study. The importance of shelf-life as in the cases where listeria monocytogenes is a significant hazard will be highlighted, as well as the supporting documents which justify the product characteristics and shelf-life; • Flexibility on the preliminary steps: specific contents included in the Commission Notice on HACCP.
<p>Reference documents:</p> <ul style="list-style-type: none"> - Codex Alimentarius, CAC/RCP 1-1969, Rev. 4-2003 – - CNHACCP - ISO 22000:2005

Module 3.2 Practical activity on flow diagram

Tutor(s): DUO 1: Elizabeta Micovic / Lisa-Marie Hedberg
 Duration: 30 minutes
 Type of activity / methodology: Case study in working groups + Debriefing

Contents
<p>A description of a manufacturing process (e.g., sliced cooked ham) will be handed out to the participants, who will have to draft a flow diagram of the described process. At the end, a flow diagram drafted by the tutors will be handed out to the participants.</p> <p>This flow diagram and the steps described in it will be used in all upcoming exercises on the HACCP principles.</p>

Module 3.3 Principles 1 and 2: hazard analysis and determining CCPs

Tutor(s): DUO 2: Panagiotis Katoikos / Maurizio Ferri
 Duration: 60 minutes
 Type of activity / methodology: Theoretical presentation

Contents
<p>Different approaches to carry out principles 1 and 2: CNHACCP - FSIS - Codex Alimentarius - and ISO 22000:</p> <ul style="list-style-type: none"> • Identification of potential biological, chemical or physical hazards that may be reasonably expected and thus relevant in the process, their causes and their description at a sufficient and adequate level of detail; • Risk assessment for each relevant hazard: determination of the likely occurrence and severity of the hazards. Tools and examples, incl. the (semi-quantitative) risk evaluation procedure included in the CNHACCP;



- Identification and description of adequate control measures at all relevant hazards. Categorization of the control measures into prerequisites, critical control points and operational prerequisites programmes;
- Determination of CCPs with a decision tree and semi-quantitative methods. FSIS and ISO 22000 approach in CCP determination;
- CCPs, CPs and OPRPs: differences and similarities, criteria to classify control measures as CCPs and OPRPs.

Reference documents:

- Regulation (EC) N° 852/2004
- CNHACCP
- Codex Alimentarius, CAC/RCP 1-1969, Rev. 4-2003
- United States Department of Agriculture, Food safety and Inspection Service (FSIS) Guidebook for the Preparation of HACCP Plans
- Directorate F Report on HACCP

Module 3.4 Case study principles 1 and 2: hazard analysis and determining CCPs

Tutor(s): DUO 2: Panagiotis Katoikos / Maurizio Ferri
 Duration: 150 minutes
 Type of activity / methodology: Case study in working groups

Contents

Case study on the hazard analysis and CCP determination. The groups will be in charge of specifically selected steps of the flow diagram used in Module 3.2.

The semi-quantitative risk evaluation procedure included in the CNHACCP will be used for the hazard analysis and CCPs determination. The most interesting steps of the process from a pedagogical point of view, described in the case study 3.2, will be covered: brine production, brine injection, cooking, cooling, and high pressure processing.

The participants will work on the same steps and will use the Codex decision tree and the simplified decision tree included in the CNHACCP.

At the end of the module, the groups will present their work and the obtained results, and will debate on the difficulties encountered, as well as the possible differences in the outcomes depending on the applied methodology.

Reference documents:

- CNHACCP

Module 3.5 Flexibility on principles 1 and 2

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch
 DUO 2: Panagiotis Katoikos / Maurizio Ferri
 Duration: 30 minutes
 Type of activity / methodology: Presentation of specific practical examples

Contents

Flexibility on Principles 1 and 2: specific contents included in the *Commission Notice on HACCP*. By presenting some specific examples the participants should get familiar with flexibility on the level of the first 2 principles. These examples presented by the tutor will be briefly discussed in plenary



and could be “acceptable” or “inacceptable” as to the applied flexibility. Participants will have to reach an ad-hoc decision on this acceptability. Justification based on the CNHACCP will be demonstrated and provided.

Reference documents:
- CNHACCP

Module 3.6 Principles 1 and 2: hazard analysis and determining CCPs: Q&A and debriefing

Tutor(s): DUO 2: Panagiotis Katoikos / Maurizio Ferri
Duration: 15 minutes
Type of activity / methodology: Qs&As - plenary discussion and debate

Contents

Due to the difficulties related to these 2 principles, a specific Q&A and debriefing session will take place to summarize and discuss the methods, approaches and difficulties encountered.

Module 3.7 Discussion on specific situations related to CCPs in different sectors and/or products

Tutor(s): DUO 2: Panagiotis Katoikos / Maurizio Ferri
Duration: 15 minutes
Type of activity / methodology: Discussion and sharing of specific practical examples identified by participants

Contents

This module will be tailored to each training session. The objective will be to clarify doubts and questions on specific / particular processes. The participants will be able to share their concerns and experience on some specific sectors, products and processes regarding CCPs that are commonly identified in the HACCP plans.

The sharing of different approaches and experiences among the participants and tutors may lead to comparisons among the different countries / regions and harmonising the approach. The goal of this module is to permit a critical discussion and make clear that there may not always be one solution or approach only.

Module 3.8 Principles 3, 4 and 5: establishing critical limits, monitoring CCPs and establishing corrective actions

Tutor(s): DUO 3: Franciscus Henderikx / Roberto Valcarce
Duration: 60 minutes
Type of activity / methodology: Theoretical presentation
+ Qs&As during the presentation and at the end

Contents

- Critical limits:
 - ✓ Critical limits, target level, tolerance;
 - ✓ Criteria, references and sources for establishing and validating critical limits;
 - ✓ Ascertain the validity of the non-regulatory (or from officials guides) critical limits;
 - ✓ The experience as a method of validation.



<ul style="list-style-type: none"> • Monitoring system: <ul style="list-style-type: none"> ✓ Considerations in monitoring and characteristics of monitoring methods; ✓ The basic information of a monitoring procedure: who, when, how and records. • Establishing corrective actions: <ul style="list-style-type: none"> ✓ Responsibilities; ✓ Requirements of corrective actions predetermined; ✓ Actions on products: identification of affected products and disposition; ✓ Actions on processes; ✓ Records. • Differences and similarities on Principles 3, 4 and 5 between the CNHACCP, Codex and ISO 22000. • Flexibility on principles 3, 4 and 5: specific contents and examples included in the Commission Notice on HACCP.
<p>Reference documents:</p> <ul style="list-style-type: none"> - Regulation (EC) N° 852/2004 - CNHACCP - ISO 22000:2005 - Codex Alimentarius, <i>CAC/RCP 1-1969, Rev. 4-2003</i> - FSIS Guidebook for the Preparation of HACCP Plans - FVO Report on HACCP

Module 3.9 Case Study on Principles 3, 4 and 5

Tutor(s): DUO 3: Franciscus Hendrikx / Roberto Valcarce
 Duration: 75 minutes
 Type of activity / methodology: Case study in working groups

Contents
<p>Each working group will focus on some of the CCPs and OPRPs which have been determined in the preceding case study 3.4.</p> <p>The participants will establish critical limits or target levels in case of OPRPs, monitoring procedures and corrective actions for the CCPs and OPRPs determined in the previous exercises. The participants will be provided with adequate references for validation of critical limits to simulate a real HACCP study. Extracts from relevant legal provisions on additives will serve as a basis regarding the brine production and injection. For the validation of the cooking and cooling processes, they will use the Food Safety and Inspection Service (FSIS) documents: Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products and the Appendix B Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization). Relevant and representative extracts from Scientific Publications may support the decision making regarding HPP.</p> <p>The results will be presented and discussed by each working group.</p>
<p>Reference documents:</p> <ul style="list-style-type: none"> - Related specific information to be used as reference for the exercise (legal reference Nitrate/Nitrite , scientific and technical docs, etc.) - Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products. FSIS - Appendix B Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization). FSIS - Legal provisions regarding food additives



- Selected extracts from Scientific Publications

Module 3.10 Principle 6: Validation and verification of the system

Tutor(s): DUO 3: Fransiscus Hendrikx / Roberto Valcarce
Duration: 30 minutes
Type of activity / methodology: Theoretical presentation
+ Qs&As during the presentation and at the end

Contents
<ul style="list-style-type: none"> • Validation and verification: key definitions and differences, methods and examples; • Elements of the verification procedures: activities, responsibilities and records; • Periodical reviews of the system and adjustment; • The role of microbiological criteria as validation and verification method. Regulation (EC) N° 2073/2005 and verification; • Differences and similarities on principles 6 between the CNHACCP, Codex and ISO 22000; • Flexibility on principle 6: specific contents and examples included in the Commission Notice on HACCP.
<p>Reference documents:</p> <ul style="list-style-type: none"> - Regulation (EC) N° 852/2004 - CNHACCP - ISO 22000:2005 - Codex Alimentarius, CAC/RCP 1-1969, Rev. 4-2003 - (FSIS) Guidebook for the Preparation of HACCP Plans - Codex Alimentations Guidelines For The Validation Of Food Safety Control Measures Cac/GI 69 – 2008 - FSIS Compliance Guideline HACCP Systems Validation. April 2015 - Regulation (EC) N° 2073//2005 - FVO Report on HACCP

Module 3.11 Principle 7: documentation and records

Tutor(s): DUO 3: Fransiscus Hendrikx / Roberto Valcarce
Duration: 30 minutes
Type of activity / methodology: Theoretical presentation
+ Qs&As during the presentation and at the end

Contents
<ul style="list-style-type: none"> • Recommended documentation of a HACCP plan; • Identification and distribution of the documents among the responsible persons; • Basic elements of a record: date, results and responsibilities; • Records of a HACCP system: monitoring activities, corrective actions and verification activities; • Records integrated in the existent documents; • Record keeping recommendations; • Flexibility on principle 7: specific contents and examples included in the Commission Notice on HACCP.
<p>Reference documents:</p> <ul style="list-style-type: none"> - Regulation (EC) N° 852/2004 - CNHACCP - ISO 22000:2005 - Codex Alimentarius, CAC/RCP 1-1969, Rev. 4-2003



- (FSIS) Guidebook for the Preparation of HACCP Plans
- FVO Report on HACCP

Module 3.12 Case Study on Principle 6

Tutor(s): DUO 3: Fransiscus Hendrikx / Roberto Valcarce

Duration: 30 minutes

Type of activity / methodology: Exercise / Case study in working groups

Contents
The participants will work in groups designing a draft verification plan for the HACCP plan resulting from the previous case study. The aim will be to draft a plan for exemplary verification activities based on a proposed template. Results should include specific activities including responsibilities and frequencies for at least the review of records, on site verification of monitoring procedures, calibration of thermometers, micro sampling according to Regulation 2073/2005.
Reference documents: - CNHACCP

Module 3.13 Case Study on Principle 7

Tutor(s): DUO 3: Fransiscus Hendrikx / Roberto Valcarce

Duration: 30 minutes

Type of activity / methodology: Exercise / Case study in working groups

Contents
The participants will work in groups producing examples of templates for recording the monitoring activities of the CCPs and OPRPs as determined in the previous case study 3.10. (Principles 3-5). The aim will be to draft exemplary templates which could be used for the proper documentation and recording of monitoring activities undertaken at previously defined steps (OPRPs or CCPs) of the production.
Reference documents: - CNHACCP

Topic 4: The audit process

Specific objectives of Topic 4:

The main objective of Topic 4 is to give information to the participants and to consolidate their knowledge of audit principles and techniques, focusing on the specific features of a “HACCP audit”. Participants will share their approaches, problems, field practices and experiences made, identifying the challenges and best practices to promote the harmonization of technical and operational methods of conducting audits. Practical application of the theoretical contents will ensue through an audit simulation and a field visit. During the module on harmonisation on audits tools, the participants will produce a “memorandum” or check list by formulated questions including the essential contents to address when auditing a HACCP system.

Module 4.1 Principles of an audit and exercises on audit techniques

Tutor(s): DUO 4: Donal Cousins / Thomas Longley

Duration: 150 minutes



Type of activity / methodology: Theoretical presentation / Qs&As during the presentation and at the end / Exercises / Role play

Contents

Official controls, audits and inspections, differences.

Requirements stated in EU law and guidance documents.

- Differences between audit and inspection;
- Principles of auditing;
- Key definitions;
- Preparing the audit: planning, background and former audits results, documentation review and identification of high risk areas;
- Audit techniques and methods: observation and questioning;
- Risk based approach to select the processes and more relevant control measures to sample during the audit;
- Stages of an audit:
 - ✓ Preparation;
 - ✓ Desk review;
 - ✓ On-site audit: opening meeting, (theory and role play), collecting evidence and findings, conclusions, recommendations and closing meeting;
 - ✓ Reporting: essential contents and quality of an audit report. Non-conformity categorisation. Recommendations on the report;
 - ✓ Follow-up activities.
- Specific aspects to assess during the audit of a HACCP plan: compliance with the legal requirements and HACCP principles, identification of the significant hazards and efficiency of the control measures to control them, CCPs determination, critical limits or targets (in case of OPRPs), monitoring systems, corrective actions and verification procedures.
- Practical considerations regarding flexibility and the design and extent of an OC when auditing a FSMS/HACCP considering the size of the FBO's production and nature of the products: low risk products and/or processes.
- Flexibility: specific aspects of auditing a HACCP plan based on a guide.

Some short exercises will be carried out for a better understanding of the terminology and main concepts related to an audit: audit criteria, audit evidences, audit findings and audit conclusions.

Reference documents:

- CNHACCP
- FVO Report on HACCP
- Regulations (EC) N° 854/2004- 882/2004 resp. upcoming Reg. 625/2017
- WHO: Guidance On Regulatory Assessment Of HACCP
- Food Safety Authority of Ireland. Guidance Note II. Assessment of HACCP Compliance (Revision 2)
- Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules
- ISO 19011:2011 -Guidelines for auditing management systems

Module 4.2 FSMS / HACCP audit checklist

Tutor(s): DUO 4: Donal Cousins / Thomas Longley

Duration: 15 minutes



Type of activity / methodology: Theoretical presentation / Feedback on practical experience / Identification of best practices

Contents
The use and purpose of check list in audits will be presented and discussed. Structure, completeness, efficiency. Advantages, disadvantages and weaknesses of the check lists will be addressed including some examples in use.
Reference documents: - CNHACCP - FVO Report on HACCP - Regulations (EC) N° 854/2004- 882/2004 resp. upcoming Reg. 625/2017 - WHO: Guidance On Regulatory Assessment Of HACCP - Food Safety Authority of Ireland. Guidance Note II. Assessment of HACCP Compliance (Revision 2) - Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules - ISO 19011:2011 -Guidelines for auditing management systems

Module 4.3 Audit Simulation

Tutor(s): DUO 5: Ita White / Gerard Barry

Duration: 165 minutes

Type of activity / methodology: Working group session and role play

Contents
For the purpose of this exercise, full HACCP documentation including a flow diagram, hazard analysis, CCP determination and all elements related to all other principles will be provided to the participants. The process chosen for this exercise will be manufacturing of a frozen ready meal range involving, pasta, rice, vegetable, meat and sauce. A documentary audit and "on-site" audit (role play) will be done, and finally each working group will document and report any non-compliances they have identified according to the failures intentionally packed in the HACCP documentation provided. Debriefing on the achieved results and approaches by the working groups and the tutors. The importance of focusing on those aspects being relevant for food safety will be emphasized. At the end of the exercise, a corrected version of the documentation highlighting the mistakes will be handed out to the participants and discussed for those issues which may have not been addressed during their discussions.
Reference documents: - CNHACCP - FVO Report on HACCP - Regulations (EC) N° 854/2004- 882/2004 resp. upcoming Reg. 625/2017 - WHO: Guidance On Regulatory Assessment Of HACCP - Food Safety Authority of Ireland. Guidance Note II. Assessment of HACCP Compliance (Revision 2) - Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules - ISO 19011:2011 -Guidelines for auditing management systems



Module 4.4 Field visit preparation

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch
Duration: 60 minutes
Type of activity / methodology: Working groups + Debriefing

Contents

Presentation of the selected food establishment and the documentation provided (translated into English) by the company to be visited.

A systematic approach to the audit process will be followed as previously explained.

The HACCP plan of one of the processes/products of the company to be visited will be assessed by the working groups. The documentation will include a flow diagram, hazard analysis, CCPs and OPRPs determination, critical limits and targets for the OPRPs, monitoring procedures, corrective actions and verification procedures.

On-site audit preparation in sub-groups, documentation review, gathering information and preparation of checklists for the onsite audit.

Module 4.5 Field visit

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch
Duration: 180 minutes
Type of activity / methodology: Field visit + Scenario audit

Contents

On-site visit:

- Presentation of the company: introduction to the food business and its activities including potential food safety issues, HACCP system and plan the visit;
- Participants will perform an audit exercise, gathering information to assess the adequacy and efficacy of the HACCP/FSMS in place and implemented measures to control the hazards;
- The exercise will focus on implemented PRPs, as well as possible CCPs and OPRPs determined by the company.

Final meeting with Q&A to the company representative/s relevant for the HACCP system audit and closing of the field visit.

Module 4.6 Field visit: exercise

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch
Duration: 30 minutes
Type of activity / methodology: Working groups

Contents

Evaluation of all implemented elements related to the FSMS/HACCP plan and creation of an audit report summarizing all evidence collected based on made observations and answers to the questions so far addressed and received.

Discussion on problems and constraints encountered during the audit and reporting.

Module 4.7 Field visit: exchange of views & debriefing

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch
Duration: 60 minutes



Type of activity / methodology: Working groups / Tutor's comments

Contents
<p>A representative from each working group will share the audits findings during the field visit.</p> <ul style="list-style-type: none"> • Discussion on the audits findings; • Exchange on the strengths and challenges of each team; • Highlighting positive aspects; • Rating the non-compliances; • Conclusions; • Identification of best practices. <p>Formalisation of key points.</p>

Module 4.8 Practical activity on harmonization of audit tools & guidelines

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch

Duration: 75 minutes

Type of activity / methodology: Working groups + Tutor's comments

Contents
<p>The participants will have to create a memorandum/check list for HACCP system auditing promoting the efficiency of the audit and the harmonization of the requirements without the application of flexibility. The CNHACCP will be used as the basis to produce the check list.</p> <p>Based on formulated key questions to address for each HACCP principle, this check list will have to cover the minimum and common requirements which a HACCP system must include. The main goal is to reach a common agreement among all the participants about what a HACCP system should include and what is essential not to forget when auditing it.</p> <p>This exercise will be useful as a recap of the HACCP principles explained during the previous days. Results will be completed by the tutors presenting a proposal of such a key memorandum/check list which will be distributed to the participants.</p>
<p>Reference documents:</p> <ul style="list-style-type: none"> - CNHACCP - FVO Report on HACCP - Regulations (EC) N° 854/2004- 882/2004 resp. upcoming Reg. 625/2017 - WHO: Guidance On Regulatory Assessment Of HACCP - Food Safety Authority of Ireland. Guidance Note II. Assessment of HACCP Compliance (Revision 2) - Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules - ISO 19011:2011 -Guidelines for auditing management systems

Topic 5: Guides and flexibility

Specific objectives of Topic 5:

The objective of Topic 5 is to improve the knowledge and understanding of the participants regarding the concept and the extent of flexibility applied to the HACCP system, including the importance of guides to good practice and generic HACCP guides as a tool to encourage and help small businesses to implement FSMS/HACCP based procedures and comply with this EU requirement. The proposal of EFSA formulated in its issued Scientific Opinion for small retail establishment will be disseminated as a flexible approach to HACCP.



Module 5.1 Flexibility

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch
 Duration: 60 minutes
 Type of activity / methodology: Theoretical presentation / Practical examples

Contents
<ul style="list-style-type: none"> • The concept of HACCP based procedure. Legal basis; • Businesses eligible for flexibility, criteria: size and nature; • The main flexibility concepts and guidelines included in the CNHACCP and already explained during the course will be reminded summarising and clarifying them. Special attention will be paid to: <ul style="list-style-type: none"> - In small business, it may suffice that the hazard analysis in the HACCP plan describes in a practical and simple way the methods to control hazards without necessarily entering into detail on the nature of the hazards; - Monitoring prerequisites, in establishments where all hazards can be controlled by PRPs only; - CCPs monitored by visual observation; - (Mandatory) records only in cases of non- compliance followed by documented corrective actions. • Guides to good practice and generic HACCP guides as a (voluntary) tool to encourage and help small businesses to implement HACCP based procedures; • Consideration when developing a guide. Contents of a guide. Role, practicability and “language” of a guide; • How FBOs can or have to use a guide to develop a FSMS for their food establishment and implement suggested activities, as well as control measures; • Individual evaluation of generic guides by each FBO before using a guide; • Guidance platform from the European Commission website. European and Member States guides; • Specific aspects to consider when auditing establishments which are following an approved guide to good practice. <p>Presentation of the EFSA Scientific Opinion: Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems.</p>
<p>Reference documents:</p> <ul style="list-style-type: none"> - Regulation (EC) N° 852/2004 - CNHACCP - EFSA Scientific - Opinion: “Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems.” - Guidance on food safety management systems for small food retailers (SFR-FSMS): the application of hazard identification, ranking and control in butcher, grocery, bakery, fish and ice cream shops - FVO Report on HACCP

Module 5.2 Case study applying the EFSA methodology: Small Food Retailer FSMS

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch
 Duration: 30 minutes
 Type of activity / methodology: Working groups + Debriefing

Contents
<p>The new approach proposed and developed in the EFSA Opinion named as the ‘simplified approach’ or ‘Small Food Retailer Food Safety Management System ‘SFR-FSMS’ will be used on a practical</p>



case.

The same product, as in the case study on Principles 1 and 2 (Module 3.4) will be used but applying the SFR-FSMS.

Debate on the results.

Reference documents:

- EFSA Scientific - Opinion: Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems

Module 5.3 Examples of flexibility and guides to good practice

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch

Duration: 45 minutes

Type of activity / methodology: Theoretical presentation + Discussion and feedback from participants on the situation in their own country

Contents

Some examples where flexibility has been applied to the HACCP system/the implementation of HACCP based procedures will be shown and discussed.

In case of the presence of participants who are from the country where examples are arising and being experienced in their implementation, the tutors will ask for their collaboration sharing real life experience.

The following examples and approaches of flexibility implementation (Guidelines) are being presented and discussed:

- European Guide for Good Hygiene Practices in the production of artisanal cheese and dairy products;
- “Safer Food – Better Business” Safer Food for Better Caterers. Food Standard Agency/UK;
- Retail Safe. Food Standard Agency. Scotland;
- Butcher Safe. Food Standard Agency. Scotland;
- National guides in Belgium and Comunidad Valenciana (Spain);
- National legislation requiring only recording of non-compliances on CCPs (Belgium);
- Clearly defined national Framework for flexibility in Food and for Feed (Germany);
- Examples of flexibility in Austria.

Interaction among the participants sharing experiences on HACCP and flexibility will be an essential part in this module.

Discussion and sharing experience regarding the implementation level of existing guidelines.

Reference documents:

- European Guide for Good Hygiene Practices in the production of artisanal cheese and dairy products
- FVO Report on HACCP
- Register of national guides to good hygiene practice
<https://webgate.ec.europa.eu/dyna/hygienelegislation/>
- Safer Food for Better Caterers. Food Standard Agency.
- Retail Safe. Food Standard Agency. Scotland.
- AFSCA website: <http://www.afsca.be/autocontrole-fr/guides/>
- [Generalitat Valenciana website:](#)
- Austrian Guideline for GHP and application of the HACCP system for slaughterhouses and cutting plants for pork, beef, sheep, goat and horse as well as for the production of meat products



Module 5.4 Q&A and closing discussion on flexibility

Tutor(s): TC DUO: Plinio Simon / Andreas Wunsch

Duration: 15 minutes

Type of activity / methodology: Plenary discussion + Debate

Contents

Q&A and a closing discussion on flexibility.

Summary and discussion of approaches and difficulties encountered.

Dissemination module	30 min
Final test of knowledge & explanation of the correct answers	30 min
Online evaluation for CHAFEA & training session conclusions	30 min
Closure & certificates	15 min