



THE DEVELOPMENT, IMPLEMENTATION AND MAINTENANCE OF HACCP SYSTEMS



Directorate-General for
Health & Consumers



Executive
Agency for
Health and
Consumers

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Foreword

To respond to the need for a sustainable and publicly available summary of the trainings delivered in the framework of the Better Training for Safer Food initiative, we decided to launch a series of training booklets in selected technical fields.

These booklets shall help the participants of our trainings to share the received information and knowledge with their colleagues back in their home countries.

The booklets shall also help in the preparation of training for future participants, and at the same time they will give a brief introduction on the latest developments to interested readers in the discussed technical field.

I hope that this booklet will be a useful tool for its readers, and I would invite those interested in the respective European legal framework and its development to visit the relevant pages of the Europa website, indicated on the back of this booklet.

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How to use this booklet

The information presented gives some of the key learning outcomes of this training course and complements these with additional information. It is not intended to provide a complete picture of EU law and regulations in this area and should be read as the training provider's interpretation of the issues affecting the development, the implementation and the maintenance of **HACCP** systems at the time of publication. **Discussion points that arose in similar courses are highlighted with blue boxes marked with an exclamation mark.**

Glossary

BTSF

The Better Training for Safer Food programme (BTSF) is a European Commission (EC) initiative that organises training in the areas of European food and feed law, plant and animal health and welfare regulations. www.ec.europa.eu/food/training_strategy and www.ec.europa.eu/eahc/food

EAHC

Based in Luxembourg, the Executive Agency for Health and Consumers (EAHC) implements the EU Health and Consumer Programmes and the BTSF initiative. Set up in 2005 as the Public Health Executive Agency, it was transformed into the EAHC in 2008. www.ec.europa.eu/eahc

EFSA

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

Contents	Page
Glossary	2
Food Safety in the EU	4
Better Training for Safer Food	4
The Approach to HACCP	5
EU Food Safety Regulations	6
The Development, Implementation and Maintenance of HACCP systems	7
<ul style="list-style-type: none">  Background to HACCP 7  Prerequisite Food Hygiene Requirements 9  Principles of HACCP 11  Principles of Auditing 17  Practical Implementation of HACCP 18  HACCP System Definitions 19 	
Contact Information	20



Food Safety in the EU

Food Safety is a key issue for the European Union. Since the launch of the White Paper on food safety in 2000, a major overhaul of food safety laws has been undertaken, based on a comprehensive food safety strategy. The central goal is to ensure a high level of protection of human health and consumers' interests in relation to food.

The EU integrated approach to food safety aims to assure a high level of food safety, animal health, animal welfare and plant health within the EU, through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. The implementation of this approach involves the development of legislative actions amongst others:

- To ensure effective control systems and evaluate compliance with EU standards in food safety and quality, animal health, animal nutrition and plant health sectors within the EU and in third countries in relation to their exports to the EU,
- To manage international relations with third countries and international organisations concerning food safety, animal health, animal welfare, animal nutrition and plant health,
- To manage relations with the European Food Safety Authority (EFSA) and ensure science-based risk management.

One way to assist in strengthening capacity in the area of food safety is through the European Union's recent initiative Better Training for Safer Food. Launched in 2005, it provides training to both European and third country officials responsible for checking that EU rules related to food, feed, animal health and welfare and plant health are properly applied.

Better Training for Safer Food

The EU integrated and global approach towards food safety requires an effective and efficient management of official control systems by competent authorities, calling for a high level of controlling competence to ensure that official controls are efficient, objective and adequate. A European dimension to training supports this approach by raising staff's capacity to perform high standards of control activities, promoting a harmonised, uniform level of service. Training is also important to exchange and spread best control practices across Europe while ensuring greater coherence, thus guaranteeing food businesses' equal treatment wherever controls are carried out.

It is essential that all involved in importing live animals, feed, food or plants are familiar with EU import requirements. The involvement of participants of third countries in training leads to better understanding of EU food laws and import procedures, therefore lowering the hurdle for third countries to place goods on the EU market. It also leads to better compliance with EU requirements, by reducing and simplifying import controls.

The main objective of the Better Training for Safer Food initiative may be summarised as follows:

- Ensuring and maintaining a high level of consumer protection and of animal health, animal welfare and plant health
- Promoting a harmonised approach to the operation of Community and national control systems
- Creating an equal playing field for all food businesses
- Enhancing trade of safe food
- Ensuring fair trade with non-EU countries and, in particular, developing countries

The Approach to HACCP

The challenges for food production in the EU have highlighted the need to develop and enforce EU law in the area of food safety. New hygiene legislation has been in force since 2006.

Since 1 January 2006, effective control of food production is the responsibility of food business operators. They have to ensure compliance with the new EU food hygiene regulations. These regulations (Regulation (EC) No 853/2004 on the hygiene of foodstuffs, Regulation (EC) No 853/2004 on the specific hygiene rules for food of animal origin and Regulation (EC) No 1831/2003 on the requirements for feed hygiene) require food and feed business operators to comply with general and specific hygiene requirements but they also require all food businesses within the EU to undergo safety management procedures.

For food operators, other than primary production producers, these procedures must be based on the principles of Hazard Analysis and Critical Control Points (**HACCP**). Legislative requirements include the implementation and maintenance of a permanent procedure or procedures based on the seven principles of **HACCP**.



HACCP is internationally recognised as the most effective means of controlling food-borne diseases and other hazards that influence food safety. It is a system of food safety assurance based on the prevention of food and feed safety problems. By identifying the critical points in the production of foodstuffs, it seeks to prevent contamination and infection, thus protecting public health.

Significant flexibility has been introduced into the legislation, so that food safety procedures can be tailored to the size and nature of the businesses.

EU Food Safety Regulations

EU food hygiene regulations focus on the need to protect public health in a way that is effective and proportional to the risk. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Food safety rules are detailed in a set of regulations setting the specific requirements for hygiene of foodstuffs and products of animal origin. Division of responsibilities within the new legislations appears clearly from the scope of these legislations.

EC Regulations for food business operators		EC Regulations for competent authorities	
852/2004	General hygiene of foodstuffs	854/2004	Specific rules for the organisation of official controls on the products of animal origin intended for human consumption
853/2004	Specific hygiene rules for products of animal origin	882/2004	Official controls to ensure the verification of compliance with feed and food law, animal health and welfare regulations

Table 1: Overview of EC Regulations setting specific requirements for hygiene of foodstuffs and products of animal origin for food business operators and competent authorities

In particular, specific requirements are laid down by Regulation (EC) No 852/2004 whereby food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations must put in place, implement and maintain procedures based on **HACCP** principles.

Regulations (EC) No 854/2004 and (EC) No 882/2004 lay down specific rules to organise controls and to ensure the verification of compliance of the implementation and maintenance of the **HACCP** system in food businesses.

This means that officials checking compliance – in the EU and beyond – should have broad expertise in food safety and be able to ensure compliance with EU regulations.



The Development, Implementation and Maintenance of HACCP Systems

Two types of training courses on **HACCP** were organised within the BTSF initiative activities.

The overall aims of COURSE TYPE 1 are:

- To enable competent authority personnel to obtain a thorough understanding of development, implementation and maintenance of **HACCP** systems,
- To provide guidance and information, on the pre-requisites and the seven principles of **HACCP**,
- To cover the audit of good hygiene practices and procedures, including procedures based on **HACCP** principles and implemented by food businesses operators.

The overall aims of COURSE TYPE 2 are:

- To enable competent authority personnel to verify implementation of **HACCP** procedures by food and feed operators and to obtain evidence of their compliance with food and feed hygiene requirements, and,
- To provide competent authority personnel with the ability to conduct detailed audits.

The core reference text for the courses is the European Commission Health & Consumer Protection Directorate General Guidance Document: "Implementation of procedures based on the **HACCP** principles and facilitation of the implementation of the **HACCP** principles in certain food businesses." This guidance document was developed by the European Commission and agreed by 25 of the Member States in the Standing Committee on the Food Chain and Animal Health (SCFCAH).

Background to HACCP

HACCP was originally developed in the 1960s by the Pillsbury Corporation (USA), United States Army Laboratories at Natick and the National Aeronautics and Space Administration (NASA) in a collaborative effort to ensure safe food for astronauts. Since then it has been updated and amended to reflect what is recognised as **HACCP** today.

The international standard for **HACCP** was developed by the *Codex Alimentarius*, an international body administered by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). The *Codex Alimentarius* Commission was created in 1963 implementing the Joint FAO/WHO Food Standards Programme and developing food standards, guidelines and related texts, such as codes of practice. Over 180 countries are members of the *Codex* and the primary aim is the development of harmonised food standards which ensure the protection of consumer health and fair practices in food trade.

Directive No 93/43/EC and a number of EC Regulations (see **Table 1**) outline the general principles and specific rules for the hygienic production of foodstuffs throughout the food chain. All food businesses (after primary production) are required to develop, implement and maintain procedures based on the seven **HACCP** principles (see section on "*Principles of HACCP*").

The seven **HACCP** principles, in the framework of EU legislation, are useful to ensure control of food safety and implementation of hygiene measures. Following **HACCP** principles should prevent problems before they arise, by introducing food safety controls at a series of validated steps.

Food safety controls, such as those that follow **HACCP** principles, should be applied at all stages of food production and implementation should be guided by scientific evidence of risks to public health. Enhancing food safety through implementation of **HACCP** can provide additional benefits, such as promotion of international trade.

Benefits	Limitations
HACCP is a proactive approach to food safety which is internationally recognised	HACCP relies upon having effective prerequisite food control in place
A well maintained system that follows HACCP principles, ensures that a FBO is fulfilling EU regulations on food safety	Prerequisite food control requires commitment from the FBO to food safety systems in general
HACCP -guided systems ensure that FBO staff work consistently as a team, driven by food safety	<p>HACCP can be viewed as too difficult to understand, it requires resources for FBOs</p> <p>Management, commitment and disciplined staff are required</p>

Table 2: The benefits and limitations to a food/feed business operator (FBO) of introducing HACCP-based food safety systems



International food safety systems

Under EU legislation, there is no legal requirement for **HACCP** certification. However, this may be required for marketing and commercial reasons and ensures that FBOs have a system that has been fully checked by a **HACCP** expert. The only assessment provided under EU law is an assessment of the competent authorities in Member States, in the context of their normal official control duties.

Other quality assurance schemes that many FBOs may use as a management structure for food safety include EN ISO 9000 and 22000 (www.iso.org/home.html) or the International Food Standard (IFS) (www.ifs.certificatetion.com/).

Procedures based on **HACCP** would be incorporated into the structure of these systems. Although EU legislation does not contain a requirement for assessment of these systems by competent authorities, an awareness of their existence is necessary as it may affect the audit approach and the quantity of information available for assessment. EU regulations present the requirements for FBO and competent authorities (see **Table 1**).

Prerequisite Food Hygiene Requirements

HACCP systems are not a replacement for other food hygiene requirements, but form a part of the package of food hygiene measures that ensure safe food.

Prerequisite food hygiene requirements provide the foundation for effective **HACCP** implementation and should be in place before a **HACCP**-based procedure is established. Typical areas that are controlled by prerequisites are:

Personnel issues	Premises	Product
Health of staff	Infrastructural and equipment requirements	Requirements for raw materials
Personal hygiene	Food waste handling	Safe handling of food
Training	Pest control procedures Sanitation procedures Water quality	Maintenance of the cold chain

Table 3: Typical area of food production controlled by food hygiene prerequisites

Article 5 of Regulation (EC) No 853/2004 on the hygiene of foodstuffs requires FBO operators to put in place, implement and maintain a permanent procedure based on **HACCP** principles. The Directorate-General Health and Consumer Protection (DG SANCO) has established a guidance document on the implementation of procedures based on **HACCP** principles and facilitation of the implementation of **HACCP** principles in certain food businesses for information purposes. This document is mainly directed at food business operators and competent authorities, aiming to give guidance on the implementation of procedures based on the **HACCP** principles and on flexibility with regard to the implementation of such procedures, especially in small businesses (http://ec.europa.eu/food/food/foodsafety/hygienelegislation/guidance_doc_HACCP_en.pdf).

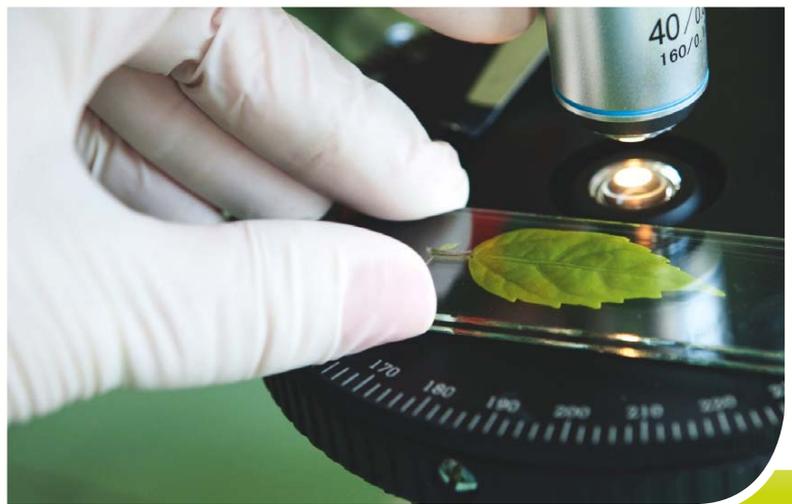
National Guides to Good Practice

Guides to good practice have been developed by industries in many Member States to assist certain FBOs in implementing prerequisite food hygiene requirements and develop procedures based on HACCP principles. A Register of National Guides to Good Hygiene Practice lists the guides. They cover many different sectors and national languages, making them very useful for use in an FBO with a multinational workforce.

http://ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf

The guides are usually a combination of good hygienic practices and HACCP-based elements. They include guidelines for the practical implementation of prerequisite requirements, a hazard analysis, predetermined CCP and the need for documentation and records.

Some of these guides are generic, some more specific. However, there is always a need for consideration of additional hazards and CCP/control methods for each FBO and each food production method.





Principles of HACCP

HACCP-based food safety systems are recognised as the most effective tool for helping food and feed businesses to improve safety standards. They aim to identify hazards and prevent them from contaminating food and feed. Effective control of production enables the verification of compliance with safety requirements.

Guidance for the application of a food safety system, based on **HACCP** principles for a FBO, can be found in the EC guidance document which has been adapted from the *Codex Alimentarius* documents (www.codexalimentarius.net/download/standards/23/cxp-001e.pdf).

The recommended approach to HACCP consists of **seven principles** which should be established.

The seven principles of HACCP

1. Hazard Analysis
2. Identification of Critical Control Points (CCPs)
3. Critical limits at each CCP
4. Monitoring procedures at CCP
5. Corrective actions
6. Verification
7. Documentation and Record keeping



Table 4: The seven principles of HACCP

1. Hazard Analysis

A food safety hazard is any biological, chemical or physical property that may make a food unsafe for human consumption. Identifying food safety hazards involves not only identifying the hazard but considers the necessary measures to control the hazard. A more detailed consideration of this process is given in Table 5. This is particularly applicable to large scale FBOs, but is harder to achieve with small FBOs.

Hazard Analysis	Steps
1. Assemble a HACCP team	Ensure that a management commitment is in place and the scope of the study is clearly laid out. Specialist assistance may be required, e.g. microbiologists and site engineers
2. Describe the products	Including relevant safety information
3. Identify intended use	Including large groups for which the product is intended
4. Construct flow diagram	Description of the manufacturing process with sufficient technical data
5. On site confirmation of the flow diagram	The multidisciplinary team should confirm the diagram on site in operating hours and any deviations should be incorporated
6. Conduct a hazard analysis and list all potential hazards	List all potential biological, chemical or physical hazards as defined in Article 3 (14) of Regulation (EC) No 178/2002
7. Consider control measures	Control measures will prevent hazards, eliminate them or reduce them to acceptable levels. More than one control measure may be required or more than one hazard may be controlled by one control measure

Table 5: Key stages in Hazard Analysis

Identification of hazards

Clear identification of hazards is central to a successful **HACCP**. An exact description of the hazard (e.g. metal, *Salmonella*, nut allergen) and whether it is contaminating, growing or surviving a processing step enables clear controls and critical limits to be determined.

When a hazard is not clearly defined it is difficult for FBOs to identify the appropriate control measure and difficult for the competent authority to assess whether food safety is sufficiently controlled.

2. Identification of Critical Control Points (CCPs)

A Critical Control Point (CCP) is a step or procedure in a food process at which a control can be applied with the resulting elimination of a food hazard or reduction to an acceptable level. The identification of a critical point for the control of a hazard requires a logical approach.

Determination of CCPs can be helped by the **HACCP** team's professional knowledge. A tool that is widely used by many **HACCP** teams is the *Codex* decision tree. This consists of four questions to help the **HACCP** team in the determination of CCPs. However, when the *Codex* decision tree was developed, **HACCP** plans did not include the prerequisite food hygiene requirements and therefore the decision tree often exposes too many CCPs. A hazard that is fully controlled by the prerequisite requirements should be recorded as such, thus rendering the *Codex* decision tree unnecessary.

Other decision trees are available that do take account of prerequisite requirements; similarly there are sector-specific decision trees for sectors where it has been recognised that the *Codex* decision tree may not be appropriate, e.g. slaughterhouses.



The identification of critical control points means that the **HACCP** team should ensure that appropriate control measures are implemented and that the monitoring systems are established for each critical point.

3. Critical Limits at each CCP

Critical limits at CCP do not always require a fixed numerical value. Some monitoring procedures rely on a visual observation, for example, the change in physical properties (e.g. colour) of food during processing. Other parameters include temperature, time, pH, additive level, etc. In both observation and measurable parameters, the emphasis is on demonstrating that the critical point is under control.

Critical limits at CCP can be established on the basis of:

- Experience (best practice)
- International documents (e.g. canning of food, pasteurisation of liquids where *Codex Alimentarius* standards exist)
- A guide to good practice

4. Monitoring Procedures at CCP

Monitoring is necessary to ensure that the production process is under the appropriate level of control at each CCP. For example, a computer system could monitor the minimum temperature required to cook a meat pie.

Observations on measurements can be made continuously or intermittently; they must be able to detect loss of control at critical points and provide information in time to correct such a fault. Records should be kept detailing who is monitoring and when and how monitoring is performed.



Monitoring procedures are sometimes confused with control measures

Control measures are activities that will eliminate or stop a hazard occurring. Clear identification of hazards helps and many hazards are controlled by the prerequisite requirements for good hygiene.

A monitoring procedure will check that controls are operating correctly. This procedure will check, at one precise moment in time that the critical limits have not been exceeded.

Monitoring procedures are practical checks carried out by one designated person/role within a FBO; control measures tend to be policies and procedures applicable to the whole company.

5. Corrective Actions

A corrective action may need to be taken when monitoring indicates that there has been a deviation from an established corrective limit. Corrective actions ensure that contaminated products, potentially detrimental to public health, do not reach the consumer. For example, if meat pies are not cooked at the correct temperature, the computer would sound an alarm, activating destruction of that particular batch of pies.

Corrective action protocols should include:

- Proper identification of the person responsible for implementing the corrective action
- Description of action required to correct the observed deviation
- Action to be taken to deal with contaminated products
- Written record of actions taken (date, time, action, etc.)

6. Verification

Verification procedures ensure that the **HACCP** plan is fulfilling its purpose – the production of a safe product. Procedures include the review of **HACCP** plans, CCP records, critical limits and microbiological sampling and analysis.



Validation and verification of a HACCP plan

There are three aspects to the verification of a **HACCP** plan: validation, verification and review. Some confusion may arise as to the differences between validation and verification and the role of the competent authority in these steps.

Validation of **HACCP** procedures is the responsibility of the FBO. They must gather sufficient evidence to show that the **HACCP** plan is capable of producing a safe product. This may be achieved by gathering scientific evidence through trials and testing. Although it is not the role of the competent authority to validate **HACCP** procedures, a review of the validation evidence provided by the FBO will form an important part of the authority's assessment. This should not be considered as a formal approval of the procedures.

Verification of **HACCP** procedures is also the responsibility of the FBO, there can be input from third party auditors and the competent authorities. Verification ensures that the FBO is conforming to the stated **HACCP** procedures, following the plan described in the written documentation. Auditing is a major part of verification, providing evidence of conformity. The FBO may use other methods such as scheduled testing and analysis.

7. Documentation and Record Keeping

Documentation and record keeping is required by HACCP regulation. Necessary documents include a hazard analysis and written HACCP plan and records documenting the monitoring of CCP, critical points, verification procedures and the handling of processing deviations.

Documentation within HACCP

The required level of **HACCP** documentation for different FBOs will vary according to the size and level of complexity of the operation. The size of operation alone should not affect the documentation required as this must be linked to the level of risk in the production process.

In some cases, for example, where visual monitoring occurs, it may be appropriate to limit the amount of recording documentation to measurements of non-compliance only, known as "recording by exception".

In general, **HACCP**-related record keeping should be based around what is necessary to ensure food safety. Documents and records should be kept for a sufficient time to allow the competent authority to audit the **HACCP** system.

Principles of Auditing

Regulation 882/2004 defines an audit as a “systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives”.

Audits can be performed internally, externally or by a third party. The purposes of a competent authority audit of a **HACCP** system is to obtain evidence that **HACCP** principles are effectively applied, the **HACCP** plan and prerequisites are correctly implemented and that the system has been maintained.

The approach to the audit should be based on the internationally agreed standard format as described in ISO19011, Guidelines for Quality and Environmental Management Systems Auditing (www.iso14000-iso14001-environmental-management.com/iso-19011.html).

The main stages of an audit are:

Stages	Steps
Audit initiation	
Document review	
Audit preparation	
Onsite auditing activities	<ul style="list-style-type: none"> Opening meeting Document review Audit process Procedures/practices/records Recording non-compliance Closing meeting
Report Preparation	Issue of report
	Closure of non compliance

Table 6: Key stages in preparing an HACCP audit

Inspection and audit

Traditionally the competent authorities have carried out inspections of premises, which concentrate on the hygiene aspects of an FBO, looking at the production process of the premises, the people and the practices (typically, the prerequisite food hygiene requirements).

An audit will also look at these aspects but should follow the structured approach as outlined above. The auditor should examine the underlying systems included in the documentation, followed by an assessment of the practical implementation of the documented approach before any conclusions are drawn.

Audit approach to small operations

The competent authority will have to audit many different operations that have a varying level of complexity, both in their systems and paperwork. In a large, complex FBO, a greater proportion of time would be spent with the documentation. In contrast, when a small amount of paperwork is involved in a less complex operation, more time may be allocated to observing and questioning staff and their practices. Regardless, the same basic approach to auditing should be taken. The ultimate aim of such audits is to establish that the FBO is able to distribute safe food or feed.

Practical Implementation of HACCP

Senior management commitment is needed to ensure that a FBO can put in place, implement and maintain **HACCP**-based procedures, which are required under EU legislation.

There are different approaches that a company can take to develop a **HACCP** plan. A linear approach is suitable for simple operations with few products, a modular approach is suitable for more complex operations where there are many products, but the same basic operations are used.

Generic **HACCP** may be sector-, company-specific or national. They are useful as a starting point for some FBOs that may struggle to meet a **HACCP** plan. FBO should be encouraged to develop **HACCP**-based procedures in house by adapting the generic plan to meet their specific requirements.



HACCP System Definitions

Control Measures

Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective Action

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

Critical Control Point (CCP)

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit

A criterion which separates acceptability from unacceptability.

Flow Diagram

A schematic representation of the sequences of steps used in the production of a particular food item.

Hazard

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

Hazard Analysis

The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety, therefore addressed to assess whether a CCP is under control.

Monitor

The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Validation

Obtaining evidence that the elements of the HACCP are effective.

Verification

The application of methods; procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Contact

Better Training for Safer Food

For information on training courses and to find the BTSF training booklets, please visit:

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National Contact Points

BTSF National Contact Points (NCP) have been designated for EU Member States and certain other countries. NCPs are involved in coordination of the BTSF initiative on a national level. They provide country-specific information on training courses to contractors and propose participants.

www.ec.europa.eu/food/training_strategy/participants/ms_contact_points_en.htm

HACCP Information

http://ec.europa.eu/food/food/controls/index_en.htm

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http://ec.europa.eu/food/food/index_en.htm

This booklet does not necessarily represent the view of the Commission Services.

