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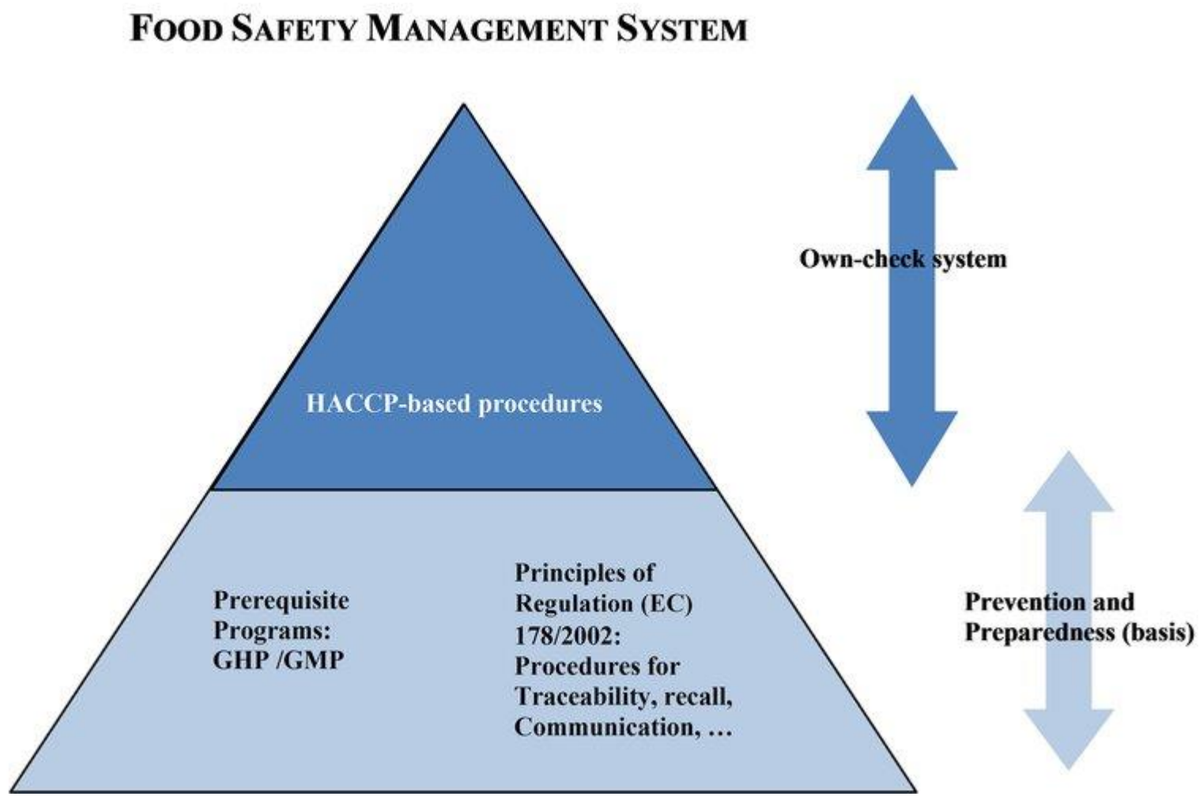
# HACCP System and Implementation

# Elements of a Food Safety Management System (FSMS)

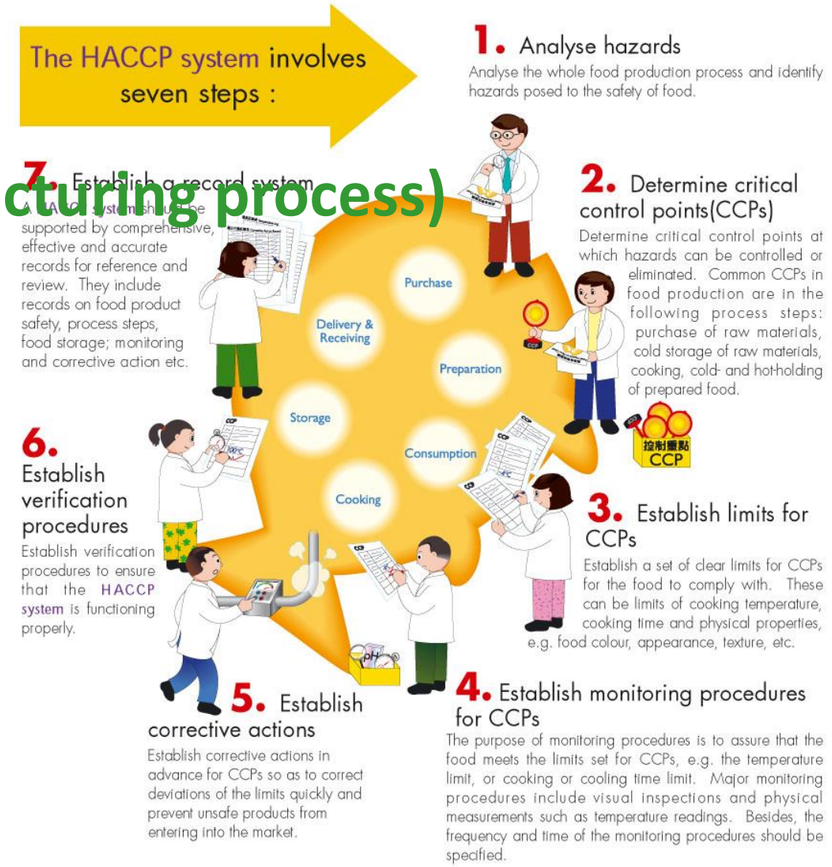



- Prior to application of the HACCP-based procedures to any business, the food business operator (FBO) should have implemented the prerequisite programs. Compliance with the procedures of regulations are the prevention and preparedness pillars of each FSMS and are needed to develop HACCP-based procedures.

# Preliminary activities

Preliminary activities prior to the implementation of the HACCP plan are as follows:

- **Assembly of a multidisciplinary HACCP team**
- **Description of the product(s) at the end of process (called hereafter ‘end product’)**
- **Identification of intended use**
- **Construction of a flow diagram (description of manufacturing process)**
- **On-site confirmation of flow diagram**



## • Assembly of a multidisciplinary HACCP team

This team, which involves all parts of the food business concerned with the product, should include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption and the associated potential hazards and should also involve as much as possible the higher management levels. The team should get the full support of the management who should consider itself owner of the HACCP plan and overall FSMS.

Where necessary, the team should be assisted by specialists who will help it to solve its difficulties as regards assessment and control of critical points.


## • Assembly of a multidisciplinary HACCP team

The team may include specialists and technicians:

- who understand the biological, chemical or physical hazards connected with a particular product group,
- who have responsibility for, or are closely involved with, the technical process of manufacturing the product under study,
- who have a working knowledge of the hygiene and operation of the process plant and equipment,
- any other person with specialist knowledge of. microbiology, hygiene or food technology.

One person may fulfil several or all of these roles, provided all relevant information is available to the team and is used to ensure that the system developed is reliable. Where expertise is not available in the establishment, advice should be obtained from other sources (consultancy, guides of good hygiene practices, etc. not excluding other companies of the same group (at sectorial or association level) where expertise is available).

- **Description of the product(s) at the end of process (called hereafter ‘end product’)**

A full description of the end product should be drawn up, including relevant safety information such as:

- Origin of ingredients/raw materials, which may help identify certain hazards,
- composition (e.g. raw materials, ingredients, additives, possible allergens etc.),
- structure and physico-chemical characteristics (e.g. solid, liquid, gel, emulsion, moisture content, pH, water activity, etc.),
- processing (e.g. heating, freezing, drying, salting, smoking, etc. and to what extent),
- packaging (e.g. hermetic, vacuum, modified atmosphere) and labelling,
- storage and distribution conditions, including transport and handling
- required shelf life (e.g. ‘use by date’ or ‘best before date’),
- instructions for use,
- any microbiological or chemical criteria applicable.

DRIED WHEY PROTEIN CONCENTRATE

**PRODUCT DESCRIPTION:** Dried Whey Protein Concentrate 34 % and 80 %.

**CHEMICAL CHARACTERISTICS:**

| CHEMICAL TESTS* | LIMITS | | TEST METHODS 34 % & 80 % |
|---|---|---|---|
| | 34 % | 80 % | |
| Protein (%) | >34.0 | 81.0–89.9 (dry basic) | LST ISO 8968-3 / calculation |
| Moisture (%) | <4.0 | <5.0 | LST EN ISO 5537 / ISO 5550 |
| Fat (%) | <4.0 | <7.5 | LST EN ISO 1736 / ISO 5543 |
| Lactose (%) | >50.0 | <12.0 | Polarimetric method / ISO 5548 |
| pH | 6.3-6.6 | <6.5 | Electrometric / ISO 5546 |
| Nonsolubility index sediments (ml) | <0.3 | <0.3 | LST ISO 8156 |
| Burnt particles | Disc A–B | Disc A–B | ADPI method |
| Ash (%) | 4.3-6.3 | <3.5 | ADPI method/ ISO 5545 (600 °C) |
| Inhibitory substances (Ultra) | absent | absent | DELVOTEST SP–NT |
| Heavy metals (mg/kg) | In compliance with EU Regulation (EC)1881/2006 | | LST EN 15763 |
| Pesticide residues | In compliance with EU Regulation 396/2005 | | LST EN 1528 / 1-4 |
| Aflatoxin M1 (mg/kg) | In compliance with EU Regulation (EC)1881/2006 | | |
| Toxical elements | In compliance with EU Regulation (EC)1881/2006 | | |
| Radioactivity | <370 No EU regulation | | SDP 5.4.4. R.01, SDP 5.4.4. R.02 |
| Cesio- 137, Bq/kg | | | |
| Stronci- 90, Bq/kg | | | |
| Chloramphenicol (µg/kg) | not detected (means that a level of Cloramphenicol is less than a limit of detection for used Method (0.2µg/kg for milk powders & milk products) | | LC–MS / MS AFSSA 200211 |

*Values of pesticides, toxins, radionuclids, heavy metals and other chemical tests are in accordance with EU legal requirements.

**MICROBIOLOGICAL CHARACTERISTICS:**

| MICROBIOLOGICAL TESTS* | LIMITS | | TEST METHODS 34 % & 80 % |
|---|---|---|---|
| | 34 % | 80 % | |
| Total plate count (TPC) (cfu/g) | $\leq 5x10^4$ | $\leq 5x10^4$ | LST EN ISO 4833 |
| Coliforms (g) | ≤10 | ≤10 | LST ISO 4831 |
| Listeria monocytogenes (25 g) | absent | absent | LST EN ISO 11290-1 |
| Coagulase- Positive Staphylococcus (cfu/g) | $\leq 1.0x10^2$ | ≤10 | LST EN ISO 6888-1 |
| Salmonella (25 g) | absent | absent | LST EN ISO 6579 |
| Enterobacteria (cfu/g) | ≤10 | ≤10 | ISO 21528-2 |
| Yeast & Moulds, (cfu/g) | $\leq 1.0x10^2$ | $\leq 1.0x10^2$ | LST ISO 6611 |

*in accordance with EU legal requirements.

**PHYSICAL DESCRIPTION:**

| | |
|---|---|
| COLOR | White, light creamy |
| BODY & TEXTURE | Dry powder with small lumps that are easily destroyed |
| AROMA & TASTE | Specific of pasteurized milk, without any off taste, soft smell and taste |

**INGREDIENTS:** Liquid whey protein concentrate

**PACKAGING:** 34% – Multi-layer paper bags with p.e. inner bag of 25 kg, 900 kg, 1000 kg.
80% – Multi-layer paper bags with p.e. inner bag of 20 kg, 15 kg.

**TEMPERATURE AT TRANSPORT AND STORAGE:** At a temperature not over +20 °C. Relative humidity not higher than 85 %.

**SHELF LIFE:** 18 months.

| NUTRITIONAL VALUE / 100 g | 34 % | 80 % |
|---|---|---|
| Energy | 372 kcal / 1576 kJ | 365 kcal / 1545 kJ |
| Protein | 34.0g | 79.0g |
| Carbohydrates | 50.0g | 8.0g |
| of which sugars | 50.0g | 8.0g |
| Fat | 4.0g | 6.0g |
| of which saturated fatty acids | 1.5g | 3.6g |
| Salt (due to the presence of naturally occurring sodium) | 1.1g | 0.1g |

**TRACEABILITY:** Information on label: XX XX X X XX (production number, day of production, number of batch supervisor, year of production, month of production).

**INFORMATION ON THE LABEL OF BAG:** Company name and address / Company's Ref. number / Name of producer / Net weight / Gross weight / Production date / Lot number / Storage conditions / Expiry date / Nutrition value.

**INFORMATION ON THE LABEL OF PALLET:** Company name and address / Company's Ref. Number / Name of producer / Net weight / Gross weight / Number of units / Production date / Lot number / Storage conditions / Expiry date / Number of pallet.

**ALLERGEN INFORMATION (2003/89/EC):** Product contains the following Allergens: Milk lactose.

GMO **STATUS (2003/1829/EC&2003/1830/EC):** Product is made without using genetic procedures & doesn't contain any GMO

**CERTIFICATIONS:** ISO 2000 / ISO 9001 / ISO 14001 / SA8000 / Kosher / HALAL.

- **Identification of intended use**

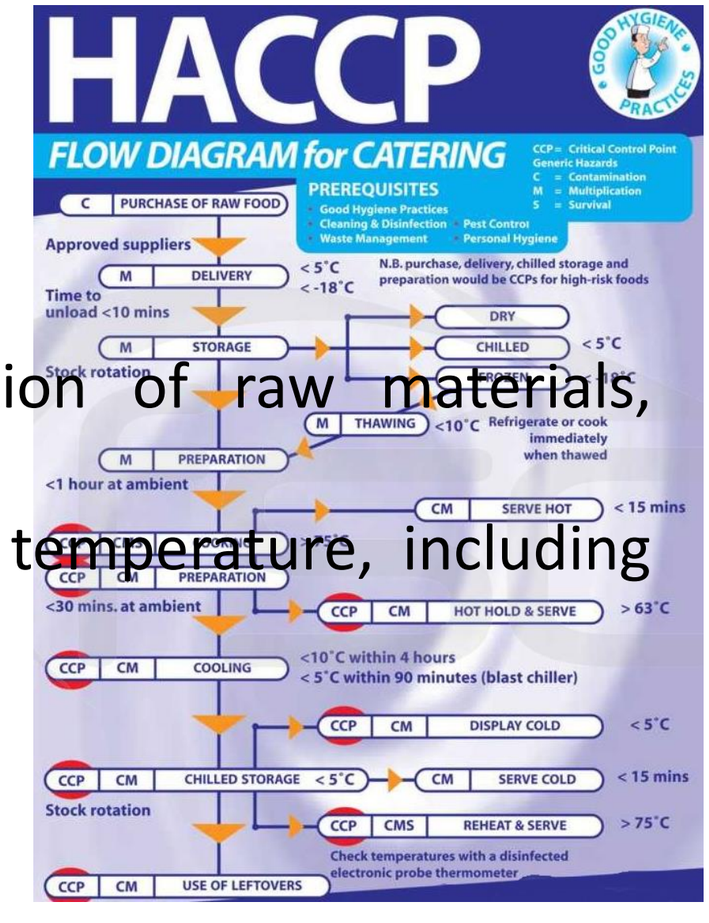
The HACCP team should also define the normal or expected use of the product by the customer and by the consumer target groups for which the product is intended. In specific cases, the suitability of the product for particular groups of consumers, such as institutional caterers, travellers, etc. and for vulnerable groups of the population may have to be considered.

## • Construction of a flow diagram (description of manufacturing process)

Whatever format is chosen, all steps involved in the process should be studied in sequence and presented in a detailed flow diagram.
All processes (from receiving the raw materials to placing the end product on the market) including delays during or between steps, should be mentioned together with sufficient technical data that is relevant for food safety, such as temperature and the duration of heat treatment.

Types of data may include but are not limited to:

- plan of working premises and ancillary premises,
- equipment layout and characteristics,
- sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps),
- technical parameters of operations (in particular time and temperature, including delays),
- flow of products (including potential cross-contamination),
- segregation of clean and dirty areas (or high/low risk areas).



# • On-site confirmation of flow diagram

After the flow diagram has been drawn up, the HACCP team should confirm it on site during operating hours. Any observed deviation must result in an amendment of the original flow diagram to make it accurate.

# Preliminary activities

In small enterprises, HACCP/FSMS activities might be carried out by one person who is (temporarily or regularly) assisted by external expertise. Where external expertise is used, it is essential that there is sufficient ownership of the FSMS by the food business itself. FBOs using this route should make sure that they know how the system works and how it is being applied to their business and that their staff is suitably trained to ensure effective implementation.

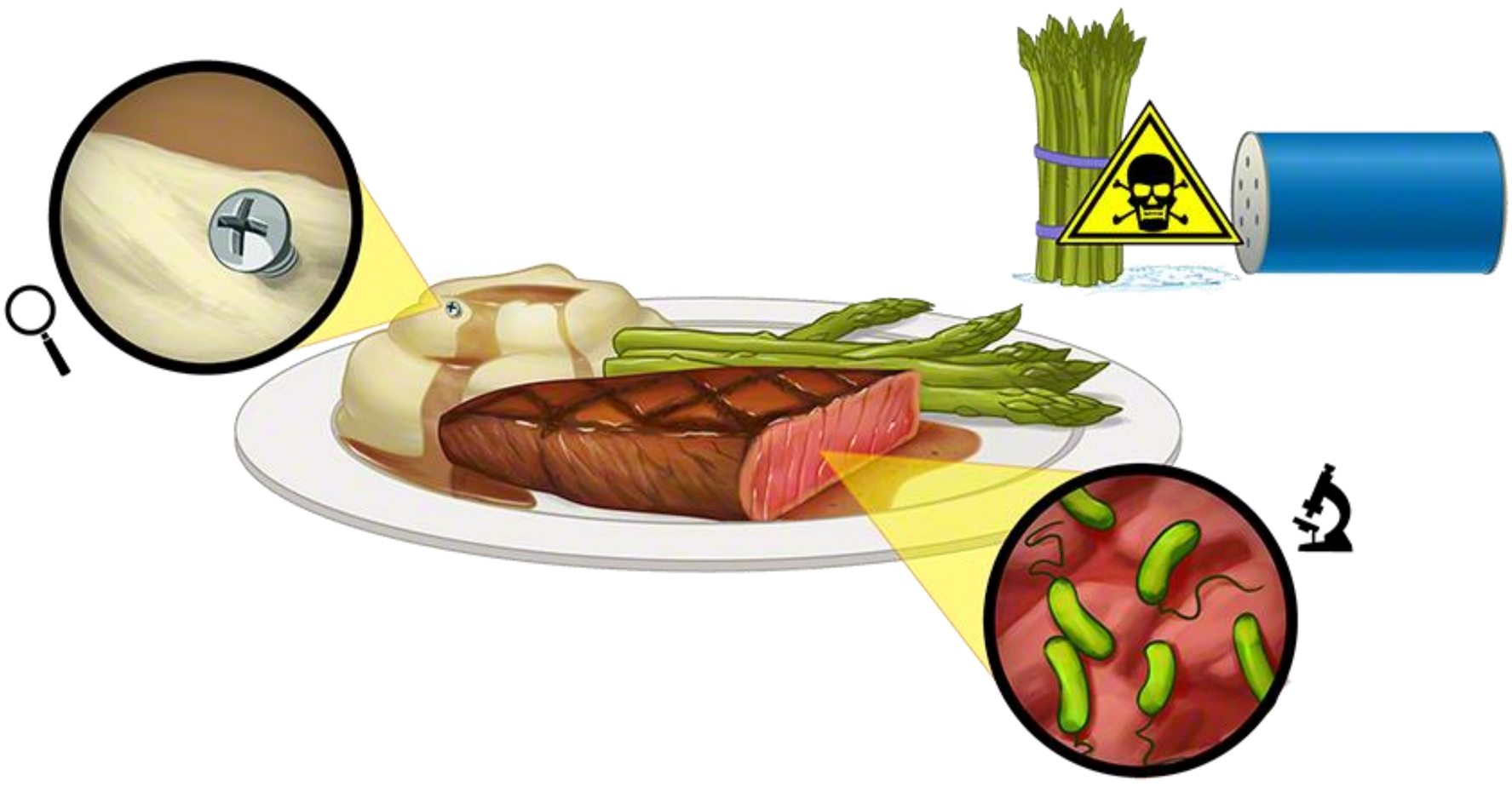
When there is no processing or other manufacturing (e.g. cutting, wrapping), the description of the product can be limited to information available on the label (prepacked food) or other information on the food extracted from reliable websites. Unless specifically targeted to certain consumers (e.g. baby food), the intended use can be considered as consumption by the general public.

The nature of the business will define the complexity of the required flow diagram, which might be very simple in certain businesses.

# Hazard analysis (Principle 1)

The steps in creating the risk analysis are as follows:

- **Listing of relevant hazards**
- **Control measures**



## • Listing of relevant hazards

A hazard is a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect (2).

All major potential biological, chemical or physical hazards that may be reasonably expected to occur at each process step (including production, acquisition, storage, transport and handling of raw materials and ingredients and delays during manufacture) should be identified and listed. It may be useful to consult external source of information (e.g. the Rapid Alert System for Food and Feed).

The HACCP team should next conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food (end product).

## • Listing of relevant hazards

In conducting the hazard analysis, the following should be:

- the likelihood of occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- the survival or multiplication of pathogenic micro-organisms and unacceptable generation of chemicals in intermediate products, end products, production line or line environment;
- the production or persistence in foods of toxins or other undesirable products of microbial metabolism, chemicals or physical agents or allergens;
- the contamination (or recontamination), of a biological (micro-organisms, parasites), chemical or physical nature, of raw materials, intermediate products or end products.

# • Listing of relevant hazards

**Example of a hazard analysis – (semi-quantitative) risk evaluation procedure**

Based on: FAO/WHO: Risk characterisation of microbiological hazards in food and on Quality management systems in the food industry.

The risk level is defined by the severity or the effect of the hazard in relation to the probability in which the hazard can occur in the end product if the considered (specific) control measures are not present or are failing – taking into consideration the next steps in the process where an elimination or reduction to an acceptable level is possible, and taking into consideration the already correctly implemented PRPs.

**P = Probability=** the probability that the hazard is occurring in the end product, if the considered specific control measures are not present or are failing – taking into consideration the next steps in the process where an elimination or reduction to an acceptable level is possible and taking into consideration the already correctly implemented PRPs.

**E = Effect=** the effect or the severity of the hazard related to human health.

# • Listing of relevant hazards

**Example of a hazard analysis – (semi-quantitative) risk evaluation procedure**

RISK LEVEL (R = P x E): SCALE 1 TO 7

| | | | | | | |
|---|---|---|---|---|---|---|
| **PROBABILITY** | High | 4 | 4 | 5 | 6 | 7 |
| | Real | 3 | 3 | 4 | 5 | 6 |
| | Small | 2 | 2 | 3 | 4 | 5 |
| | Very small | 1 | 1 | 2 | 3 | 4 |
| | | | 1 | 2 | 3 | 4 |
| | | | Limited | Moderate | Serious | Very serious |
| | | | **EFFECT** | | | |

# • Listing of relevant hazards

**PROBABILITY**

**1 = very small**

- Theoretical chance – the hazard never occurred before;
- There is a next step in the production process which will eliminate or reduce the hazard to an acceptable level (e.g. pasteurization, fermentation);
- The control measure or the hazard are of such a nature that when the control measure is failing, no production is possible any more or no useful end products are produced (e.g. too high a concentration of colorants as additives);
- It is a very limited and/or local contamination.

**2 = small**

- The probability that due to failing or absence of the PRPs the hazard will occur in the end product is very limited;
- The control measures for the hazard are of a general nature (PRPs) and these are well implemented in practice;

**3 = real**

- Failing or lacking of the specific control measure does not result in the systematic presence of the hazard in the end product but the hazard can be present in a certain percentage of the end product in the associated batch.

**4 = high**

- Failure or absence of the specific control measure will result in a systematic error, there is a high probability that the hazard is present in all end products of the associated batch.

# • Listing of relevant hazards

**EFFECT (or severity)**

**1 = limited**

- There is no problem for the consumer related to food safety (nature of hazard e.g. paper, soft plastic, large size foreign materials);
- he hazard can never reach a dangerous concentration (e.g. colorants, S. aureus in a frozen food where multiplication to higher counts is highly unlikely or cannot happen because of storage conditions and cooking).

**2 = moderate**

- No serious injuries and/or symptoms or only when exposed to an extremely high concentration during a long period of time;
- A temporary but clear effect on health (e.g. small pieces).

**3 = serious**

- A clear effect on health with short-term or long-term symptoms which results rarely in mortality (e.g. gastro-enteritis);
- The hazard has a long-term effect; the maximal dose is not known (e.g. dioxins, residues of pesticides, mycotoxins, …).

**4 = very serious**

- The consumer group belongs to a risk category and the hazard can result in mortality;
- The hazard results in serious symptoms from which mortality may result;
- Permanent injuries.

# • Listing of relevant hazards

**DETERMINATION OF CCPs and oPRPs when considered relevant**

**Risk levels 1 & 2:** no specific actions, control covered by PRPs.
**Risk levels 3 & 4:** possible oPRPs. Additional question to be answered by the HACCP team: Is the general control measure(s) as described in the Pre Requisite Program's (PRPs) enough as monitoring for the identified risk?

- If YES: PRP
- If NO: oPRP

**Risk levels 5, 6 and 7:** CCP or if no measurable critical limit exists this may be an oPRP (e.g. controlling an allergen).

CCPs are the points in a production process where a continuous/batch wise control via a specific control measure is required to eliminate or to reduce the hazard to an acceptable level. The monitoring must be demonstrable and a record must be kept. In the case of a breach of the critical limit, a corrective action towards product and process is necessary.

## • Listing of relevant hazards

oPRPs are points in the production process with a smaller food safety risk or where no measurable limits exists. These points can be controlled via more elaborated general basic control measures belonging to the PRPs e.g. more frequent control, recording etc. Due to a regular control and adaptation of the process/product requirements these risks can be considered as controlled. An immediate corrective action towards the product is not required. Examples of oPRPs include:

- Raw material reception → sampling plan for verification of safety/hygiene approaches by suppliers.
- Cross-contamination between batches for allergens → intermediate cleaning and check by adenosine triphosphate (ATP) measurements.
- Contamination of food in high care area → mouth masks and extra protection of personnel, weekly hand hygiene check.

# • Listing of relevant hazards

**ALTERNATIVE/SIMPLIFIED APPROACH**

The same approach is used in a simpler way, for example:

- Risk levels 1 to 5 instead of 1 to 7 by using 3 instead of 4 subdivisions of the probability and effect (subdivisions 3 and 4 are merged).
- oPRPs are not included when identifying ‘intermediate’ risk, but only differentiation is made between hazards that can be controlled by PRPs only and those requiring a CCP.

## • Control measures

The FBO should consider and describe what control measures, if any, can be applied for each hazard.

Control measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or likelihood of occurrence to acceptable levels. Many preventive control measures are part of PRPs and are intended to avoid contamination from the production environment (e.g. personnel, pest, water, maintenance). Other control measures aiming at reduction or elimination of hazards are more specifically linked to particular production process e.g. pasteurization, fermentation and may result in the establishment of CCPs or operational PRPs.

More than one control measure may be required to control an identified hazard e.g. pasteurization controlled by time, temperature and flow rate of the fluid and more than one hazard may be controlled by one control measure e.g. pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of several pathogenic micro-organisms such as *Salmonella* and *Listeria*.

Control measures should be validated.

Control measures should be supported by detailed procedures and specifications to ensure their effective implementation.

# Identification of critical control points (CCP) (Principle 2)

The identification of a CCP requires a logical approach. Such an approach can be facilitated by the use of a decision tree or other methods, according to the knowledge and experience of the HACCP team.

The identification of CCPs has two consequences for the HACCP team which should then:

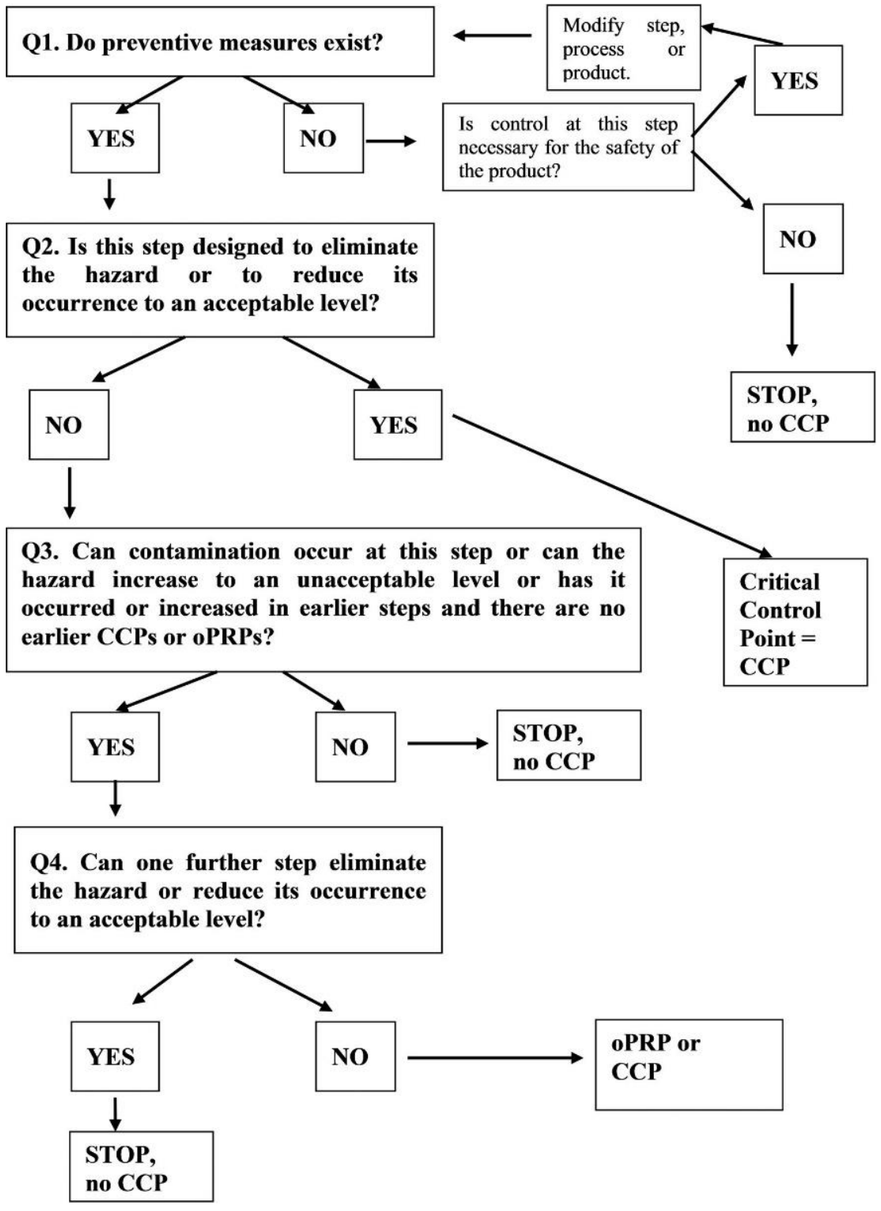
- ensure that appropriate control measures are effectively designed and implemented. In particular, if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step, or at any other further on in the production process, then the product or process should be modified at that step or at an earlier or later stage, to include a control measure;
- establish and implement a monitoring system at each CCP.

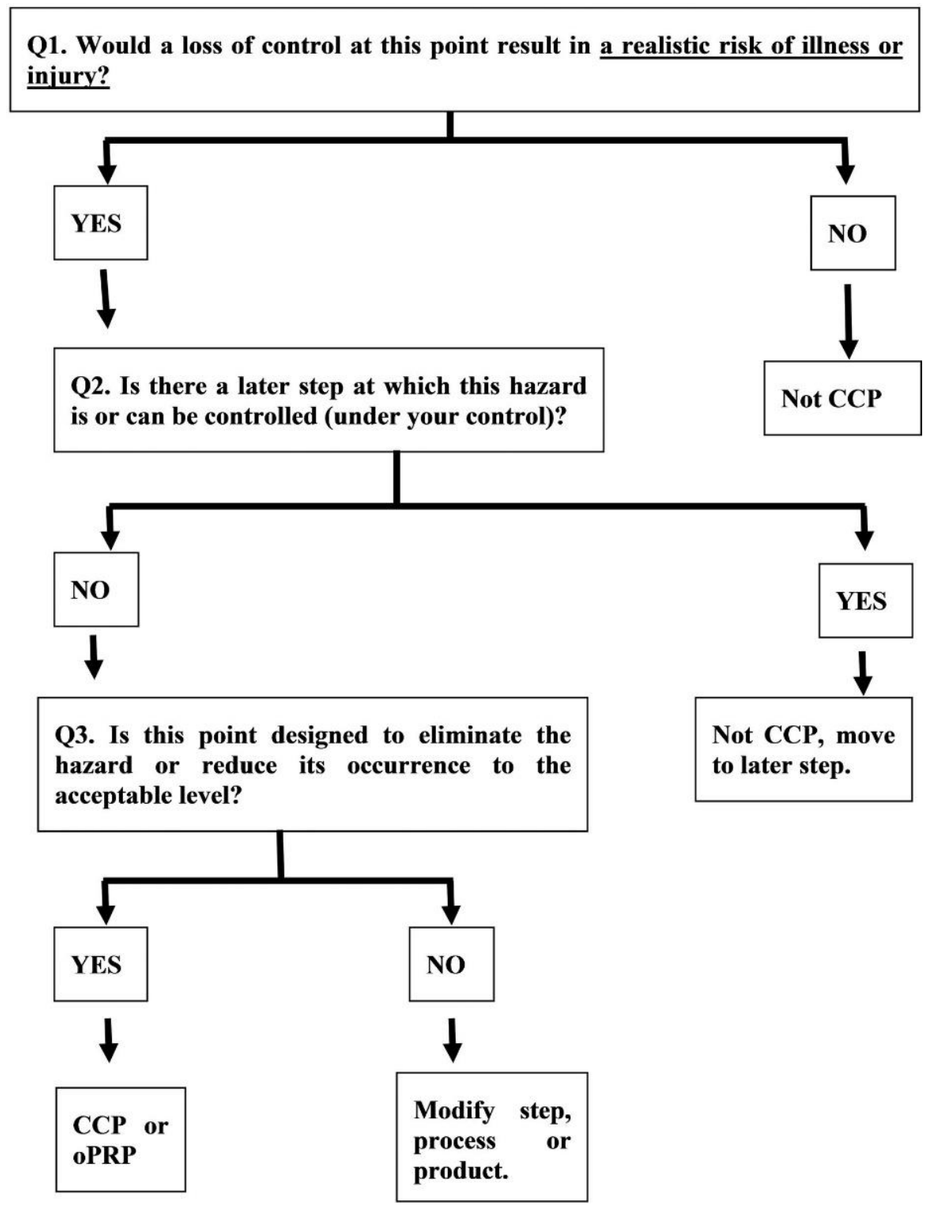
# Identification of critical control points (CCP) (Principle 2)

Each process step identified in the flow diagram should be considered in sequence. At each step, the decision tree and/or risk evaluation should be applied to each hazard that may be reasonably expected to occur or be introduced and each control measure identified. Application should be flexible, considering the whole manufacturing process in order to avoid, whenever possible, unnecessary CCPs. Training in the application of a method to identify CCPs is recommended.

# Identification of critical control points (CCP) (Principle 2)

Examples of a decision tree to identify critical control points (CCPs). The questions shall be answered in sequence. Example of simplified decision tree is on the right.:



# Identification of critical control points (CCP) (Principle 2)

The hazard analysis may identify different levels of risks for each process step:

- For lower risk levels it can be concluded that, if robust PRPs are in place, these PRPs are sufficient to control the hazards.
- For intermediate levels of risks identified, ‘intermediate’ measures can be proposed, such as operational PRPs.

oPRPs are PRPs that are typically linked to the production process and are identified by the hazard analysis as essential, in order to control the likelihood of the introduction, survival and/or proliferation of food safety hazards in the product(s) or in the processing environment. Similarly to CCPs, operational PRPs include measurable or observable action criteria or action limits (but targets rather than critical limits), monitoring of the implementation of control measures, monitoring records and corrective actions if needed. Examples are:

- Control of washing process of vegetables (e.g. by frequency of wash water refreshment to avoid microbial cross-contamination, mechanical action in the water to remove physical hazards as stones, pieces of wood).
- Control of blanching process for the deep freezing industry (time/temperature).

# Identification of critical control points (CCP) (Principle 2)

Washing and blanching processes can usually not be considered as CCPs because neither full elimination of the microbial hazards nor reduction to an acceptable level can be achieved or is aimed at. However, they will impact the microbial load of the processed products.

- More intensive cleaning and disinfection in high care areas, more strict personal hygiene in high care areas, for example in packaging areas of ready to eat food.
- More severe incoming check upon reception of raw materials if supplier is not guaranteeing the desired quality/safety level (e.g. mycotoxins in spices).
- Control of allergens by a sanitation program

- For high level of risks, which are not controlled by PRPs or oPRPs, CCPs should be established.

# Identification of critical control points (CCP) (Principle 2)

## Comparison of PRPs, oPRPs and CCPs

| Type of control measure | PRP | OPRP | CCP |
|---|---|---|---|
| **Scope** | Measures related to creating the environment for safe food: measures impacting food suitability and safety | Measures related to the environment and/or product (or combination of measures) to prevent contamination, or to prevent, eliminate or reduce hazards to an acceptable limit in the end product.<br>These measures are implemented after the implementation of PRPs. | |
| **Relation to hazards** | Not specific to any hazard | Specific to each hazard or group of hazards | |
| **Determination** | Development based on:<br>✓ Experience,<br>✓ Reference documents (guides, scientific publications, …),<br>✓ Hazard or hazard analysis. | Based on the hazard analysis taking PRPs into account.<br>CCPs and oPRPs are product and/or process specific | |
| **Validation** | Not necessarily carried out by FBO.<br>(i.e.: cleaning products manufacturer has validated the efficiency of the product and determined product spectrum and instructions of use – FBO has to follow instructions and keep technical specifications of product) | Validation has to be carried out<br>(in many cases, guides to good practice provide guidance on a validation methodology or gives ready to use validation material) | |
| **Criteria** | / | Measurable or observable criteria | Measurable critical limit |
| **Monitoring** | Where relevant and feasible | Monitoring of the implementation of control measures: usually recorded | |
| **Loss of control:<br>Corrections/corrective actions** | Corrective actions and/or corrections on the implementation of PRPs where relevant | Corrective actions on the process<br>Possible corrections on the product (case by case)<br>Records kept | Pre-set corrections on the product<br>Possible corrective actions on the process<br>Records kept |
| **Verification** | Scheduled verification of implementation | Scheduled verification of implementation, verification of achievement of planned hazard control | |

# Identification of critical control points (CCP) (Principle 2)

## Summary of examples on flexibility for certain FBOs

| Activity | Flexibility |
|---|---|
| 1 Prerequisites programs | — Exclusions from scope of Regulations (EC) No 852/2004 and (EC) No 853/2004<br>— Less descriptive PRPs for primary production and associated operations<br>— Less descriptive PRPs for movable and/or temporary premises, …<br>— Exclusion of most retailers from the scope of Regulation (EC) No 853/2004<br>— Possible adaptation under national law for use of traditional methods, FBOs in regions with geographic constraints and for any establishment as regards construction lay-out and equipment<br>— Use of generic sectorial guides for good hygiene practice |
| 2 Preliminary HACCP activities | — No permanent HACCP team, one person responsible for HACCP/FSMS<br>— Use of existing product information (label, internet)<br>— Simple flow diagram |
| 3 Hazard analysis and CCP identification | — Simplified decision trees or (semi-)quantitative risk evaluation methods<br>— Pre-determination of hazards from generic HACCP guide or a generic hazard analysis only.<br>— No need for detail on the nature of the hazards.<br>— Similar products can be grouped. |

**CCP identified** / **No CCP identified**

| | | |
|---|---|---|
| 4 Critical limits | — Pre-determined limits from legislation, scientific opinions, …<br>— No need for fixing numerical values | Low risks: Activities 1 to 3 are considered as compliance with the HACCP-based procedures<br>Intermediate risks: compliance might require oPRPs |
| 5 Monitoring procedure | — Regular visual observation instead of continuous recording<br>— Use of check lists with boxes to tick in case of compliance<br>— Use of standard processing procedures | |
| 6 Verification and validation | — Verify that monitoring is done by checking the records or checking actual monitoring, like checking that measuring temperature is done according the procedures and guides.<br>— Use of results from analyses as validation/Analysing the products against criteria | |
| 7 Documents and records | — Use of generic guides as documentation<br>— Only records on non-compliance and corrective actions | |

# Hazard analysis and identification of CCPs.

Several simplified methods have been described to carry out the hazards analysis and identify possible CCPs e.g. simplified decision trees and semi-quantitative risk evaluation methods.

In certain cases, due to the nature of the food business and the food that is handled by it, a (generic) hazard analysis may demonstrate that no very significant hazard has been identified and therefore there is no need for CCPs. In this case all food hazards can be controlled by the implementation of the PRPs only or in combination with the application of certain oPRPs. It must however be stressed that flexibility on the hazard analysis is not directly linked to the size of the establishment and is not appropriate even when the business is small e.g.:

- when there is a high likelihood of failure in the method of processing such as canning, vacuum packing,
- food production for vulnerable groups of consumers,
- allergen controls in products declared to be allergen free.

# Hazard analysis and identification of CCPs.

For certain categories of food businesses with very identical, standardised and limited handling of the food (e.g. retail shops), it may be possible to pre-determine hazards that need to be controlled. Guidance on such hazards and on the control thereof can be addressed in a generic HACCP guide or a generic hazard analysis only.

In certain cases, due to the nature of the food business and the food that is handled by it, the hazard analysis may demonstrate that significant hazards do not exist and there are no control measures, which could be categorized as CCPs. In these cases oPRPs are the control measures.

In small businesses 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. Such analysis should nevertheless cover all significant hazards in a business and should clearly define procedures to control these hazards and the corrective action to be taken in case of problems.

# Critical limits at CCPs (Principle 3)

Each control measure associated with a critical control point should give rise to the specification of critical limits.

Critical limits correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are set for observable or measurable parameters which can demonstrate that the critical point is under control. They should be based on substantiated evidence that the chosen values will result in process control.

Examples of such parameters include temperature, time, pH, moisture content, amount of additive, preservative or salt, sensory parameters such as visual appearance or texture, etc.

In some cases, to reduce the likelihood of exceeding a critical limit due to process variations, it may be necessary to specify more stringent levels (i.e. target levels) to assure that critical limits are observed.

Critical limits should be validated and should have clear, specific values.

Critical limits may be derived from a variety of sources. When not taken from regulatory standards or from guides of good hygiene practices, the HACCP team should ascertain their validity relative to the control of identified hazards at CCPs.

# Critical limits at CCPs (Principle 3)

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

- Experience (best practice);
- International documentation for a number of operations, e.g. canning of food, pasteurisation of liquids etc. for which internationally accepted standards (*Codex Alimentarius*) exist; critical limits can also be established;
- Guides to good practice on this specific issue;
- Scientific publications;
- EU legislation, EFSA opinions.

The requirement to establish a critical limit at a CCP does not always imply that a numerical value must be fixed. This is in particular the case where monitoring procedures are based on visual observation e.g.:

- The faecal contamination of carcases in a slaughterhouse,
- The boiling temperature of liquid food,
- The change of physical properties of food during processing (e.g. cooking of food).

# Monitoring procedures at CCPs (Principle 4)

An essential part of HACCP-based procedures is a program of observations or measurements performed at each CCP to ensure compliance with specified critical limits.

Observations or measurements must be able to detect loss of control at CCPs and provide information in time for corrective action to be taken.

Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be made before a deviation occurs (the critical limit is not met). Data derived from monitoring must be evaluated by a designated and experienced person with knowledge and authority to carry out corrective actions when indicated.

Observations or measurements can be made continuously or intermittently. When observations or measurements are not continuous, it is necessary to establish a frequency of observations or measurements which provides information in time for corrective actions to be taken.

# Monitoring procedures at CCPs (Principle 4)

The HACCP plan should describe the methods, the frequency of observations or measurements and the recording procedure for monitoring at CCPs:

- who is to perform monitoring and checking,
- when monitoring and checking is performed,
- how monitoring and checking is performed.

The frequency of monitoring should be risk based e.g. depending on the likelihood of hazard occurrence in the product, the volume of production, the distribution of the product, the potential consumers, the number of workers directly handling the product, …

Records associated with monitoring CCPs must be signed by the person(s) doing the monitoring and when records are verified by staff of the company responsible for reviewing.

# Monitoring procedures at CCPs (Principle 4)

Monitoring is not only achieved by measuring. Monitoring may in many cases be a simple procedure, e.g.:

- A regular visual verification of the temperature of cooling/freezing/heating facilities using a thermometer;
- A visual observation to monitor whether the correct de-hiding procedure is being applied during slaughter where this part of the slaughter process has been identified as a critical control point for preventing carcase contamination;
- A visual observation to verify whether a food preparation submitted to a particular heat treatment has the correct physical properties reflecting the level of heat treatment (e.g. boiling or to making sure food is steaming hot all the way through).

Monitoring should be as frequent as necessary to ensure that critical limits and targets are permanently met. It should confirm that the critical limit or target is not exceeded. The type of CCP determines the frequency of monitoring. Monitoring of a CCP can in some cases occur intermittently, e.g. in a case of reduced frequency of monitoring after prolonged period of good results.

# Monitoring procedures at CCPs (Principle 4)

Standard processing procedures can be used:

- Certain foods may sometimes be processed in a standard way using a standard calibrated equipment, e.g. certain cooking operations, roasting chicken etc. Such equipment ensures that the correct time/temperature combination is respected as a standard operation. The cooking temperature of the product then needs not to be systematically measured if it is ensured that the equipment is functioning properly, that the required time/temperature combination is respected and that the necessary controls for that purpose are carried out (and corrective action taken where necessary).
- In restaurants, food is prepared in accordance with well-established culinary procedures. This implies that measurements (e.g. food temperature measurements) need not be carried out systematically if the established procedures are followed.

# Corrective actions (Principle 5)

For each CCP, corrective actions should be planned in advance by the HACCP team, so that they can be taken without hesitation when monitoring indicates a deviation from the critical limit.

Such corrective actions should include:

- proper identification of the person(s) responsible for the implementation of the corrective action,
- means and action required to correct the observed deviation,
- action(s) (sometimes called ‘corrections’ to differentiate from other corrective actions) to be taken with regard to products that have been manufactured during the period when the process was out of control,
- written record of measures taken indicating all relevant information (for example: date, time, type of action, actor and subsequent verification check).

Monitoring may indicate that preventive measures (PRPs or their robustness) or the process and its CCPs shall have to be reviewed if corrective actions for the same procedure have to be taken repeatedly.

# Verification (and validation) procedures (Principle 6)

The HACCP team should specify the methods and procedures to be used for determining if the HACCP-based procedures are working correctly. Methods for verification may include in particular random sampling and analysis, reinforced analysis or tests at selected critical points, intensified analysis of intermediate or end products, surveys on actual condition during storage, distribution and sale and on actual use of the product.

The frequency of verification should be sufficient to confirm that HACCP-based procedures are working effectively. The frequency of verification shall depend on the characteristics of the business (output, number of employees, nature of the food handled), the monitoring frequency, the accuracies of the employees, the number of deviations detected over time and the hazards involved.

# Verification (and validation) procedures (Principle 6)

Verification procedures may include:

- Audits of HACCP-based procedures and their records,
- Inspection of operations (people compliance),
- Confirmation that CCPs monitoring is implemented and maintained,
- Review of deviations and product dispositions; corrective actions taken with regard to the product.

The frequency of verification will greatly influence the amount of recheck or recall required in case a deviation exceeding the critical limits has been detected. Verification should comprise all of the following elements, but not necessarily all at the same time:

- check on the correctness of the records and analysis of deviations,
- check on the person monitoring processing, storage and/or transport activities,
- physical check on the process being monitored,
- calibration of instruments used for monitoring.

# Verification (and validation) procedures (Principle 6)

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

At the start of a process or in case of a change, validation activities should be carried out and should gather evidence to confirm the efficacy of all elements of the HACCP plan. Such evidence includes scientific publications, in-house testing, predictive microbiology, … demonstrating that the critical limits set, will, if adhered to, result in the intended effect on the hazard (no growth, reduction, …). Additional guidance and examples of validation activities are in CAC/GL 69-2008.

# Verification (and validation) procedures (Principle 6)

Examples of changes that may require re-validation include:

- change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning and disinfection program),
- change in packaging, storage or distribution conditions,
- change in consumer use,
- receipt of any information on a new hazard associated with the product.

Where necessary, such a review must result in the amendment of the procedures laid down. The changes should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.

# Verification (and validation) procedures (Principle 6)

**Validation, verification or monitoring?**

- **Validation:** evidence before the start (or change) of a process demonstrating that the considered control measures (PRPs, oPRPs or CCPs) are effective when correctly applied and will be protective of human health e.g. evidence that the targeted hazard does not grow to an unacceptable level at the proposed critical limit of storage temperature.

- **Monitoring:** ongoing (real-time) collection of information at the step where the control measure is applied e.g. the continuous or intermittent monitoring of the storage temperature.

- **Verification:** periodic activity to demonstrate that the desired outcome has indeed been reached e.g. sampling and testing of the food to evaluate the presence of the targeted hazard below the acceptable threshold by storage at a certain temperature.

# Verification (and validation) procedures (Principle 6)

**Example 1: milk pasteurization**

- Validation: before production activities: Experimental proof that the process used will heat milk to 72 °C for 15 seconds and will destroy *Coxiella burnetti*. Calibrated probes, microbiological tests and predictive microbiology can be used.
- Monitoring: during production activities: System (time – temperature – pressure – volume throughput) which will enable the companies to see that the critical limit (72 °C for 15 s) is attained during process.
- Verification: fixed frequency per year: Periodic microbiological tests on the end product, regular check of temperature of the pasteurizer with calibrated probes.

**Example 2: Fermentation of dry cured sausages**

- Validation: pH, water activity, time/temperature combination, not allowing *Listeria monocytogenes* to grow by predictive modelling or by challenge testing;
- Monitoring during fermentation: measurement of pH, weight loss, time period, temperature, humidity of fermentation chamber, *L. monocytogenes* sampling in fermentation environment;
- Verification: *L. monocytogenes* sampling plan in the end product.

# Verification (and validation) procedures (Principle 6)

Verification may in many cases be a simple procedure by which it is possible to check that monitoring is done in a proper way in order to achieve a required food safety level.

Simple verification procedures may include:

- physical audit or check on the monitoring;
- physical audit or check on the monitoring records including the checking of corrective actions whenever a non-compliance or exception reporting has been recorded.

Generic HACCP guides should include examples of necessary verification procedures, and when standard processes are concerned, there should be a validation of the considered control measures on the targeted hazards as well. The validation of the HACCP plan and activities of the FBO can focus on the sampling and testing of the food to evaluate the presence of the targeted hazards.

# Documentation and record keeping (Principle 7)

Efficient and accurate record keeping is essential to the application of HACCP-based procedures. HACCP-based procedures should be documented in the HACCP-plan and continuously supplemented by records on findings.

Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP-based procedures are in place and being maintained.

Documents and records should be kept for a sufficient period of time beyond the shelf life of the product for traceability purposes, for the regular revision of the procedures by the FBO and to allow the competent authority to audit the HACCP-based procedures.

Expert developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business. Documents should be signed by a responsible reviewing official of the company.

# Documentation and record keeping (Principle 7)

Recommended documentation includes:

- PRPs applied, working instructions, standard operational procedures, control instructions;
- Description of the preparatory stages (before 7 principles);
- Hazard analysis;
- CCP (+/- oPRPs) identification;
- Critical limit determination;
- Validation activities;
- Corrective actions anticipated;
- Description of planned monitoring and verification activities (what, who, when);
- Record forms;
- Modifications to the HACCP-based procedures;
- Supporting documents (generic guides, scientific evidence, …).

# Documentation and record keeping (Principle 7)

A systematic, integrated approach can be taken by using worksheets for the development of the HACCP plan as provided in the Annex to CAC/RCP 1-1969, Diagram 3. Starting from the flow diagram, at each step of processing the potential hazards are described, relevant control measures (PRPs) listed, CCPs identified (if appropriate based on the hazards analysis) along with their critical limits, monitoring procedures, corrective actions and available records.

Record examples are:

- Outcome of CCP monitoring activities;
- Observed deviations and executed corrective actions;
- Outcome of verification activities.

# Documentation and record keeping (Principle 7)

Records should be kept for an appropriate period of time. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. For certain foods the date of consumption is certain. For instance, in food catering, consumption takes place shortly after the time of production. For food for which the date of consumption is uncertain, records should be kept for a reasonably short period after the expiry date of the food. Records are an important tool for the competent authorities to allow verification of the proper functioning of the food businesses' FSMS.

A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

# Documentation and record keeping (Principle 7)

This section refers to HACCP related documentation only and not to other documentation on issues such as stock management, traceability etc.

HACCP-based procedures, documents and records must be commensurate to the nature and the size of the food business.

As a general rule, the need for HACCP-related record keeping should be well-balanced and can be limited to what is essential with regard to food safety. It is important to consider that recording is necessary but not the goal in itself.

HACCP related documentation includes:

- Documents on the HACCP-based procedures appropriate for a particular food business, and
- Records on measurements and analysis carried out.

# Documentation and record keeping (Principle 7)

Taking into account the above, the following general guidelines could be used:

- Where generic HACCP guides exist, documentation on hazard analysis, CCP determination, critical limit determination, possible modification of the FSMS and validation activities can be substituted for individual documentation on HACCP-based procedures. Such guides could also clearly indicate where there is a need for records and the period of time during which records must be kept.
- In particular in the case of visual monitoring procedures, it may be considered to limit the need for establishing a record only to measurements of non-compliance (e.g. failure of equipment to maintain the correct temperature) that are detected.
- Carrying out monitoring effectively is in general more important than recording it. Therefore, flexibility on the recording could be more easily accepted than flexibility concerning the monitoring itself (e.g. its frequency).
- In particular for small businesses keeping the right temperature is far more important than actually recording it.

# Documentation and record keeping (Principle 7)

Taking into account the above, the following general guidelines could be used:

- The records of non-compliance should include the corrective action that has been taken. The use of a diary or a checklist might be a suitable way of record keeping in such cases. FBOs can simply tick boxes to indicate how they act or provide more detailed information by writing in text boxes how they comply with a control point. Daily record-keeping is based on confirming opening and closing checks with a tick and a signature to confirm that safe methods have been followed. When a box ticking approach is used, only problems or changes to procedures are recorded in more detailed additional writing (i.e. exception reporting).
- (Generic) models regarding auto-control documents should be provided by stakeholders' organisations or competent authorities. These should be easy to use, understandable and simple to implement.
- A x-weekly review of methods only requires completing a check list of activities and possible impact on safe methods.

# The role of microbiological criteria and limits set in the EU or national law

Although EU legislation does not provide for critical limits at critical control points, microbiological criteria can be used in validation and verification of HACCP-based procedures and other food hygiene control measures, as well as for the verification of the correct functioning of these control measures. For a particular operation or type of food, the guides to good practice can refer to these limits and the HACCP-based procedure can be formatted in such a way as to ensure that these limits are met.

# HACCP Quiz

## Question 1

**What is a HACCP Plan?**

A. A form that has to be filled in by all food handlers.

B. A food hygiene rating scheme.

C. A written document which is based upon the seven principles of HACCP, which clearly states the safety procedures to be followed to identify any hazards that must be avoided, removed or reduced.

D. A system used in food hygiene auditing.


**C**

# HACCP Quiz

## Question 2

**What is a HACCP Team?**

A. A team of highly trained chefs.

B. A group of people who have the skills and knowledge needed to develop, implement and maintain a HACCP system.

C. A team of government investigators.

D. An office based team of administrative officials who specialise in food hygiene matters.


**B**

# HACCP Quiz

## Question 3

**What hazards does HACCP address?**

A. It is used to guide businesses through the process of identifying food safety hazards.
B. It highlights inaccuracies in an organisations administrative processes.
C. It shows food handlers which utensils to use when cooking meals.
D. It focuses on potential fire hazards within the food preparation area.

**A**

# HACCP Quiz

## Question 4

**Which of these would be a critical limit?**

A. Washing vegetables before using them.
B. Cooking chicken to reach a temperature of 165°F (74°C) for 15 seconds.
C. Checking the use by date on canned ingredients.
D. The temperature food is kept at in a fridge.

**B**

# HACCP Quiz

## Question 5

**What is the first stage of putting together a HACCP system?**

A. Putting together a HACCP team.

B. Making sure everyone has the correct forms that have to be filled in.

C. Determining the product lines and distribution channels that should be included in the HACCP plan.

D. Creating a flow diagram that gives a simple and clear outline of the steps involved in the food process of the company.


**A**

# HACCP Quiz

## Question 6

**How many HACCP Principles are there?**

A. 4.

B. 5.

C. 7.

D. None of these.


**C**

# HACCP Quiz

## Question 7

**What is the Third HACCP Principle?**

A. Establish Critical Limits

B. Conduct a Hazard Analysis

C. Assemble the HACCP Team

D. None of these

**A**

# HACCP Quiz

## Question 8

**What are the categories of food hazards?**

A. Biological, Chemical, Metal

B. Biological, Metal, Jaundice

C. Biological, Physical, Allergens

D. Biological, Physical, Chemical.

**D**

# HACCP Quiz

## Question 9

**When a Deviation from a Critical Limit occurs, what must happen?**

A. Documentation of Corrective Actions

B. Reassessment of the HACCP Plan

C. Stop the line and immediately inform your Supervisor and/or Quality Personnel

D. All of the these.

**D**

# HACCP Quiz

## Question 10

**A Critical Control Point (CCP) is?**

A. I dentyfying hazards and preventive measures.

B. A point, step or porcedure in a food process at which a hazard can be controlled

C. Product sampling and testing

D. All of the above.

**B**

# HACCP Quiz

## Question 11

**What is the first step in developing a HACCP plan?**

A. Identify corrective actions.
B. Conduct a hazard analysis.
C. Establishing monitoring procedures
D. Determine critical control points.

**B**

# HACCP Quiz

## Question 12

**Reviewing temperature logs and other records to make sure that the HACCP plan is working as intended is an example of which HACCP principle?**

A. Monitoring
B. Hazard Analysis
C. Verification
D. Record keeping


**C**

# HACCP Quiz

## Question 13

**Which of the following statements is NOT true about HACCP?**

A. Combines science and common sense for food safety.
B. Is a preventative measure.
C. Includes seven principles.
D. Is a reactive measure.

**D**

# HACCP Quiz

## Question 14

**Which of the following is NOT a task HACCP is designed to do?**

A. Identify hazards.
B. Develop production goals.
C. Establish controls.
D. Monitor controls.

**B**

# HACCP Quiz

## Question 15

**Which of the following is NOT a type of critical limit?**

A. Nutritional content.
B. Time.
C. Temperature.
D. Aw (Water Activity).

**A**

# HACCP Quiz

## Question 16

**What sectors is HACCP applicable to?**

A. The motor industry and specifically the production line.

B. The airline industry.

C. Software development.

D. It is suitable to be implemented by organisations directly or indirectly involved in various sectors of the food industry and related supply chain.


**D**

# HACCP Quiz

## Question 17

**HACCP can not only prevent cases of food poisoning, it can also…..**

A. Increase a company’s profits.
B. Make foot taste better.
C. Help a company to comply with relevant food law regulations.
D. Make food look more palatable..

**C**

# HACCP Quiz

## Question 18

**The recordkeeping requirements of a HACCP plan enables:**

A. Food handlers to work faster.

B. The company to save money by using less paper than it otherwise would.

C. Investigators to audit a company and see how well they are complying with food safety laws over a set period.

D. People to know what their colleagues are doing.


**C**

# HACCP Quiz

## Question 19

**Why must food must be thoroughly cooked to the correct time and temperature combination?**

A. It helps to improve the taste.
B. It makes the food look more attractive.
C. It is a requirement of the law.
D. It helps to kill harmful microbes that can cause disease.


**D**

# HACCP Quiz

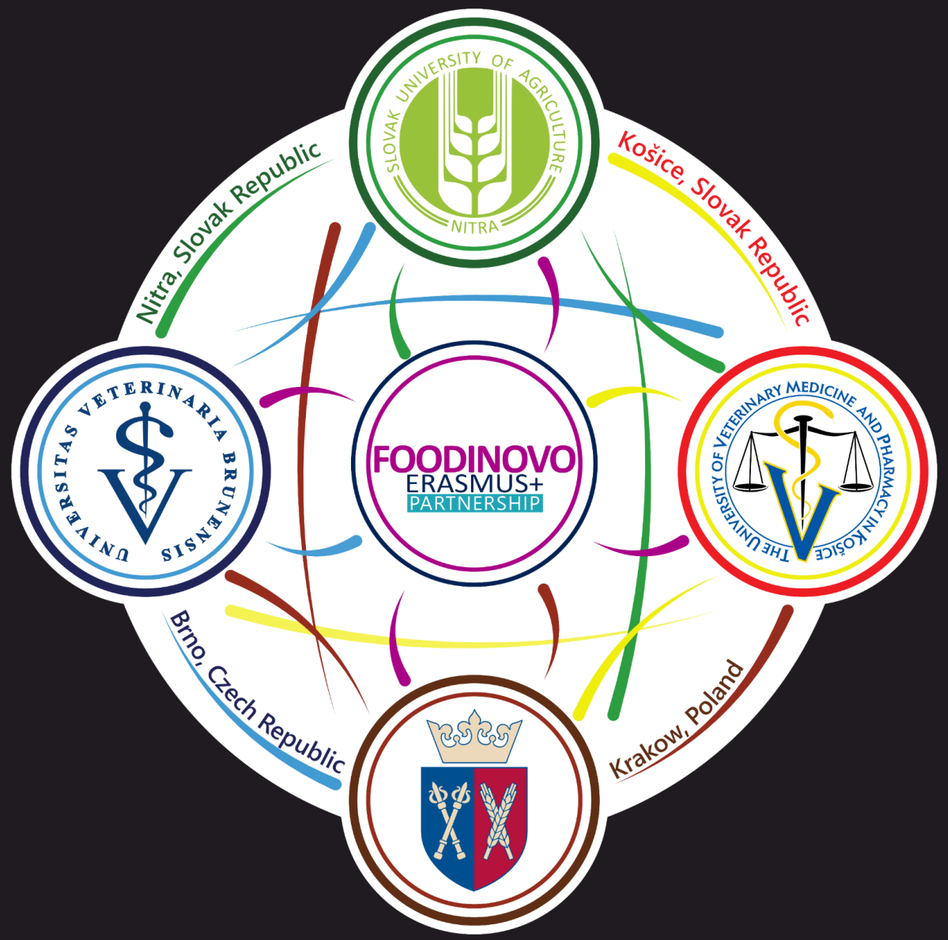
## Question 20

**Why do you need to create a flow diagram?**

A. To show a step-by-step for each process.
B. To show employees how things work.
C. To identify where equipment is needed.
D. To help food inspectors understand your business.

**A**

# Thank you !

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