

Manual for Official Controls: Amendment 95

Chapter 4.2 HACCP Based Procedures

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1. Introduction

1.1 Legislation

1.2 Characteristics of HACCP based procedures

1.1 Legislation

1.1.1 HACCP legislative framework

The following table summarises the different pieces of legislation that cover FBO and OV responsibilities in relation to HACCP based procedures.

Regulation		Issue	Who is responsible?	Other documents
Reg (EC) 852/2004	Ch II, Article 5	Put in place, implement and maintain a permanent procedure based on HACCP principles	FBO	<ul style="list-style-type: none"> • Commission Guidance • Food Safety Management Diary for Meat Producers
	Annex II, Ch XII	Train staff responsible for the development and maintenance of HACCP based procedures in the application of HACCP principles	FBO	<ul style="list-style-type: none"> • Commission Guidance
Reg (EC) 853/2004	Annex II, Section II	List of HACCP based objectives for incoming animals accepted for slaughter	FBO	<ul style="list-style-type: none"> • Commission Guidance
Regulation (EU) 2017/625	Article 14 Article 18	Audit and verification that FBOs implement and apply HACCP-based principles continuously and properly	OV	<ul style="list-style-type: none"> • Food Safety Management Diary for meat producers

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	Annex II Ch I			
Commission Delegated Regulation (EU) 2019/624	Article 7 Article 9 Annex II Ch I Ch II Ch III	Audit and verification that FBOs implement and apply HACCP-based principles continuously and properly Training requirements for OVs Training requirements for OAs Training requirements for 'other staff designated by the competent authority'	OV	<ul style="list-style-type: none"> • Food Safety Management Diary for meat producers
Commission Implementing Regulation (EU) 2019/627	Article 3 Article 4 Article 7 Article 25	Audit and verification that FBOs implement and apply HACCP-based principles continuously and properly	OV	<ul style="list-style-type: none"> • Food Safety Management Diary for meat producers

1.1.2 (EC) 852/2004 evidence

The FBO shall provide the OV with evidence of their compliance with the HACCP legal requirements, taking into account the nature and size of the business, and ensure that any documents describing the procedures are up to date at all times.

The instructions in this chapter reflect the minimum requirements expected to consider an FBO plan of HACCP-based procedures adequate and in compliance with the Regulations.

Reference: (EC) 852/2004, Chapter II, Article 5.

1.1.3 Regulation (EU) 2017/625 OV verification of FBO HACCP based procedures

The OV is required to conduct audits to verify that food business operators apply HACCP based procedures continuously and properly. In particular, audits must take account of:

- identified risks
- information which may mislead the consumer
- FBO past records
- Results of FBO own verification
- Results of third party or private quality assurance schemes¹
- Any other information which might indicate non-compliance

1.1.4 Delegated Regulation (EU) 2019/624

Official veterinarians, official auxiliaries and other staff designated by the competent authority must be suitably trained and authorised by the competent authority to gather evidence on FBO HACCP based procedures.

OAs and other staff designated by the competent authority working under the responsibility of the OV may collect information on GHP and HACCP based procedures to contribute to the audit process.

1.1.5 Implementing Regulation (EU) 2019/627 on the specific requirements of auditing HACCP based procedures

Determine to the extent possible that FBO procedures continuously and properly guarantee that fresh meat:

- complies with microbiological criteria;
- complies with legislation regarding chemical and physical hazards; and
- complies with legislation regarding faecal contamination and contamination with specified risk material.

And that the food business:

- Uses guidance and third-party assurance data correctly, where applicable.

¹ Only for the purpose of ascertaining compliance with food safety, animal health and welfare rules

- Has sufficiently competent staff to comply with the requirements.

1.1.6 Key reference documents

The European Commission has produced a guidance document for the implementation of procedures based on HACCP principles and to facilitate the implementation of HACCP principles in certain food businesses.

Reference: MOC, Volume 2 Legislation for additional information.

'The Diary' has been produced by the FSA for smaller operators and can be found within the MOC titled as 'Food Safety Management Diary'.

The Diary is specifically designed to facilitate FBOs to keep records relating to the hygienic operation of their businesses. It also includes draft documentation on prerequisites and HACCP.

The use of the Diary by FBOs is voluntary.

Reference: See the topic 2.10 on 'Principle 7: documentation' in part 2 for additional information.

1.2 Characteristics of HACCP based procedures

1.2.1 Purpose

HACCP principles are a tool for FBOs to use to control hazards that may occur in food.

HACCP is a set of 7 principles used to assess hazards and establish control systems that focus on prevention of problems rather than relying solely on end-product testing.

1.2.2 Implementation requirements

The successful application of HACCP based procedures requires the following:

- the FBO must already have implemented the hygiene controls that are required by legislation (prerequisites / good hygiene practice)
- requires the full commitment of management and the involvement of the work force

1.2.3 ‘Traditional’ HACCP vs. HACCP based procedures

‘Traditional’, ‘classic’ or ‘technical’ HACCP is not the same as ‘HACCP based procedures’.

Traditional HACCP evolved from spacecraft manufacture to guarantee the safety of astronauts’ food. It remains appropriate for industrial production of processed foodstuffs involving for example, sterilisation or pasteurisation steps.

It is however acknowledged in (EC) 852/2004 and particularly in the Commission’s guidance on HACCP that such a technical approach may not be appropriate for all types and sizes of food businesses. In the case of meat plants, for example, it can be sufficient to apply the principles in a more flexible way following guides to practice.

1.2.4 ‘Flexibility’: Nature and size of the operations

Flexibility regarding the application of HACCP principles may be applied, taking into account:

- the nature of the operations
- the size of the business

Flexibility taking into account	Comments
Nature of the operations	<p>In businesses handling food with no significant food safety hazards (for example, greengrocers) a hazard analysis confirming that is the case can be sufficient.</p> <p>In businesses handling many foods (for example, restaurants) a simplified approach using a diary can be sufficient.</p> <p>In businesses involving simple processing (for example, slaughterhouses and cutting plants) a generic plan with a diary for record keeping can be sufficient as long as they are adapted to reflect company conditions.</p> <p>In food manufacturing businesses, particularly with procedures that will eliminate hazards (for example, canning plants) full technical HACCP is more appropriate.</p> <p>OV auditors should consider whether the HACCP based procedures are appropriate for the type of business.</p>

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Size of the business / documentation	<p>The size of business and resources available will have a bearing on the complexity of the HACCP based system; however a simple, easily managed system can achieve the safe production of food as well as a more complex system.</p> <p>A traditional HACCP system relies heavily on recording that all the procedures are being followed correctly, probably by the Quality Control, Quality Assurance or HACCP team.</p> <p>Small and medium sized businesses rarely require the same level of documentation. They may choose to record when things go wrong, called 'exception reporting'.</p> <p>Reference: See the topic 2.10 on 'Principle 7: Documentation' in Part 2 for additional information.</p> <p>OV auditors should note that there is no value in FBO documentation being disproportionate to the level of risk and the recording of HACCP based monitoring procedures being a burden to small-medium businesses.</p>
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1.2.5 Flexible application of HACCP principles

FBO application of HACCP principles should meet the following criteria:

- identify the main hazards associated with the type of product produced and the operations carried out
flexibility: hazards - generic descriptions of hazards may be sufficient
- identify those Critical Control Points (CCPs) / Control Points (CPs) necessary to control those hazards; the FBO may choose to have in the plan only CPs which are legal requirements
flexibility: CCPs - **generic guidance may include pre-determined CCPs** in the preparation, manufacturing and processing of food
- establish critical (or legal) limits against which to monitor the effectiveness of control measures at CCPs / CPs
flexibility: critical limits - it is not always necessary to fix a numerical value, especially where monitoring procedures are based on visual observation (for example, the faecal contamination of carcasses in a slaughterhouse)
- monitor CCPs / CPs

flexibility: monitoring - may be a simple procedure, for example, 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 CCP for preventing carcase contamination

- take the necessary corrective actions based on the results of the monitoring activities
- record the observations and corrective actions taken; the requirement of retaining documents needs to be flexible in order to avoid undue burdens for small / medium businesses

flexibility: recording – in the case of visual monitoring procedures it can be acceptable to record results only when there is a problem and the corrective action that has been taken; that is, ‘exception reporting’; a diary can be a suitable method of record keeping

- verify the HACCP-based procedures

flexibility: verification – checking all aspects of the HACCP plan can be spread throughout the year so that all aspects are verified at least once a year to meet the requirement for ‘regular’ verification

1.2.6 Review of HACCP based procedures

The HACCP procedures should be reviewed and necessary changes made by the FBO when any modification is made in the product, process or any step.

1.2.7 OV role

OVs, through auditing, need to determine the level of FBO compliance with HACCP principles always taking into consideration the possibility of implementing simplified HACCP based procedures particularly in small / medium sized businesses.

2. Common Issues of HACCP Auditing

- 2.1 Introduction
- 2.2 Training
- 2.3 Implementing and maintaining HACCP based procedures
- 2.4 Principle 1: Hazard analysis
- 2.5 Principle 2: Determine Critical Control Points (CCPs) / Control Points (CPs)
- 2.6 Principle 3: Establish critical limits (CLs) / legal limits (LLs)
- 2.7 Principle 4: Monitoring of CCPs / CPs
- 2.8 Principle 5: Corrective action procedures
- 2.9 Principle 6: Validation, verification and review
- 2.10 Principle 7: Documentation

2.1 Introduction

This section covers common issues for OVs to consider when auditing a food safety management system based on HACCP principles in compliance with the regulation.

2.2 Training

2.2.1 Staff responsible for HACCP based procedures

Those responsible for the development and maintenance of HACCP-based procedures have received adequate training in the application of HACCP principles.

Reference: (EC) 852/2004, Annex II, Chapter XII, 2.

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2.2.2 Training: common issues

The following table contains examples of common issues that the OV and OV auditors could find when auditing HACCP based procedures and guidance on how the OV should make the assessment to determine FBO compliance:

Common Issues	OV advice / guidance
<p>No member of staff with formal training</p>	<p>Formal training is not a legal requirement; the FBO however, should show that they have received ‘supervision, instruction and / or training’.</p> <p>This can be achieved in a number of ways including (list not exhaustive):</p> <ul style="list-style-type: none"> • one to one instruction • day courses • in house courses • distance learning courses. <p>These may or may not be accredited courses; however, there should be evidence of training. Examples include: certificates, completed test papers, questionnaires, personal assessment papers and individual training records showing instruction or training received.</p>
<p>The FBO believes they do not require any training at all as the HACCP based system has been written by an external adviser / consultant</p>	<p>If external advisers / consultants are used, they should do so as part of a HACCP team, providing instruction and guidance rather than working independently and writing the system for the FBO. It may mean that the FBO is unable to answer questions or make amendments without reference to the adviser. This raises the question of whether the staff can be maintaining their HACCP-based procedures and has adequate training to do so.</p> <p>Instruction given by the external adviser / consultant to the FBO should be recorded on individual training records.</p> <p>Primary responsibility for food safety rests with the FBO, so ownership of the food safety system should be that of the FBO.</p> <p>Reference: (EC) 852/2004, Chapter I, Article 1, 1(a).</p>

2.3 Implementing and maintaining HACCP based procedures

2.3.1 HACCP implementation and maintenance

FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles taking into account the nature and size of the business.

Reference: See Section 10.6 of Volume 2 of the MOC and Regulation (EC) 852/2004, paragraph 15 of the recital as well as Article 5, 1.

2.4 Principle 1: Hazard analysis

2.4.1 Hazard identification

The FBO is responsible for identifying any significant hazards that must be prevented, eliminated or reduced to acceptable levels.

Reference: (EC) 852/2004 Article 5, 2(a).

2.4.2 Hazard identification: common issues

The following table contains examples of common issues that the OV and OV auditors could find when auditing HACCP based procedures and guidance on how the OV and OV auditors should make the assessment to determine FBO compliance:

Common Issues	OV / OV auditor advice / guidance
The product description does not include technical information	Flexibility as to what is included should relate to the technical nature of the production process. For example, a meat plant producing a meat preparation and / or meat product is likely to require a greater amount of data such as microbiological criteria, moisture content. than a meat plant that simply cuts and packs a raw product. Large meat plants that have qualified technical teams / advisers may have the necessary skills to write a very detailed and validated technical description of the process; this may not be the case in small – medium businesses with fewer resources.
Flow diagram does not show all steps in a process	A flow diagram (CODEX HACCP guideline) used in a traditional HACCP system will describe all inputs into the food business (such as packaging and ingredients), the different stages of process, the

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	<p>outputs (including food and waste) as well as how different foods are stored and despatched, where applicable. Generic systems based on HACCP principles may use a 'simplified' flow diagram; this is an identification (rather than description) of each process step. Certain process steps may be grouped together when the risks are the same, for example, removing bones from a carcass and cutting the boneless meat into cubes. Although these are two different procedures, the hazards will be the same, therefore the process step may be written and simplified as follows:</p> <ul style="list-style-type: none"> • remove bone and prepare meat. <p>Note: It is essential that flow diagrams accurately reflect the whole process (are validated), so that the remaining HACCP principles are correctly considered and described.</p>
<p>Hazards identified do not specify individual contaminants such as <i>salmonella</i>, rust, chemicals, peanuts</p>	<p>A technical HACCP study completed by a multi-disciplinary team will be based on extensive research to ensure that all potential hazards, biological, physical, chemical and allergenic are identified for example, the effect of competition from spoilage bacteria on the survival of food-borne pathogens.</p> <p>This level of detail is unlikely to be achieved by small – medium businesses with limited resources, who may address individual hazards by groups, for example,</p> <p>Biological contamination:</p> <p>The naming of each type of pathogenic bacteria that may be a contamination / cross-contamination hazard would be appropriate for larger plants but not for businesses following a generic plan.</p> <p>At the chilling step, a generic hazard will be 'Growth of bacteria due to inadequate temperature control'. It is unnecessary for the FBO to have an in-depth understanding of microbiology.</p> <p>It is sufficient that the plan recognises the dangers of poor temperature control in relationship to bacterial growth.</p> <p>Importantly, FBOs should recognise the need to minimise the level of micro-organisms at each stage of the supply chain as there is a risk of cross contamination of ready-to-eat products by raw meat before it is itself cooked.</p>
<p>Hazards identified do not specify individual hazards</p>	<p>Physical contamination:</p>

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<p>such as <i>salmonella</i>, rust, chemicals, peanuts</p>	<p>Individual hazards, such as parts from machinery, contamination from building fabric, may be combined and identified as ‘contamination due to foreign objects’.</p> <p>Chemical contamination:</p> <p>The plan may not identify a significant chemical hazard. Cleaning chemical hazards should be controlled by the application of hygiene controls, such as appropriately adhering to cleaning procedures (as documented in Cleaning Schedules) which should include a list of chemicals used.</p> <p>In respect of allergenic reactions, few people display allergic reactions to meat, so in raw meat slaughter / processing it is unlikely to be a significant hazard, however this risk would need to be considered when processing a meat preparation or product, which may contain relevant products such as soya, egg, sesame.</p> <p>OVs and OV auditors should note the above differences applying flexibility.</p>
	<p>Contamination from specified risk material (SRM) or the leakage of fluid from the central nervous system (CNS)</p> <p>The plan may not identify the specific hazards associated with contamination of fresh meat or meat products as a result of ineffective TSE/SRM controls.</p> <p>Reference: See EU and national legislation regarding controls required</p>
<p>Inaccurate control measures identified</p>	<p>‘Control measures’ are necessary to control significant hazards from contaminating a food, for example, the chilling of meat down to a desired temperature and the implementation of maintenance procedures.</p> <p>The plan of HACCP-based procedures may not distinguish control measures from monitoring procedures and may include visual inspections / observations as control measures.</p> <p>Even though visual inspection (observation) is technically a monitoring procedure rather than a control measure, it can still be accepted as a control, provided it is accurately documented and that action is taken where and when non-compliance is observed</p>

2.5 Principle 2: Determine CCPs / CPs

2.5.1 CCP / CP Identification

Identifying the CCPs or control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels.

Reference: (EC) 852/2004 Article 5, 2(b).

2.5.2 Difference between CCP and CP

In the processing of fresh meat and offal, it may not be possible to prevent or eliminate hazards and reduction steps may not be measurable in the same way as, for example, when food is canned.

Therefore, FBOs may consider that for their product and / or operations there are no 'traditional' CCPs. There are process steps, however, where controls are necessary to meet legal objectives. If these process steps are not chosen as CCPs they should nevertheless be included in the plan of HACCP-based procedures as control points (CPs) required by legislation and records of monitoring and corrective actions should be kept.

Examples of those control points are:

- acceptance of animals for slaughter, to ensure animals are identified, clean and healthy
- evisceration and dressing, to ensure absence of visible contamination
- SRM controls, to ensure absence and proper disposal of SRM
- temperature controls to limit growth of micro-organisms
- receipt / pre-cut inspection of raw meat, to ensure raw materials are free from contamination

2.5.3 CCPs / CPs common issues

The following table contains examples of common issues that the OV and OV auditor could find when auditing and/or verifying HACCP based procedures. The table also provides advice and guidance on how the OV and OV auditors should make the assessment to determine FBO compliance:

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Common Issues	OV advice / guidance
CCPs either not present or not identified correctly	<p>In certain food businesses, there will be steps in the process that are critical to the safe production of food, for example, cooking a raw food to a specified core temperature. A decision tree may be used to determine CCPs.</p> <p>On the other hand, a small-medium slaughterhouse or cutting plant handling raw meat may follow a generic approach where CCPs / CPs are pre-determined and so, whilst decision trees can be very useful in certain circumstances, there are times when a decision tree may not be needed.</p>

2.6 Principle 3: Establish critical limits / legal limits

2.6.1 Establishing limits

Establishing critical limits (or legal limits) at CCPs (or control points) which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards.

Reference: (EC) 852/2004 Article 5, 2(c).

Limits do not need to be a fixed numerical value that requires measurement. Limits can be monitored through visual observation, for example, faecal contamination of carcasses.

2.6.2 Difference between critical limits and legal limits

Critical limits separate acceptability from unacceptability or safe from unsafe food at CCPs. Critical limits must be at least as strict as legal requirements that apply at that process step for example, temperatures for raw meat.

LLs are values set out in the legislation, for example, storage temperatures for meat, absence of SRM and must be complied with, regardless of whether or not the FBO identifies a CCP based on a risk assessment.

2.6.3 Critical limits / legal limits – common issues

The following table contains examples of common issues that the OV and OV auditors could find when auditing and/or verifying HACCP based procedures. The table also provides advice and guidance on how the OV and OV auditors should make the assessment to determine FBO compliance:

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Common Issues	OV advice / guidance
Hygiene controls set as Critical Limits	<p>In a technical HACCP system CLs may include:</p> <ul style="list-style-type: none"> • values of temperature, time • maximum residue limits • maximum levels (of contaminants) • microbiological criteria • levels of chlorine
Hygiene controls set as Critical Limits,	<p>In some cases, the plan of HACCP-based procedures may not distinguish critical limits from the application of hygiene controls for example, cleaning procedures, maintenance procedures and pest control.</p> <p>Where FBOs have decided to have CPs (instead of CCPs) which are legal requirements, the LLs may include strict adherence to a hygiene control.</p>
Understanding the difference between compliance (through LLs) and risk assessment (through CLs)	<p>Ensure the FBO is fully aware of the need for compliance with legal limits first and foremost.</p> <p>Compliance should not be confused with the FBO risk assessment.</p>

2.7 Principle 4: Monitoring of CCPs / control points

2.7.1 Monitoring procedures

Establishing and implementing effective monitoring procedures at CCPs (or CPs).

Reference: (EC) 852/2004 Article 5, 2(d).

2.7.2 Monitoring procedures: common issues

The following table contains examples of common issues that the OV and OV auditors could find when auditing and/or verifying HACCP based procedures. The table also provides advice and guidance on how the OV and OV auditors should make the assessment to determine FBO compliance:

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Common Issues	OV advice / guidance
Monitoring procedures not recorded	<p>Monitoring procedures are an important part of a HACCP based system, in some cases monitoring may not be recorded, or recorded just to pass an audit or a verification check.</p> <p>FBO monitoring procedures should be meaningful, easy to understand and should relate directly to SOPs.</p> <p>Reference: See topic 2.10 on ‘Principle 7: Documentation’ in part 2.</p>
Plan not a true reflection of reality	<p>The monitoring procedures described in the plan should reflect what is actually happening at each process step and with each product.</p> <p>Where SOPs are documented, these should accurately reflect the activity they are related to.</p>
Disproportionate monitoring procedures	<p>Extensive record keeping may prove to be burdensome for an FBO to maintain (for instance when documentation / records have been produced by a third party (consultant) who does not understand the food business operations, for example,</p> <ul style="list-style-type: none"> • twice daily recordings carried out by staff of the temperature of all knife sterilisers using a probe thermometer; resulting in hundreds of manual checks per week • daily manual recordings of the air temperature of a chiller using a probe thermometer that is already monitored automatically and linked to a warning alarm. <p>Monitoring is ‘the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP (or CP) is under control’ therefore monitoring may or may not include written records of any checks carried out.</p> <p>Information recorded will be dependent on the risk of the operations; that is, the type of food and size of the business.</p> <p>Documentation should not cause an unnecessary burden to small – medium businesses.</p> <p>The FBO may choose to record by exception (using a diary such as the Food Safety Management Diary for Meat Producers) in</p>

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	<p>which case the amount and type of records will not be the same as those used in a traditional HACCP system.</p> <p>The Diary may also be the preferred choice of the FBO to record occasional checks, for example, product temperatures taken on a daily basis, rather than recording on separate sheets of paper.</p> <p>Reference: See the topic 2.10 on ‘Principle 7: documentation’ in part 2 for additional information.</p>
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2.8 Principle 5: Corrective action procedures

2.8.1 Establishing corrective actions

The food business needs to establish the corrective actions to be taken when monitoring procedures indicate that either a CCP or a CP is not under control.

Reference: (EC) 852/2004 Article 5, 2(e).

2.8.2 Corrective actions: common issues

The following table contains examples of common issues that the OV and OV auditors could find when auditing and/or verifying HACCP based procedures. The table also provides advice and guidance on how the OV and OV auditors should make the assessment to determine FBO compliance:

Common Issues	OV advice / guidance
Plan not a true reflection of reality	The corrective action procedures described in the plan should be reflected in what actually happens when the FBO loses control.
Corrective actions not recorded	<p>Corrective actions are an important part of a plan of HACCP-based procedures to help the FBO regain control of the process. In some cases, the actions taken may not be recorded as the FBO does not want to admit to failures. The impression given is that the FBOs never have any problems with their hygiene control procedures.</p> <p>In fact, the record of corrective actions shows that the plan based on HACCP principles is a ‘healthy’ plan that works effectively.</p> <p>Corrective actions should ensure that the risk to consumers are eliminated, prevented or reduced for example, immediate trimming of faecal contamination followed by a root cause analysis to prevent recurrence</p>

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Corrective actions not recorded	<p>Problems always occur and records should be made when they do.</p> <p>These records are important, not only for the FBO to validate and verify their own systems but also to enable verification of the HACCP based system by the OV and auditors.</p> <p>Examples on how to record corrective actions may include:</p> <ul style="list-style-type: none">• a comment made on a cleaning check-sheet identifying a non-compliance and a further comment when corrective action has been carried out in accordance with the HACCP plan.• Non-compliances recorded and the corrective action taken by use of a diary.
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2.9 Principle 6: Validation, verification and review

2.9.1 Validation

Validation in HACCP terms refers to obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

Validation is performed at the time a control measure or a food safety control system is designed, or when changes indicate the need for re-validation.

Validation of control measures is, whenever possible, performed before their full implementation.

2.9.2 Verification

Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan and aims to respond to the question: is it working?

FBOs need to establish verification procedures which shall be carried out regularly to verify that what is written in the HACCP plan is actually being carried out in the workplace.

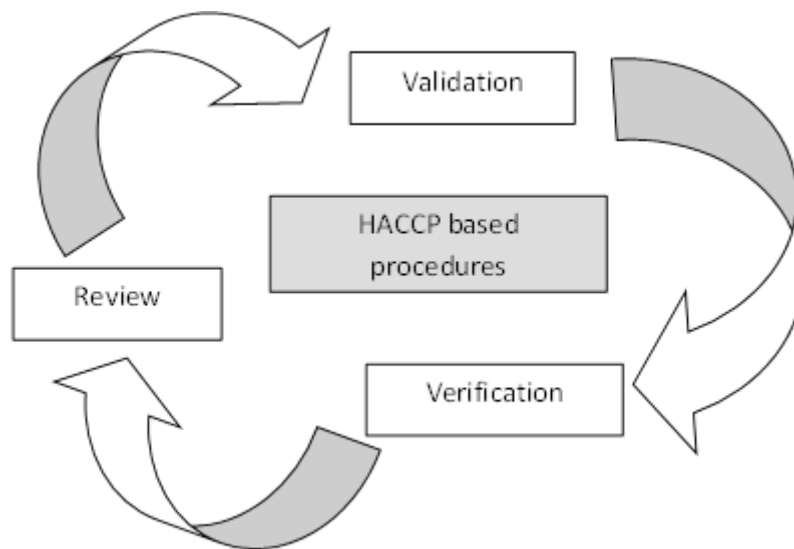
Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working and is effective.

Reference: (EC) 852/2004 Article 5, 2(f).

2.9.3 Review

When any modification is made in the product process, or any step, the food business operators shall carry out a review of the HACCP based procedure plan(s) to ensure that the plan(s) and associated documentation are up to date.

Reference: (EC) 852/2004 Article 5, 2.



2.9.4 Validation / Verification / Review: common issues

The following table contains examples of common issues that the OV and OV auditors could find when auditing and/or verifying HACCP based procedures. The table also provides advice and guidance on how the OV and OV auditors should make the assessment to determine FBO compliance:

Common Issues	OV advice / guidance
Plan not a true reflection of reality	The validation, verification and review procedures described in the plan should be reflected in what actually happens on the ground. The FBO should comply with the requirements set up in their food safety management programme or amend those if appropriate.
No records of Verification / Validation /	Plans based on HACCP principles allow for flexibility in the application. The FBO may combine validation (of the HACCP

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<p>Review of the HACCP plan(s)</p>	<p>plan), verification and review (of the system); as it may be difficult for the FBO to distinguish between them.</p> <p>Absence of separate validation / verification / review checks does not necessarily mean these have not been carried out.</p> <p>Verification of these procedures may be completed by an internal audit / or external audit(s) carried out by the competent authority or third party auditors.</p> <p>Examples of separate validation, verification and HACCP plan review forms are provided in the Food Safety Management Diary for Meat Producers, which the FBO may choose to use.</p> <p>If the Diary is used the 4-weekly reviews also accomplish verification of the FBOs hygiene controls.</p>
<p>Procedures not updated following modification of a product or process</p>	<p>Encourage the FBO to always consider, at the earliest opportunity, how modifications will impact on their HACCP based procedures.</p> <p>Although the modification may initially impact on a single product or process, it is just as important to review all products and processes to ensure any collateral impact is addressed.</p> <p>Ensure validation of new equipment is in accordance with technical specifications where appropriate.</p>

2.9.5 Microbiology

Microbiological testing is another way for the OV to verify (and the OV auditor to audit) the microbiological aspect of FBO HACCP based procedures.

Minimum microbiological requirements applicable to the FBO are contained in Regulation (EC) 2073/2005.

Surface microbiological testing is normally not a legal requirement but the FBO may decide to do so as a way of verification of the effectiveness of their cleaning procedures. However, FBOs producing ready to eat foods which pose a *Listeria monocytogenes* risk to public health must sample processing areas and equipment as part of their sampling scheme.

It is most important that if the OV or OV auditor wishes to verify HACCP based procedures using microbiological testing, that they use the same sampling sites, methods and techniques as the FBO.

Reference: See part 3 section 3 on ‘Verification of microbiological criteria’ for additional information.

2.10 Principle 7: Documentation

2.10.1 Establish documents and records

Establishing documents and records commensurate with the nature and size of the business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f):

- a. identifying hazards
- b. identifying CCPs (or control points)
- c. establishing critical limits (or legal limits) at CCPs (or control points)
- d. establishing and implementing monitoring procedures
- e. establishing corrective actions
- f. establishing verification procedures (including validation and review)

Reference: (EC) 852/2004 Article 5, 2(g)

2.10.2 Types of documents and records

Three types of paperwork are necessary:

- HACCP plan(s) documenting application of HACCP principles (may be a generic plan – amended to reflect the company procedures including prerequisites that are control measures)
- the company’s HACCP-based procedures, policies, staff instructions, SOPs etc (should include prerequisites as control measures)
- records of monitoring, corrective action, validation, verification and review (the Food Safety Management Diary may be used where appropriate)

2.10.3 Documentation: common issues

Common Issues	OV advice / guidance
Plan not a true reflection of reality	The documentation referred to in the plan of HACCP-based procedures should be reflected in those actually used on the ground by the FBO.
Disproportionate documentation	Documentation, especially if it is produced by an external adviser, may be disproportionate to the size, type of business and type of

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	<p>food produced. It may be too technical for the FBO or plant staff to understand or follow; it may duplicate existing records or seek to introduce a far more complex system of recording than is appropriate.</p> <p>Staff instructions and SOPs should be written in such a way that they are easily understood by users and verifiers (including OVs and auditors).</p> <p>Version control is of paramount importance to ensure that all FBO staff, OVs and auditors have the most up-to-date instructions.</p> <p>In these cases, it may be appropriate to encourage the FBO to consult with their adviser / consultant and work together to produce a workable, more easily managed HACCP based system, reminding the FBO that the HACCP based system is their control system and they should retain ownership.</p>
Inadequate documents/records	While documentation/records need not be complex and onerous it should provide sufficient information about the FBO procedures and controls

2.10.4 Food safety management diary for meat producers ('The Diary')

The use of the FSA's Food safety management diary for meat producers (the 'Diary') is an acceptable method of record keeping.

When using the diary, the FBO or any other responsible person should sign the Diary every day to confirm in a meaningful way that:

- opening, operational and closing checks have been carried out
- hygienic production has been followed
- what (if any) corrective actions have been taken

These should not be just a tick in a box for the sake of keeping a record: if these have been ticked the workplace must accurately reflect the check carried out. For example, areas are clean /, equipment is clean, knife sterilisers are working correctly.

The daily Diary pages are **not** intended to replace all existing documentation. They will need to be supported by additional record forms and procedures / staff instructions such as:

- individual staff training records
- cleaning schedules

- maintenance plans

The Diary provides examples of such documents that FBOs may adapt for their own use. FBOs may choose to keep such prerequisite records in the Diary binder.

The use of the Diary by FBOs is voluntary. It will not be appropriate in businesses that already have good existing records, and may not be entirely sufficient where, for example, the business is accredited to a Quality Assurance scheme or customers require more extensive documentation.

Reference: An [electronic version of the Diary](#) can be found online.

2.10.5 Exception recording

FBOs may choose to do exception recording, only to make record when a problem or something out of the ordinary is identified and the corrective actions to regain control. This applies particularly to checks that are more or less continuous for example, visual monitoring of each carcass, or where separate checklists are kept for example, cleaning checks.

Examples of exceptional recording:

- record when temperatures exceed the critical limit / legal limit and the action taken to regain control instead of having to tick / cross a separate list
- instead of making ticks and crosses in a cleaning checklist every day, an alternative could be recording only when cleaning problems are identified including the corrective action
- trimming contamination from a carcass
- recording problems that occur during a process for example, gut spillage during evisceration
- action taken when there are signs of pest infestation
- action taken if refrigeration equipment requires repair
- problems with faulty equipment and what was done to put it right
- staff not adhering to pre-requisite or other procedures and what corrective actions were required for example, supplementary or refresher training, cleaning of a piece of equipment
- knife sterilisers that are not working at 82°C or above and what corrective actions were required for example, repair / renew equipment

FBOs should nevertheless be encouraged to record the results of occasional checks to demonstrate that their procedures are working effectively, for example,

- periodic checks of knife sterilisers
- chiller temperatures

Note: The recording of corrective actions taken to regain control can be used to demonstrate that the HACCP plan is working effectively.

2.10.6 Management checks

Management checks are an integral part of FBO food safety management to ensure that management are fully engaged in the implementation of the HACCP plan and that prerequisite controls are working effectively.

Four weekly checklists are provided in the Diary to encourage FBOs to undertake a regular review of all aspects of their hygiene controls. There is space to record any persistent problems (which may include concerns raised by OV inspections or audits) or any significant changes that have been made and how they are being dealt with, including any consequences for their HACCP-plans.

Reference: See the topic 2.9 on 'Principle 6: validation, verification and review' in part 2 for additional information.

3. Audit and Enforcement

- 3.1 OV audit of HACCP principles and microbiological testing
- 3.2 Enforcement: HACCP

3.1 OV audit of HACCP principles and microbiological testing

3.1.1 Audit 9/3 form

OV auditors should use the audit report form AUD 9/3 on K2 to audit FBO compliance in the application of HACCP based procedures.

Reference: see K2 for the AUD 9/3 audit report form.

When one establishment has several HACCP based procedures plans, the OV auditor only needs to complete one 'HACCP based procedures' section of the form AUD 9/3 which will cover the audit findings for all the HACCP based procedures plans of one establishment.

3.1.2 Confidence in FBO's food safety management systems AUD 9/3

The results of the audit of the FBO compliance in the application of HACCP based procedures is one of the main audit components to be used by the OV auditors to determine the 'Food safety systems based on HACCP principles' (confidence in FBOs food management systems) score in part 2 of the form AUD 9/3.

3.1.3 HACCP audit objective

The objective of the OV audit should be to establish whether the FBO can show that they have implemented and are maintaining a system based on HACCP based procedures in compliance with the regulations and to the satisfaction of the competent authority.

Note: HACCP based procedures will not work without sufficient / adequate / appropriate prerequisites (good hygiene practices) being in place (as required by (EC) 852/2004 in particular).

3.1.4 Technical deficiencies

The plan based on HACCP principles may not be technically correct, but this does not make it invalid (or require formal enforcement action) as it may still be able to achieve the main purpose of controlling those hazards identified by the FBO.

Example:

A flow diagram may not correctly reflect the operations carried out; however, it is possible that there is no risk for public health as the risks have been correctly identified.

Reference: See sub-topic 3.2.1 on 'OV advisory role' in part 2 for additional information.

3.1.5 OV HACCP audit

The OV auditor should determine the FBO level of compliance through Section 5, (HACCP based procedures section) of the AUD 9/3.

The assessment in each section of the AUD 9/3 describes the compliance criteria as either 'compliant', or in the case of non-compliance, categorises that non-compliance as minor, major, or critical. The auditor uses their professional judgement to reach a decision on each criterion based on the evidence and also on the guidance provided in this chapter.

3.1.6 Microbiological testing audit

The OV auditor should verify that the FBO complies with the microbiological sampling requirements, laid down in Regulation (EC) 2073/2005, in accordance with Regulation (EU) 2017/625 and Regulation (EU) 2019/627.

OV auditor verification and reporting through question 3.9 (for slaughterhouses) or 3.13 (for cutting plants) of AUD 9/3 includes FBO responsibility for:

- sampling at the required frequency
- following the sampling rules
- interpretation of the sampling results (do these look manufactured or unrealistic?)
- identification of patterns and trends in test results

- identification of failures in the processing techniques that should have been identified and addressed
- corrective action, where necessitated by the results obtained
- a product recall, where necessitated as a result of unsatisfactory food safety criteria results

3.2 Enforcement: HACCP

3.2.1 OV advisory role

Where the OV finds that the FBO has HACCP based procedures but there are deficiencies that do not pose a public health risk, the OV should not serve a formal notice, but advise, educate and encourage rectification of the HACCP based procedures.

Reference: For [guidance on HACCP implementation](#).

The [electronic version of the Diary](#) can be found online.

The OV advisory role does not extend to personally writing any part of the FBOs food safety system for example, HACCP plans and monitoring documentation.

3.2.2 Objective evidence

It is essential to gather evidence of legal contraventions for example,

- the slaughter for human consumption of animals whose identity cannot be reasonably ascertained
- carcasses presented with faecal contamination at post mortem inspection, when these are related to the inadequacy (or non-existence) of the FBOs HACCP-based food safety management procedures

3.2.3 Notification to the FBO of deficiencies

If after verbal advice and an advisory letter the FBO has made:

- no effort to implement a food safety management system based on HACCP based procedures, or
- negligible effort to implement a food safety management system based on HACCP based procedures, or

- once implemented, the FBO has failed to maintain a system based on HACCP based procedures

The OV is to serve a Hygiene Improvement Notice (HIN) for each of the HACCP principles that are not being complied with, in line with the principles of enforcement in Chapter 7.

Reference: (EC) 852/2004, Chapter II, Article 5 and (EC) 853/2004, Annex II, Section II.

3.2.4 Establishment functions

Separate HIN's are to be served on each of the establishment's approved functions, in line with the principles of enforcement in Chapter 7, such as slaughtering and cutting. Separate notices avoid:

- having to withdraw an entire notice that has only be partially complied with
- the suspension of entire notices because of appeals over one issue
- the service of more notices on those areas still outstanding

3.2.5 Time scales for compliance with formal notices

The timescale for compliance with the HIN will depend upon the size of the establishment, the nature and complexity of the operations and the history of compliance of the FBO. The OV is responsible for making an assessment of the specific circumstances for the plant to provide a reasonable timescale in line with the enforcement concordat and risk based procedures (it is proportionate).

3.2.6 Failure to comply with the notice

If the FBO fails to comply with a formal notice, the OV should consult with their regional manager before deciding on the next step.

Reference: See chapter 9 on 'Forms'.

The OV must keep a record of the FBOs progress on HACCP implementation made after a recommendation for prosecution has been made. This will help identify actions that should have been taken earlier and will help to counter any mitigating factors that the FBO puts forward if the case goes to court.

3.2.7 OV records of FBO compliance

The OV must keep records of any advice given to the FBO in the establishment daybook.