Food Standards Scotland
Inbhe Bìdh Alba

sfelc
Scottish Food Enforcement Liaison Committee

OFFICIAL CONTROL VERIFICATION

Guidance on the application of Official Controls within Food Establishments subject to approval under Regulation (EC) No 853/2004

Version 1

FOREWORD

This document provides a methodology to be applied when undertaking official control activities within establishments subject to approval under Regulation (EC) No 853/2004 in Scotland. Its objective is to provide a framework which, when uniformly applied across all Competent Authorities in Scotland, will ensure a methodical and consistent approach that meets the requirements of the legislation, secures a high level of public health protection and protects the reputation of Scottish food businesses.

The document is primarily intended to be applied by officers delivering official controls in establishments subject to approval under Regulation (EC) No 853/2004, however, these principles and tools may be used when delivering official controls in high risk manufacturing establishments. Implementation of this approach in this sector should be considered at a local level.

FSS recognises this approach as key to ensuring that Scottish businesses are approved and inspected in a consistent manner and that a high degree of public health protection is afforded. The Society of Chief Officers of Environmental Health in Scotland supported the creation and development of this document and welcomes the introduction of scientific rigor and structure to the inspections that are key to driving continuous improvement. The Scottish Food Enforcement Liaison Committee, endorsing the document, has indicated that the application of the principles and techniques espoused within will help to ensure that Official Control inspections within relevant establishments will be delivered in a systematic and rigorous manner.

All three organisations would like to extend their gratitude to the Scottish Food Enforcement Liaison Committee Approved Establishments Working Group for the commitment, time, expertise and support its members have demonstrated in the development of this document. It is also appropriate to recognise the specialist expertise provided by Andy MacLeod of Argyll and Bute Council, who provided the genesis of the principles and approach enshrined in the guidance and Lorna McCoull of Glasgow City Council, who was instrumental in the document's progress.

Approved Establishments Working Group

Chair	William Hamilton	Glasgow City Council
Members	Lynne Bisset	Falkirk Council
	Rita Botto	Food Standards Scotland
	Izzy Childs	City of Edinburgh Council
	Graeme Corner	The Highland Council
	Grainne Gilson-Smith	Food Standards Scotland
	Lynsey Glover	Aberdeenshire Council
	Andy MacLeod	Argyll and Bute Council
	Dawn Manson	Shetland Islands Council
	Lorna McCoull	Glasgow City Council
	Andy Morrison	Aberdeen City Council
	Lorna Murray	Food Standards Scotland
	Derek Oliver	East Lothian Council
	Oana Tatura	Food Standards Scotland

The Approved Establishments Working Group is also pleased to acknowledge the helpful contributions provided by:

Julie Baxter	Dumfries & Galloway Council
Samantha Bull	Aberdeen City Council
Vikki Halliday	Food Standards Scotland
Marlene Munro	The Highland Council
Lorna Ross	Aberdeenshire Council
Gillian Scott	Dumfries & Galloway Council
Amber Souter	Food Standards Scotland

Pilot Authorities: Aberdeen City Council, Aberdeenshire Council, Argyll and Bute Council, Dumfries and Galloway Council, East Lothian, Fife Council, Food Standards Scotland, Glasgow City Council, The Highland Council, and Shetland Islands Council.

CONTENTS

1. INTRODUCTION TO OFFICIAL CONTROL VERIFICATION (OCV) 3

1.1 Background 3

1.2 Scope of the Guidance 3

1.3 Aim of the Guidance 5

1.4 Objective of the Guidance 5

1.5 Inspection Context 5

2. THE OFFICIAL CONTROL VERIFICATION APPROACH 6

2.1 The Aims of OCV 6

2.2 The Objectives of OCV 6

2.3 The OCV Principle 6

2.4 Overarching Approach to OCV 7

2.4.1 The OCV Process 7

2.4.2 Verifying the Food Control Management System (FCMS) 8

2.4.3 Verifying Implementation (Reality Check 1) 10

2.4.4 Verifying Implementation (Reality Check 2) 11

2.5 OCV Evidential Considerations 13

2.5.1 Elective Sampling 13

2.5.2 Random Sampling 13

2.5.3 Combined Elective and Random Sampling 13

2.5.4 Evidential Triangulation 13

2.6 The OCV Modular Approach 14

2.7 Tools for the Application of OCV 15

3. APPLICATION OF OFFICIAL CONTROL VERIFICATION 16

3.1 Preparation and Planning for OCV 17

3.1.1 Document Request 17

3.1.2 Business Profile 17

3.1.3 Concept Mapping 17

3.1.4 Resource Requirements 17

3.1.5 The Scope of OCV 17

3.1.6 The OCV Inspection Cycle 18

3.1.7 Timing, Advance Notice and Co-ordination of Inspections 18

3.1.8 Project Planning Tools 18

3.1.9 Adapting to Different Scales and Types of Establishment 19

3.1.10 Examples Showing the Application of the OCV process 20

3.2 OCV Document Review and Inspection Preparation 24

3.2.1 The Use of Forms 24

3.2.2 Business Profiling 24

3.2.3 OCV Study and FCMS Review 24

3.2.4 Verification of the Hazard Analysis 24

3.2.5 Evaluation of the Validation Process 26

3.3 The OCV Reality Check 26

3.3.1 Verifying FCMS 26

3.3.2 Reality Check Methods 29

3.3.3 Evidential Triangulation 32

3.4 The Closing Meeting 32

4. OFFICIAL CONTROL VERIFICATION TOOLS 33

4.1 Business Profiling 34

4.2 Concept Mapping 35

4.3 The Staircase Model 37

4.4 Triangulation and Gap Analysis 39

4.5 Evidential Triangulation 41

4.6 Elective Sampling 42

4.7 Random Sampling 43

4.8 Random Number Generation 44

4.9 Work Breakdown Structure 45

4.10 PERT Chart 47

4.11 Gantt Chart 48

4.12 Structured Interview Techniques 50

4.13 5W 1H Analysis 52

4.14 Mass Balance and Product Recall/Withdrawal 53

4.15 Root Cause Analysis 56

4.16 Statistical Analysis and Predictive Modelling 59

5. FORMS 63

Form A
Inspection Cycle Summary Sheet 64

Form B
Business Profile Form 66

Form C
FCMS Review Form 71

Form D
Physical and Prerequisites Inspection Check 83

Form E
Reality Check 94

6. ANNEXES 98

ANNEX 1
Resource Calculation 98

ANNEX 2
Pre-Inspection Documentation Schedule 104

GLOSSARY 108

1. INTRODUCTION TO OFFICIAL CONTROL VERIFICATION

This document promotes the implementation of broad principles which may be used when verifying food control management systems (FCMSs) during Official Control inspections within approved and some manufacturing establishments.

1.1 BACKGROUND

An effective Food Control Management System (FCMS) is critical to the protection of consumers against foodborne illness and prejudice. Consequently, any verification of a FCMS conducted during an Official Control inspection must be systematic, structured and scientific. It must ensure that the FCMS is verified – both in terms of its validation and of its implementation.

Official Control Verification (OCV) has been developed to fulfil these criteria. OCV was developed by the application of deductive logic to the challenge of delivering the most effective and consistent Official Controls. In its practical application, OCV represents both the application of deductive and inductive logic.

Hazard Analysis and Critical Control Point (HACCP) is an internationally-recognised, scientific and systematic approach to assuring food safety. Accordingly, HACCP is integrated into OCV and this document steers officers towards a similarly systematic inspection process incorporating HACCP as an inspection tool. It is assumed that any person applying the guidance within this document has sufficient awareness of HACCP principles and their application in practice.

Officers are guided towards the use of the techniques of cross-referencing and triangulation between three 'cardinal points' of reference which are integral to the verification of FCMSs. In so doing, the confidence in the verification of the safety of a food production process and the relevant FCMS is enhanced.

The process of gap analysis, incorporating all three cardinal points is used to verify the safety of the operation.

1.2 SCOPE OF THE GUIDANCE

For the purposes of this document, the scope of a FCMS is taken to include Food Safety, Food Standards, Food Fraud and General Food Law. This approach integrates issues such as Article 5 of Regulation (EC) 852/2004 (hazard analysis and critical control point), allergens, labelling and product disposition control within the scope of the FCMS as well as wider issues such as Threat Assessment Critical Control Point (TACCP) and Vulnerability Assessment Critical Control Point (VACCP).

This guidance defines an approach which can assist in delivering effective and consistent verification inspections. The approach relates both to the initial approval process as well as to subsequent routine full inspections and other Official Control interventions.

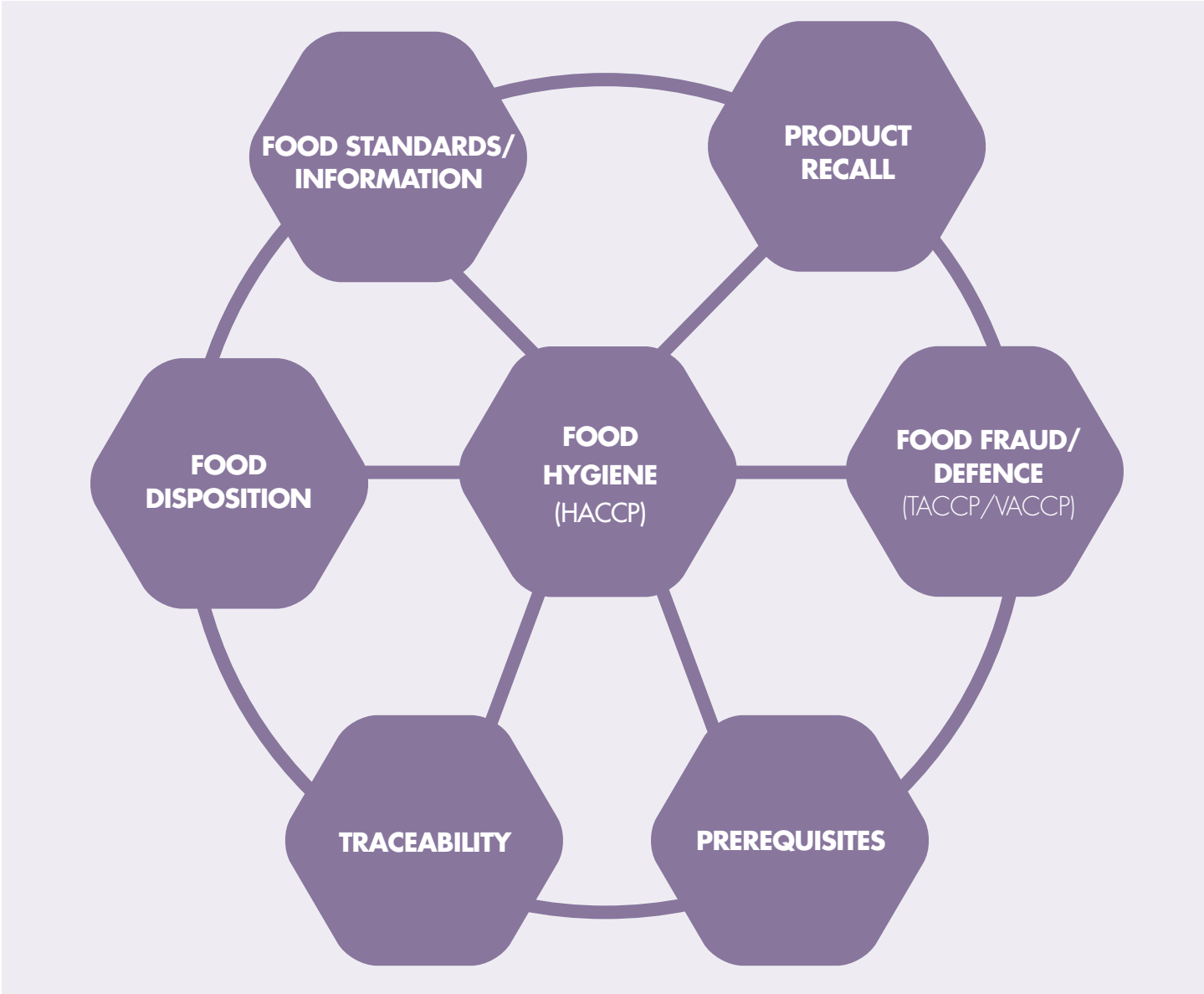
All of the elements of a FCMS are considered, including the prerequisite programmes, traceability, HACCP Studies, HACCP plans and product description. By applying the principles, the officer should be able to make judgments on the validity of the FCMS and on the effectiveness of food controls being applied by the Food Business Operator (FBO).

In order to ensure consistency, this document uses the term "inspection" throughout. The term relates to the intervention type most applicable to the concepts and processes contained within. However, it should be noted that the term "intervention" is used when referring to Official Control visits in the general sense.

The approach should be applied in its entirety at least once during approval and during any subsequent inspection cycle post-approval. In practice, this is likely to require multiple inspections/ partial inspections, the use of a modular approach and sampling techniques to ensure that the FCMS is verified.

In recognition of the fact that manufacturing and processing establishments are diverse in nature, the document is, necessarily, generic. It focuses on a general approach to be applied by officers of Competent Authorities. It does not seek to provide in-depth examination of specific food processes. However, it does – where appropriate – provide examples of specific processes in order to illustrate certain aspects of the approval/inspection process.

Figure 1.1: Considerations within Food Safety Management Systems



1.3 AIM OF THE GUIDANCE

The aim of this document is to provide guidance to the officers of Competent Authorities on the verification of FCMSs in general terms and, more specifically, of those within establishments subject to Approval under Regulation (EC) 853/2004. In particular, it aims to provide assistance when verifying compliance with Article 5 of Regulation (EC) 852/2004.

1.4 OBJECTIVE OF THE GUIDANCE

The key objective is to promote a science-based, structured and systematic approach to verifying a FCMS. This approach has both integrated and developed the guidance on the Regulatory Assessment of HACCP published by the WHO/FAO. Accordingly, the guidance closely integrates the concept of the HACCP Study and verifying techniques into the inspection process.

This document is not intended as a guide to HACCP. Nor is it designed to be a replacement for training and an in-depth knowledge of HACCP and FCMS verification techniques. Both are considered to be essential core skills for the verification of FCMS.

1.5 INSPECTION CONTEXT

The overarching procedures associated with the receipt of a new application may differ significantly from those relating to routine, programmed intervention. This document does not seek to specify how approval applications should be processed but rather to describe the approach which should be applied to the inspection process in all contexts.

When assessing a new application, the officer must verify the FCMS in its entirety, before granting approval. However, when carrying out routine, programmed official controls, an officer may see fit to split the FCMS verification process into a series of shorter, partial inspections (see Chapter 3).

2. THE OFFICIAL CONTROL VERIFICATION APPROACH

This chapter is intended to provide an overview of the Official Control Verification (OCV) approach. More detailed guidance is contained within subsequent chapters.

2.1 THE AIMS OF OCV

The ultimate aim of OCV is to protect the consumer. The OCV process includes the verification of both the safety of the food production process and the authenticity of the food produced together with the supporting elements of process control. The OCV process constitutes an integrated Official Control, addressing all of the requirements of Food Law.

OCV aims to provide a scientific, structured and systematic set of principles. It is the application of the critical thinking processes necessary for establishing Official Controls as a discipline and for supporting effective and consistent Official Controls in practice. OCV was developed from the standpoint of the practical application of Official Controls.

2.2 THE OBJECTIVES OF OCV

The objectives of OCV are to verify whether:

- The FCMS is capable of eliminating (or reducing to an acceptable level) all food hazards; and
- The FCMS is capable of producing authentic food that is without prejudice to the consumer; and
- The FCMS is effectively controlling the food production process, i.e. that there is overall process control over:
  - the disposition of food products and ingredients;
  - non-conforming products;
  - waste products and packaging; and
  - traceability, lot-marking and product recall/ withdrawal systems.
- The FBO has carried out, has validated and is verifying an appropriate and effective HACCP Study on their food production process (including Prerequisite Programmes and Operational Prerequisite Programmes as appropriate).

2.3 THE OCV PRINCIPLE

OCV is based on the premise that food must be safe and authentic when the FBO places it on the market. On this basis, it is essential that two aspects must be true, i.e. that the FBO **intends to do** the correct thing and the FBO is, in fact, **doing** the correct thing.

Thus, there are two considerations, as follows:

1. FBO Proposal – (Validation)
   Is the FCMS valid?
   (i.e. does the FBO intend to do the right things in the first place?)
   - Is the FCMS capable of satisfying food control requirements?
   - Are all of the components of the FCMS (including process control, identification and analysis of hazards, control measures, critical limits, monitoring activities, corrective actions, verification systems, documentation systems and authenticity measures) actually validated in terms of protecting the consumer?

2. FBO Implementation – (Verification)
   Is the FCMS verified?
   (i.e. Is the FBO actually doing what he or she intended to do?)
   - Is the FBO doing what the FCMS says that they should be doing?
   - Are all of the components of the FCMS (including process control, identification and analysis of hazards, control measures, critical limits, monitoring activities, corrective actions, verification activities, documentation systems and food authenticity systems) actually being carried out in reality?

2.4 OVERARCHING APPROACH TO OCV

The two questions above can be answered by a process of Triangulation between the 3 Cardinal Points, i.e:

1. The FCMS;
2. The OCV Study; and
3. The Implementation of the FCMS in reality.

This is a simple process, where the officer applies Gap Analysis, i.e. compares and contrasts, in order to verify the adequacy, suitability and implementation of the FCMS. This involves two main steps:

1. Gap Analysis between the FCMS and the OCV Study; and
2. Reality Check – Gap Analysis between the FCMS and its actual implementation in practice (while also carrying out Gap Analysis between the OCV Study and the FCMS in practice).

Overall, OCV inspection is essentially a process of 'triangulation' between three points of information.

Where there is a fully-validated and a fully-verified FCMS, the 3 cardinal points will reconcile and the officer will have verified a process that can be considered to be "under control", i.e. producing safe and authentic food. This situation of reconciliation is called 'Triangulation'.

Where there is neither a fully validated nor a fully verified FCMS, then the 3 cardinal points will not reconcile and the officer will have verified that the process may indeed not be "under control", i.e. it may not be producing safe and authentic food. This is called a Gap – see Chapter 4.

The OCV Study plays a critical role, by providing a reference point that is **external** to and **independent** of the FCMS and the operation in practice. The OCV provides a sound standpoint from which the validity of the FCMS can be verified.

The OCV Study should be based upon the WHO-CODEX. Accordingly, the scientific principles of Food Control Management (including HACCP) are embedded within the OCV methodology (described in subsequent sections) enabling the officer to verify the validity of the FCMS before then verifying its implementation. Crucially, the OCV Study avoids the error of simply verifying the implementation of an invalid FCMS.

2.4.1 The OCV Process

The Triangulation and Cardinal Points concepts are described below (and in further detail at Chapter 3).

The triangulation process helps to answer the key questions:

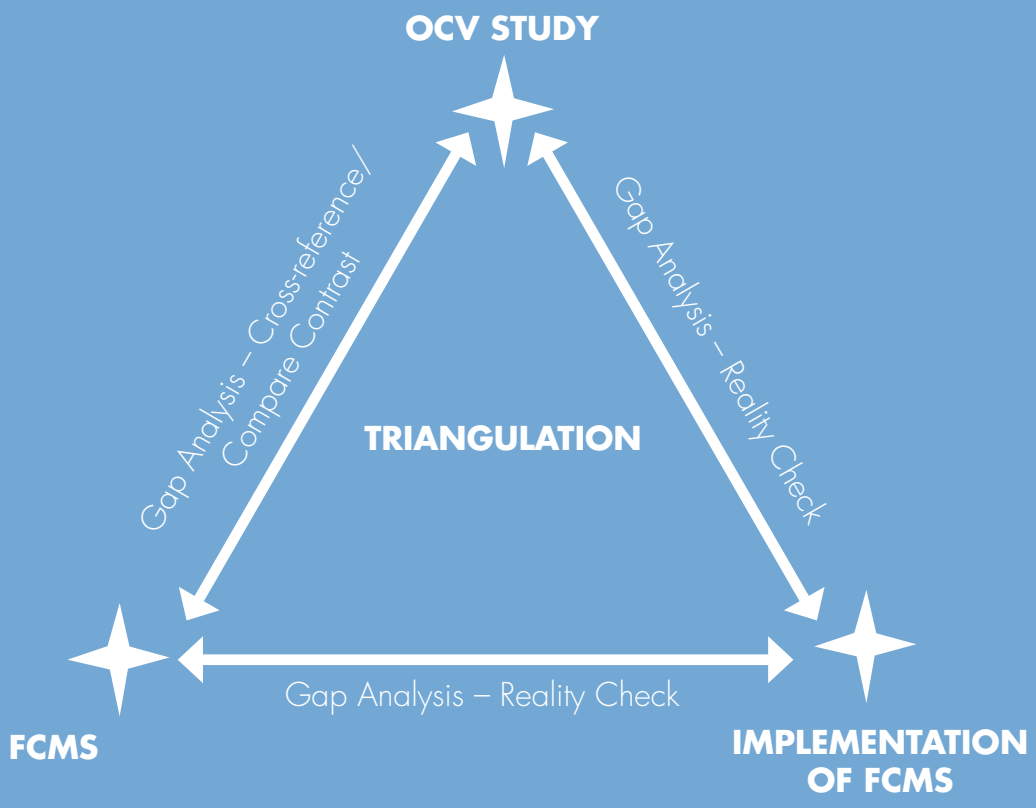
- Does the FBO say that they intend to do the right things?
  This is answered by Gap Analysis between the OCV Study and the FCMS. This constitutes Official Control Verification of FBO Validation; and

- Is the FBO actually doing what they intended to do?
  This is answered by Gap Analysis between the FCMS and its implementation in reality. This constitutes OC verification of FBO verification. A related question is: Are both the OCV Study and the FCMS verified in situation?

This related question of reality-checking verifies that the OCV Study and the FCMS are both verified as accurate and effective in the actual context of production. This also integrates a natural reality check for the OCV Study (which might, in whole or part, be conducted off-site) and ensures that OCV reaches valid conclusions.

The second question also identifies those situations where the operation is actually functioning safely, but has deviated from the written FCMS, i.e. the FCMS 'on paper' has become invalid. This is common in small and medium-sized establishments, where the operation is altered and the documented FCMS is revised afterwards. This process need not be inherently unsafe, although it indicates a lack of rigour which could lead to loss of control in the future.

Figure 2.1: The OCV Process



The OCV Study and the processes of GAP Analysis tend, as they are undertaken, to be simultaneous. This approach can be applied flexibly to any element within the FCMS.

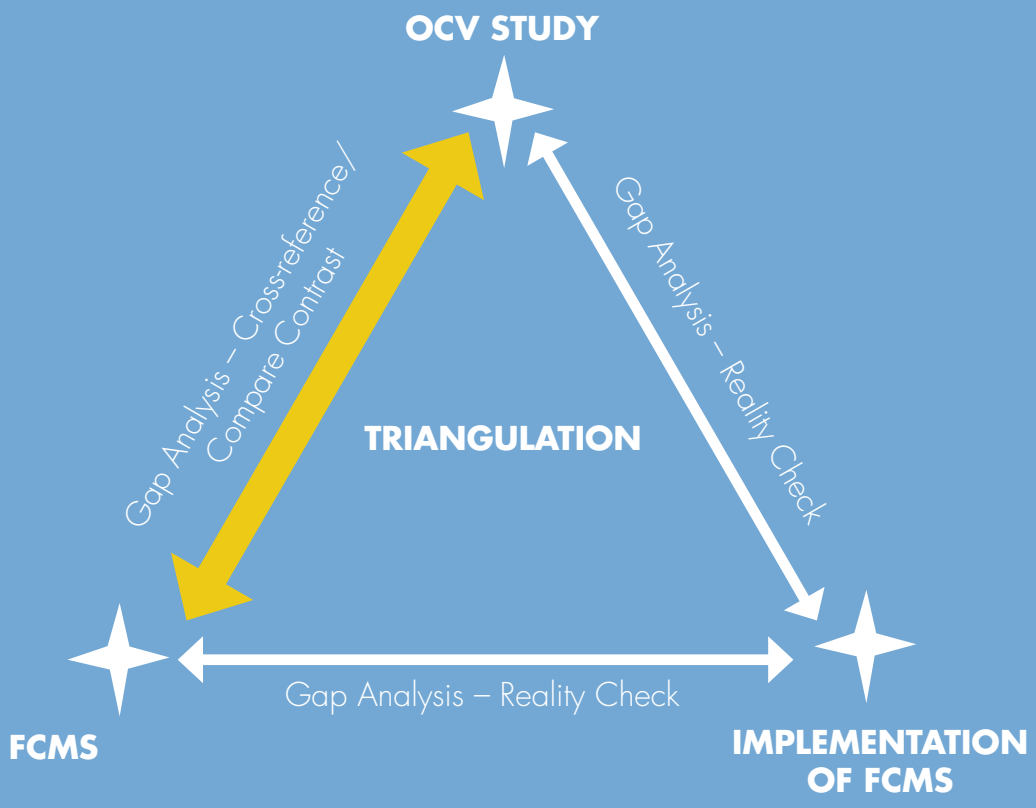
In fact, both the OCV Study and the FCMS will be composed of a large number of parts (e.g. process control, hazard identification and analysis, prerequisite programmes etc) each of which can be extracted from the OCV Study and the FCMS and treated as individual triangulations. Such an approach breaks down the overall OCV Study and the FCMS into modules, which are easier to verify in practice. The outcome of this process will amount to verification of the entire FCMS as above. This approach is returned to in subsequent Chapters.

While the underlying concept of triangulation is relatively simple, its application to all relevant aspects of the FCMS can be a complex process. Officers require to be suitably trained and supported by this guidance document, the use of a suite of tools (see Chapter 4) and the use of a suite of Forms (see Chapter 5 – Forms A-D).

2.4.2 Verifying the FCMS

This process is intended to establish whether the proposed actions of the FBO are correct in the first place. The validity of the FCMS is challenged by the process of Gap Analysis between it and the OCV Study. Figure 2.2 represents this process.

Figure 2.2: Comparison between the OCV Study and the FCMS



Example 2.1:
Invalid FCMS – Botulism caused by consumption of Hazelnut Yoghurt

The largest outbreak of foodborne botulism in the UK occurred in 1989, when 27 people became ill and one person died, after eating hazelnut yoghurt made with cans of hazelnut purée. The purée was the source of botulinum toxin.

Control of the outgrowth of C. botulinum is achieved by one or more factors:

- appropriate heat treatment;
- maintaining an acid pH (<4.5); or
- water activity (a_w <0.97) throughout the food.

The pH of the puree was >4.5 and the heat process employed in its manufacture was insufficient to destroy spores of C. botulinum. The manufacturer normally relied on the growth of C. botulinum being inhibited by low a_w – as a consequence of the product's sugar content.

The product formulation of the puree was altered by the FBO without a re-validated hazard analysis. Sugar was replaced by aspartame – which does not lower water activity to the same degree as sugar. This, together with storage of the purée at room temperature, permitted growth of the organism and production of toxin type B to levels of 600-1800 MLD/ml.

A properly-conducted gap analysis between the FBO – Step 6 and OC Step 6 would have identified the existence of the gaps which made the FCMS invalid and led to a food poisoning incident.

Example 2.2: Invalid Product Formulation – Gourmet Foods – Nata de Coco Cubes and Wasabi Cream

A specialist manufacturer of gourmet foods claimed that Nata de Coco (fermented coconut juice solidified into cubes) and wasabi was "100% natural". An officer applied a tool called Elective Sampling in order to select products that were known to be the subject of food-fraud. The officer then conducted a Gap Analysis referencing the OCV Study and the FCMS verifying that the Nata de Coco was being imported from the Philippines and that its formulation included added sugar and water, i.e. it was not made entirely out of coconut milk.

Similarly, the officer verified that the wasabi formulation contains UK-sourced horseradish, mustard and a blend of colourants composed of spirulina, annatto and turmeric, in order to impart a green coloration. In effect, the product was not pure wasabi.

The gap analysis between the OCV Study and the FCMS verified that the FBO had made a false claim regarding these products.

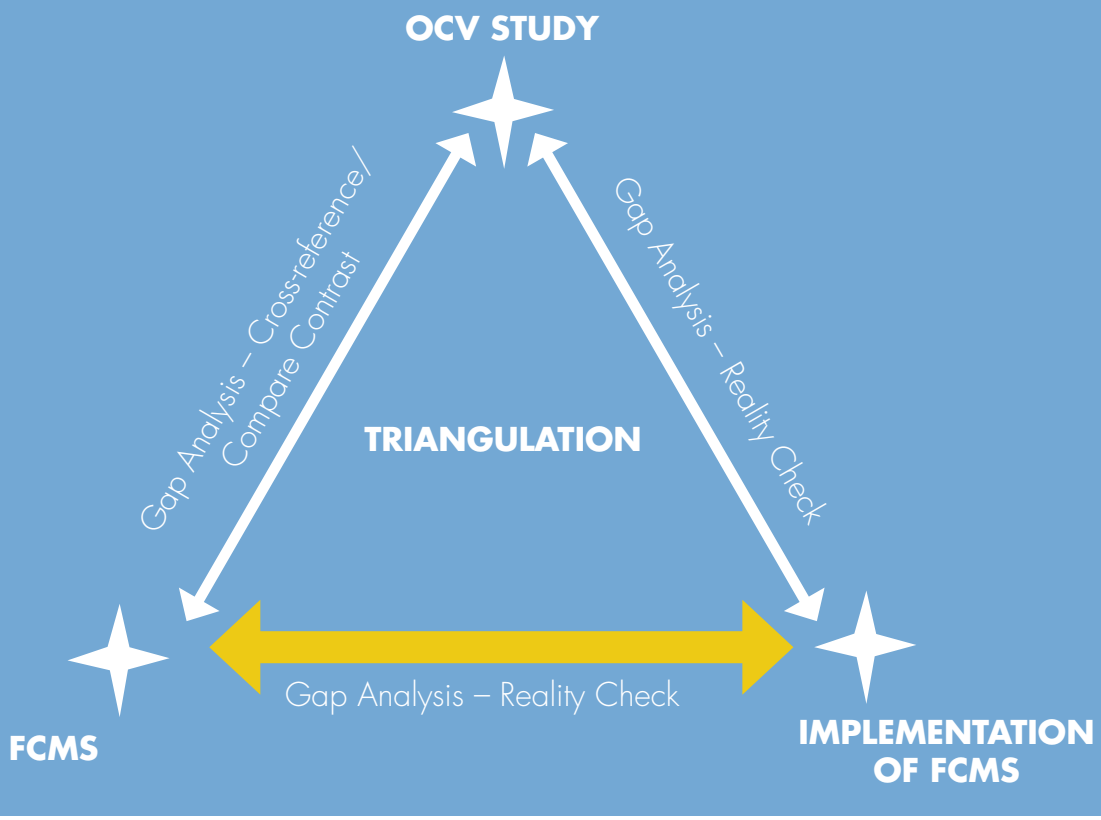
2.4.3 Verifying Implementation (Reality Check 1)

(see also Chapter 3)

This process is intended to establish if the FBO is actually doing what he/she says that they intended to do.

Implementation is verified by a process of Gap Analysis between the FCMS and the operation in practice. This may be captured in Form D. Figure 2.3 below represents this process.

Figure 2.3: Gap analysis between the FCMS and the implementation of the same in reality



Example 2.3: Reality Check – Salmonella Typhimurium in Peanut Products

In 2008/2009, nine people died and at least 691 people fell ill in 46 US states due to food poisoning from eating products containing peanuts. Half of those affected were children. The illness was established to have been caused by S. typhimurium.

A combination of epidemiological analysis and laboratory testing by state officials in Minnesota and Connecticut, the Food and Drug Administration (FDA) and the Centre for Disease Control and Prevention (CDC) confirmed that the sources of the outbreak were peanut butter, peanut paste, and peanut meal produced by the Peanut Corporation of America (PCA) at its Georgia processing plant. Significant on-going non-conformance with basic prerequisite programs, and recurrent FBO-authorised overrule of EPT-based Positive Release systems (which had previously detected the presence of salmonella on several occasions) were the cause of the outbreaks.

If conducted within the appropriate timeframe, OCV would detect a gap between the FCMS and the operation in reality, in the form of prerequisite programmes and HACCP Steps 10 and 11.

Example 2.4: Reality Check – Monitoring of Metal Detection in Wild Game Processing

During an inspection of a wild game establishment, the officer verified the FCMS for the production of small wild game breast fillets. The FCMS stated that the last CCP was the metal detection at the packaging step.

During the inspection, the officer discussed the methodology behind the metal detection checks and established that there was only one Quality Assurance (QA) officer carrying out these checks. However, there were 3 lines used for packaging this product, most of the time working simultaneously. The monitoring sheets used had pre-printed times on them, all with 8 am, 12 pm and 4 pm. It would be impossible for one person to carry out an elaborate test on 3 lines at the same time.

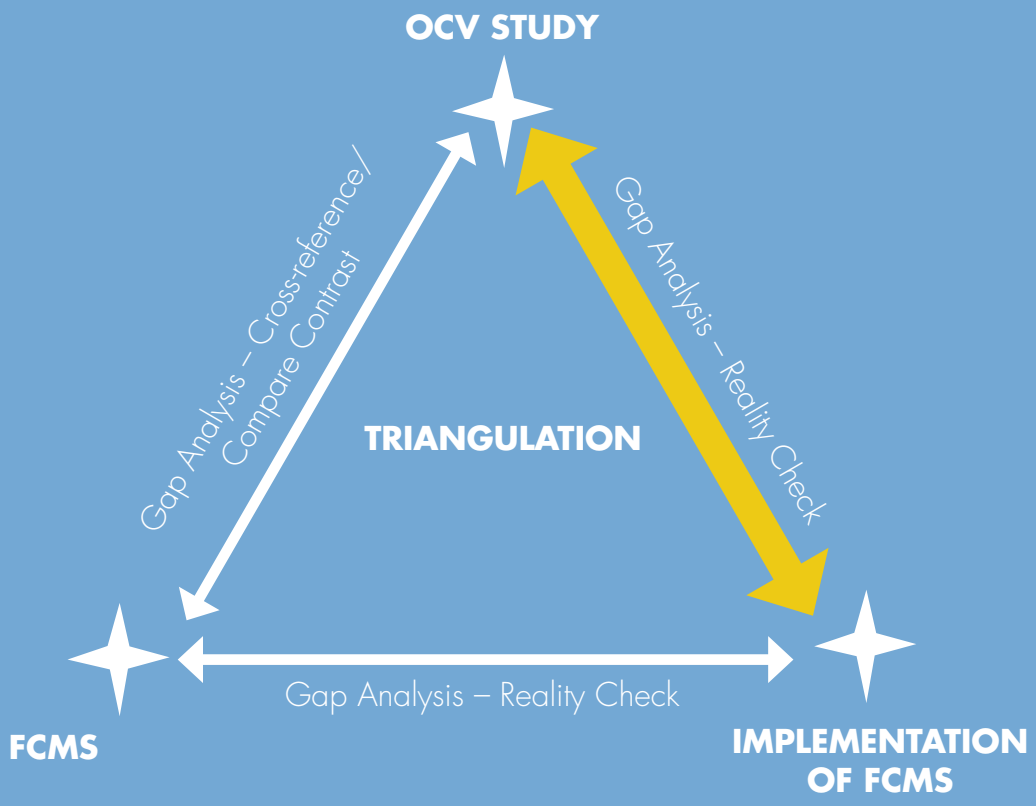
A gap analysis between the FCMS and its implementation has identified that the FBO was unable to actually implement the documented FCMS in reality.

2.4.4 Verifying Implementation (Reality Check 2)

(see also Chapter 3)

This process is intended to establish whether the FBO is producing safe and authentic food in the actual production environment, i.e. it verifies that the OCV Study and the FCMS are validated and verified in situ. This process complements the reality check process described by Figure 2.3 above and is represented in Figure 2.4 above (see also Chapter 5 – Form D).

Figure 2.4: Gap analysis between OCV Study and Implementation of the FCMS



Example 2.5: Reality Check – Listeriosis Caused by Mexican-Style Soft Cheese

In 1985, a California listeria outbreak led to 52 confirmed deaths, including 19 stillbirths and 10 infant deaths. This represented the deadliest recorded foodborne illness outbreak in the United States. The food vehicle was Mexican-style soft cheese made by the Jalisco Company in California. Jalisco had a non-licensed technician perform the pasteurisation process. It is believed that pasteurised milk was contaminated with non-pasteurised milk by the same technician.

If conducted within the appropriate timeframe by a suitably trained officer, OCV would be equipped to detect a 'Gap' between the OCV Study, the FCMS (both requiring the use of a licensed competent technician) and the operation of the process in situ which did not provide such a competent person.

2.5 OCV EVIDENTIAL CONSIDERATIONS

OCV requires that conclusions relating to both the **positive** and the **negative** aspects of the FCMS are based upon objective evidence. OCV also requires that both the **positive** and the **negative** aspects are also recorded, including the objective evidence that supports the conclusions reached. Adequate recording – both negative and positive – is critical to the effectiveness of OCV.

2.5.1 Elective Sampling

FCMSs in larger or complex manufacturers are often very extensive and it may not be desirable or effective to verify the entire FCMS at one time. Elective sampling offers a potential alternative whereby specific and representative elements of the FCMS are selected for verification (see Chapter 4).

Notwithstanding the need to representatively sample elements of the FCMS, certain elements will naturally be more significant than others – such as those that address high risk products. The following list includes examples of the most significant elements that officers may elect to verify:

- All Critical Control points – including HACCP Steps 6 to 12;
- All Operational Prerequisite programmes;
- Validation of all control measures and of critical limits;
- Process flow diagrams within high risk zones;
- Rework operations particularly those related to corrective actions;
- Waste disposal operations relating to high risk RTE foods;
- Labelling of allergenic products; and
- Provenance and traceability of raw materials, e.g. shellfish, beef or high value foods.

2.5.2 Random Sampling

Random sampling techniques may offer efficiency at low risk elements (see Chapter 4). In order for this approach to be valid, the representativeness of the sampling is critical. The elements of the FCMS that are selected for verification must be sufficient in number and must also be representative of the entire FCMS, i.e. they must be sampled without any bias. One approach is to use a random number tool (see Chapter 4) in order to ensure that there is no bias. This technique may also be used to select which element of the FCMS to verify.

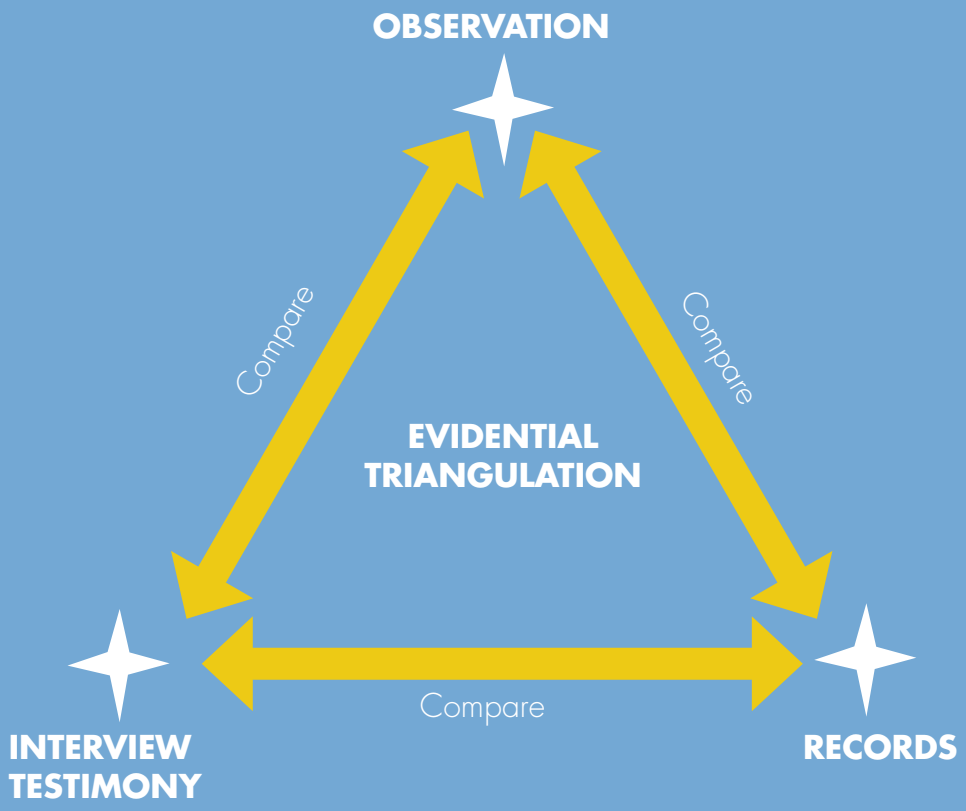
2.5.3 Combined Elective and Random Sampling

OCV also promotes combinations of Elective and Random sampling, for example the Elective sampling of Steps 6-10 of the FBO's HACCP and the random sampling of the associated records.

2.5.4 Evidential Triangulation

As well as being applicable to the overarching process of verification of the FCMS, the technique of triangulation can also be applied to all aspects of the system and to different sources of evidence. Where there is confirmation between three or more sources of evidence, the findings have been shown to be more robust. Figure 2.5 represents how Triangulation can be applied to different sources of evidence, in order to enhance the certainty of verification (see Chapter 4).

Figure 2.5: Evidential Triangulation Model



2.6 THE OCV MODULAR APPROACH

A modular approach can help simplify the inspection of complex manufacturing operations. It can be used, together with concept mapping, to identify critical connections between associated parts of the FCMS for verification purposes (see Chapter 4).

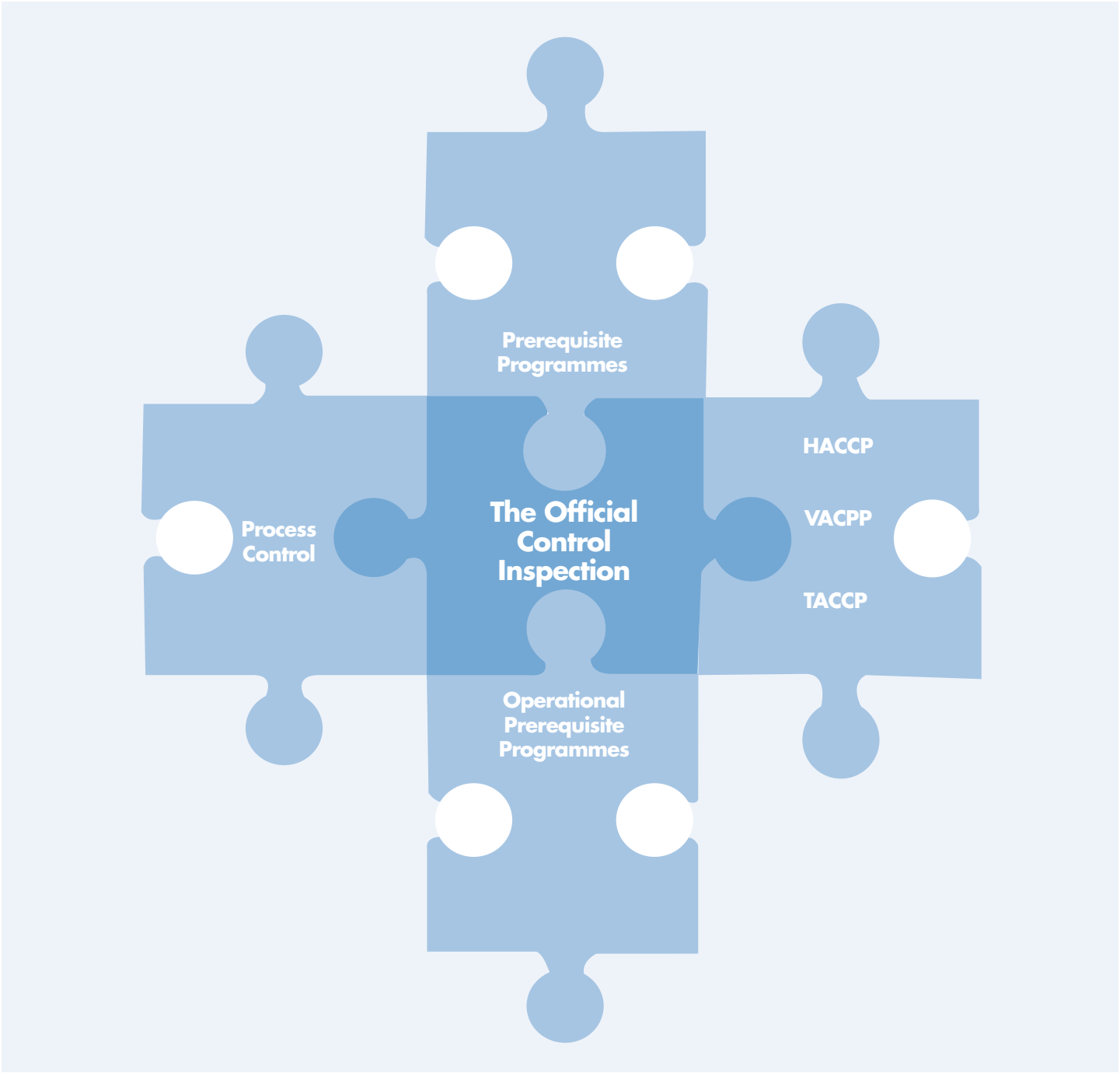
Once the nature of the task has been mapped out, the officer may then determine how the overall inspection will be planned and delivered.

Consequently, each stage of the FBO's own HACCP Study and other elements of the FCMS – such as product disposition control, product recall, cleaning and disinfection and pest control, may each become the subject of separate focus.

This approach can be applied flexibly throughout the entire inspection process during, for example, the Document Review and the Reality Check phases. This may be applied during the course of one visit, e.g. one officer focusing on Traceability and Product Recall/Withdrawal, while another is carrying out a check of the production of a specific product.

Ultimately, however, the officer must retain a sufficiently wide focus, in order to be able to draw any critical inferences linking different elements of the FCMS.

Figure 2.6: Official Control Inspection



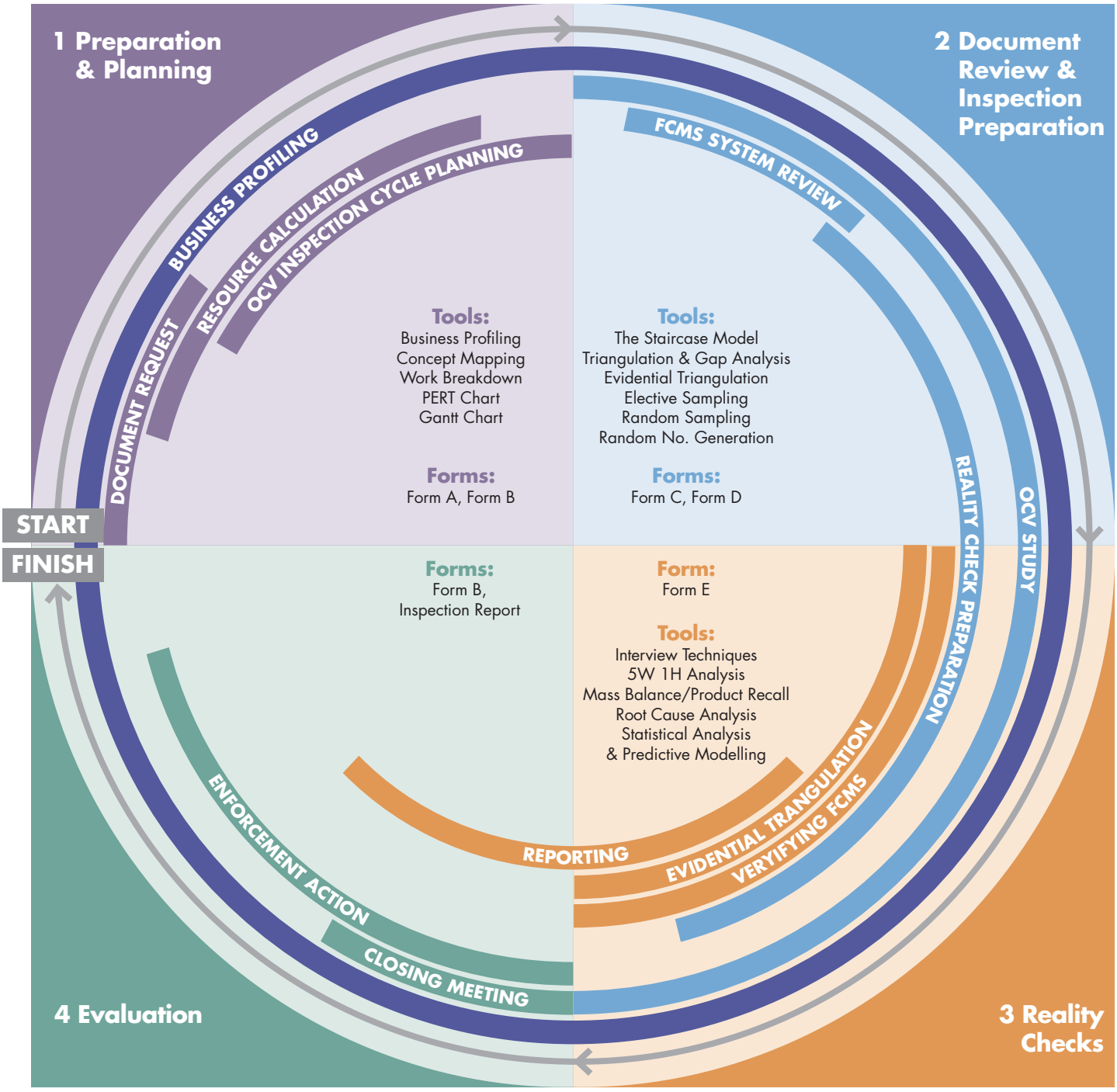
2.7 TOOLS FOR THE APPLICATION OF OCV

The OCV process is supported by the use of a range of tools. The core concepts of OCV, i.e. Triangulation and Gap Analysis, can be applied in practice through the application of these tools which are described within Chapter 4.

3. APPLICATION OF OFFICIAL CONTROL VERIFICATION

The OCV approach should be applied in its entirety at least once during each inspection cycle. In practice, this should comprise a Preparation and Planning stage, a Document Review stage and a Reality Check stage with Triangulation and Gap Analysis integrated throughout. In practice, this is likely to require the use of the Verification Tools contained in Chapter 4, multiple/partial inspections, the use of a modular approach and sampling techniques to ensure that the FCMS is verified in full. Chapter 3 looks at each of these in detail.

Figure 3.1: The OCV Inspection Cycle Model



3.1 PREPARATION AND PLANNING FOR OCV

During the preparation and planning stage, the officer gathers information in order to profile the business, to fully understand the processes, (the food science and technology of the process, its hazards and its epidemiological history) and also to define the scope of the verification activities.

3.1.1 Document Request

Gathering objective evidence to support the verification of both the positive and negative aspects of a complex FCMS is a major task. One rational approach is to use the FBO's FCMS itself as objective evidence. According to this approach, the FBO provides the appropriate elements of the FCMS in advance of the main inspection and the officer carries out the review while off-site.

Officers will be selective when requesting information for off-site review. The template document request form (see Annex 2) provides numerous, generalised elements of a FCMS.

3.1.2 Business Profile

The Business Profile Form (see Chapter 5 - Form B) can be used to record the profiling of the FBO's establishment. This captures the more or less static information about the establishment including broad risk profile. This is covered in more detail at Chapter 3.

3.1.3 OCV Mapping

A useful technique for both understanding and representing the broad shape and form of the FCMS and for planning such an inspection is the Concept Map. This method enables the officer to map the broad shape of the FCMS, identify its most critical elements and assist with the planning verification (see Chapter 4).

Another related technique is to break the inspection down into manageable elements which are the subject of systematic focus, i.e. a modular approach (see Chapter 2).

This has the benefit of allowing the officer to focus on specific areas, thereby gaining a better understanding of the documentation/processes etc under review. This approach also allows officers to consider the nature of each establishment individually.

3.1.4 Resource requirements

To allow the effective planning of inspections and effective allocation of resources, it is necessary to estimate the time required to undertake the full verification process in accordance with this document.

A standard method, based on ISO 22003:2007, for estimating the minimum time required for an inspection can be found in Annex 1.

The Inspection Cycle Summary Sheet (Chapter 5 – Form A) provides a record for the resource calculation.

3.1.5 The Scope of OCV

Defining the scope of the inspection is a key activity which will ensure that the inspection is a rigorous and systematic process, applying the aims and objectives of the inspection appropriately to the circumstances of the individual food business. The officer must take into account the factors listed below and adjust the scope accordingly. For example, if at the document review stage it is established that there are shortcomings with the validation of the FCMS, then it is appropriate that validation should become the principle part of the inspection.

Whether a full or partial assessment is carried out will depend upon the original purpose of the inspection. For example, a partial inspection (or some other intervention) might be appropriate where it is related to a particular incident or issue and is for investigatory purposes or for closing out non-compliances.

Accordingly, defining the scope of the inspection will assist in planning the inspection.

The following is a non-exhaustive list of the factors that will influence the scope of verification:

- Whether it is an initial assessment or follow-up;
- Whether it is a full inspection or another type of intervention specified within the Food Law Code of Practice;
- The nature and complexity of the operation, i.e. the type of products (e.g. RTE which require more attention based on risk than non-RTE) and processes, particularly the food science and technology, used by the business;
- The number of HACCP studies to be assessed;
- The nature of prerequisite programmes;
- The volume of production/throughput/turnover;
- The level of in-house expertise and adequacy of resources available to the HACCP team;
- The number of employees;
- The validation status of the FCMS;
- The nature of the Food Safety Management System, e.g. ISO 22000/ISO9000/BRC/SALSA;
- The results of previous assessments; and
- The population at risk.

(see Annex 1)

3.1.6 The OCV Inspection Cycle

When planning a programmed official control intervention in existing establishments, it is essential that the entire FCMS will be verified within each Inspection Cycle. The officer may choose to break the verification process down into two or more visits, taking account of the likely time demands involved. Each of the visits would involve the verification of different aspects of the FCMS.

The Inspection Cycle Summary Sheet (Chapter 5 – Form A) can be used by officers to document the purpose and outcome of the visits.

3.1.7 Timing, Advance Notice and Co-ordination of Inspections

In addition to the resource allocation required, there are several other factors that should be considered when planning inspections:

- The optimum time to view specific processes or operations;
- The operating times of the establishment;
- The need for occasional out-of-hours visits during evenings or weekends, i.e. when visits are 'not expected';
- The need to speak to a particular person or persons, e.g. the FBO or the Quality Assurance Manager; and
- The need for an appointment.

Officers should note that in most cases, official control inspections should be unannounced.

It is acknowledged, however, that in order to apply the OCV approach in full it may be necessary to give advance notice of at least one of the inspections in each inspection cycle. For example, at some large manufacturing establishments, prior notice of inspection may be needed to ensure that the appropriate management and/or technical representatives are present for the visit. Alternatively, in some small operations, the only person with sufficient knowledge of the business may be absent – unless prior notice is given.

3.1.8 Project Planning Tools

FCMSs are often highly complex. Accordingly, the inspection must be planned systematically – in cognisance of the amount of time required. The extent of the FCMS must be assessed and the number of FBO HACCP Studies, CCPs and prerequisite programmes determined. There are many different planning tools which could be utilised. Officers should understand that these are optional – a flexible approach to planning is recommended.

Three related tools are as follows:

A. The Work Breakdown Structure (WBS) (see Chapter 4)

A WBS is often the first stage of a project plan. It considers the whole scope of the complex project and breaks it down into bite-sized chunks.

B. The PERT Chart (see Chapter 4)

PERT stands for "Program Evaluation Review Technique". It is a tool used to schedule, organise and co-ordinate tasks in the completion of official control verification (see Chapter 4).

A PERT chart defines and makes visible pathways between WBS elements. Each activity is identified. The chart is built-up with tasks, mapping whether it is a parallel or sequential task.

The PERT chart can be used to inform the Gantt chart.

C. The Gantt Chart (see Chapter 4)

The Gantt chart is used to produce the final verification plan as per the WBS and PERT approaches. The Gantt chart (which takes the form of a horizontal bar chart) illustrates the start and end dates of the project and shows the relationships between tasks (some tasks will need to be completed before others can begin, whilst others can run simultaneously). The Gantt chart will evolve as verification progresses (see Chapter 4).

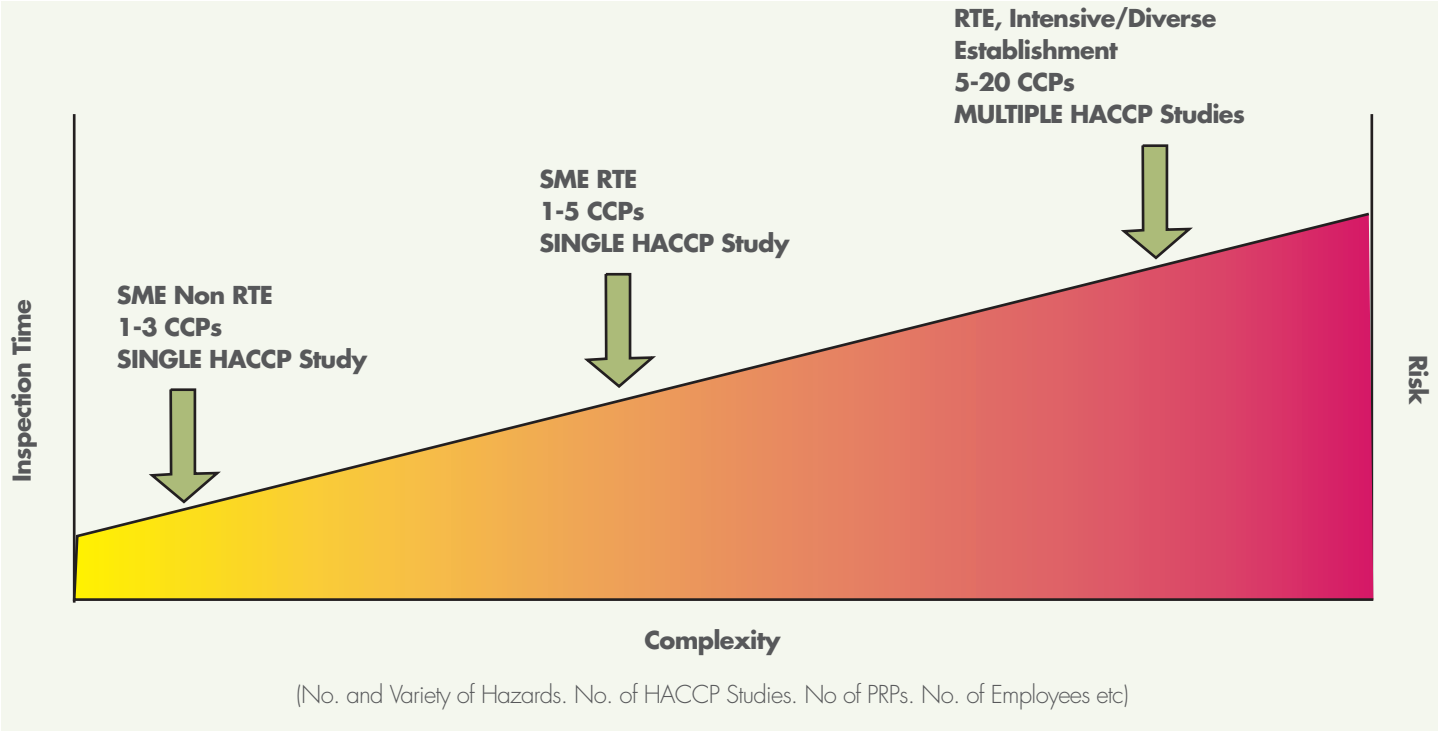
These planning tools inform and follow on from each other in a sequence that can produce a systematic verification plan scheduled over an inspection cycle.

3.1.9 Adapting to Different Scales and Types of Establishment

The nature and scale of food establishments can vary enormously. Some businesses are very small and may involve simple processes and/or produce low risk foods. Conversely, some establishments may be very large or have highly complex processes and/or produce high-risk foods. The principles and processes contained within this document can be applied to all establishments which are covered by the scope referred to in Chapter 3.

It is acknowledged that complex, large and high-risk establishments will place greater demands upon Competent Authority resources than their simpler, smaller and lower-risk counterparts. This principle is represented in the graph at Figure 3.2 below.

Figure 3.2: Graph showing relationship between complexity, risk and inspection time



3.1.10 Examples showing the application of the OCV process

OCV can be applied in all circumstances. The officer resources required will vary according to the nature and scale of the establishments.

Example 3.1: Application of the OCV Process – Simple Process, Cold Store Establishment Synopsis

- Independent cold store – storing poultry, red meat and meat preparations;
- Located in Central Scotland, supplying caterers in Central Scotland;
- Five employee in the cold store and three delivery drivers. (Own their own delivery vehicles);
- The FBO is generally based on site;
- No electronic record of sales or storage, traceability is by incoming and outgoing invoices;
- One HACCP study covering storage of all products.

Planned Inspection Time/Resources

Applying the Resource Calculation in Annex 1 and their experience of the establishment, the officer anticipates that the inspection cycle will comprise:

- Document Review – 0.25 days;
- On Site Time – 0.75 days.

It is estimated that one single, unannounced visit will be sufficient to allow the full FCMS to be audited.

Activities

- Using the Pre-Inspection Documentation Schedule (Annex 2) as a guide the officer identifies the relevant information they require from the business and e-mails this request to the FBO;
- During the week prior to the proposed inspection date, the officer reviews:
  - All updated information provided by the FBO (if provided);
  - The Business Profile Form; (Chapter 5 – Form B);
  - The OCV study – making updates if required;
  - The previous FCMS retained on file (if an updated copy has not been provided) (The FCMS Review Form (Chapter 5 – Form C) is updated if necessary at this time);
  - Establishment file, including history of compliance and previous inspection reports;
  - On the day of the inspection, the officer arrives unannounced at the premises. The inspection is timed to coincide with incoming deliveries which are known to arrive early in the morning. The officer meets briefly with the FBO, who is based on-site to update the information on the Business Profile Form (Chapter 5 – Form B).
- The officer begins the process of auditing the FBO's FCMS by observing the incoming delivery process. Each stage in the HACCP chart is then audited, finishing with the outgoing delivery process. At all stages, the officer carries out a gap analysis recording details of any deviation from the FBO's FCMS or the OCV Study. The officer uses evidential triangulation to verify compliance with the FCMS, recording their evidence including:
  - Details of the members of staff interviewed;
  - List of records viewed;
  - Details of measurements taken, e.g. officer's temperature checks;
  - Physical observations;
  - Photographs.

The findings are summarised in Chapter 5 – Form E.

- Following the Reality Check of the establishment, the officer meets with the FBO and conducts a mock recall/mass balance exercise for a product randomly selected by the officer. The officer also requests additional prerequisites documentation, completing Chapter 5 – Form D.

Example 3.2: Application of the OCV process – Small/Medium Process – Fish Processor (see also Annex 1 – Resource Calculation)

Establishment Synopsis

- Fishmonger filleting raw fish for retail sale to the final consumer and wholesale to caterers;
- Customers within approximately 100 miles of the premises;
- Establishment also has cold store approval for fishery products (including ready-to-eat) and live bivalve molluscs which are not processed on site;
- Three employees process fish, two sales staff and three delivery drivers;
- The FBO is generally based on site, however, is actively involved in the processing of fish so is often too busy to sit down and discuss information with officers in detail;
- No electronic record of sales or storage, traceability is by incoming and outgoing invoices;
- Two HACCP studies – one for processing of fish and one for cold storage.

Planned Inspection Time/Resources

Applying the Resource Calculation in Annex 1 and their experience of the establishment, the officer anticipates that the inspection cycle will comprise:

- Document Review – 0.75 days (increased from estimated 0.5 in calculation tool due to handling (but no processing) of RTE foods);
- Unannounced Inspection – 0.5 days;
- Announced Inspection – 0.5 days;
- **Total = 1.75 officer days**.

Although the on-site aspect of the inspection could reasonably be completed within one day, the officer anticipates that an announced visit would be beneficial at a time convenient to the FBO to allow time to discuss in detail some aspects of the FSMS. The processes carried out have changed very little over the years and reports of inspection indicate that issues tend to relate to non-compliance with the food safety management system. Therefore, the officer considers it appropriate to carry out the unannounced inspection first to allow them to identify areas of concern for more detailed discussion with the FBO at the announced inspection.

Activities

The inspection is planned and conducted as follows:

- Prior to the proposed inspection date, the officer e-mails the FBO and requests the relevant information from the Pre-Inspection Documentation Schedule (Annex 2);
- During the week prior to the unannounced inspection, the officer reviews:
  - All updated information provided by the FBO (if provided);
  - The Business Profile Form (Chapter 5 – Form B);
  - OCV Study – making updates as required;
  - The current FCMS system retained on file (if an updated copy has not been provided). (The FCMS Review Form (Chapter 5 – Form C) is updated, if necessary, at this time);
  - The establishment file, including history of compliance and previous inspection reports.

[Input = 0.75 FTE Days]

On the day of the unannounced inspection, the officer arrives at the premises and briefly meets with the FBO to update the information on the Business Profile Form and clarify that the version of the HACCP charts they are preparing to audit is current.

The officer begins to audit the FBO's FCMS by 'walking the line', discussing – and, where possible observing – each stage of the HACCP charts, annotating a copy of the relevant Process Flow Diagram as they do so. At all stages, the officer carries out a gap analysis recording details of any deviation from the FBO's FCMS or the OCV Study. The officer uses evidential triangulation to verify compliance with the FCMS, recording the following evidence:

- Members of staff interviewed;
- Records viewed;
- Measurements taken e.g. officers temperature checks with calibrated probe thermometer, ATP swab results;
- Physical observations;
- Photographs.

The findings are summarised on Form E Chapter 5 cover sheet.

A general physical inspection of the premises is also conducted and observations recorded in the 'other observations' section of the Reality Check Form (Chapter 5 – Form E).

Before leaving the premises, the officer discusses any potentially uncontrolled hazards or gaps with the FBO and arranges a suitable date and time for the announced visit to complete the inspection cycle. **[Input = 0.5 FTE Days]**

On the day of the announced inspection, the officer clarifies the information on the Business Profile Form (Chapter 5 – Form B) and updates it where appropriate.

They then discuss their comments from the FCMS review carried out before the inspection, non-compliance observed at the reality check audit and the HACCP validation and verification with the FBO.

The officer then completes the Physical and Pre-requisites Form, reviewing copies of relevant documentation and records and detailing the evidence on the inspection form (Chapter 5 – Form D).

Whilst reviewing incoming invoices, the officer randomly selects a product received two days previously from a supplier and requests that the FBO carry out a mock recall/mass balance for the product. While the FBO is looking out the relevant invoices and customer contact details, the officer inspects the processing area to assess the effectiveness of actions taken to address the non-compliances noted at the unannounced inspection.

A final closing meeting is then held with the FBO to discuss the officer's findings and proposed actions and recommendations (see Chapter 3). **[Input = 0.5 FTE Days]**

The activities described in the preceding case studies should be compared with those undertaken in a larger, more complex operation.

Example 3.3: Application of the OCV Process – Complex, High-Risk Manufacturer

Establishment Synopsis

Manufacturer of a wide range of ready-to-eat smoked fish and shellfish products where the shelf life is extended by vacuum.

- Products are grouped into modular HACCP studies; there are six HACCP studies to verify;
- There are 17 CCPs and 5 OPPs;
- The FCMS is comprehensive and is accredited to ISO 22000;
- Cleaning and disinfection is undertaken throughout the night by a separate dedicated night shift team;
- The establishment is supplied by a private water supply;
- There are 140 employees.

Planned Inspection Time/Resources

Applying the Resource Calculation in Annex 1, the officer determines that the main verification inspection will require the following input:

- Document Review – 1 day (1 Officer day);
- Research – 0.5 Days (1 Officer day);
- Main Verification Inspection – 1 day (2 Officer days);
- Announced and unannounced Reality Check Inspection – 3.5 days (7 Officer days).

Total = 11 Officer days (e.g. 55 FTE hours)

The officer decides that it is appropriate to break the inspection down into manageable portions and to schedule the inspection into 6 partial inspections over the 12 months of one inspection cycle, ensuring that the entire FCMS is verified during this period.

Activities

The Inspection is planned, diarised and conducted as follows:

- **Pre-Inspection** – Documentation Schedule is issued annually;
- **Document Review** – Pre-inspection Document Schedule (Annex 2), studied along with FBO's FCMS documentation (**Input = 1.4 FTE days**);
- **OCV Study;**
- **January 12th – FCMS Verification & plan of elective and random sampling of the FCMS.** The officers complete the FCMS Verification and plan to verify the high-risk elements of the FCMS as early as possible during the Reality Check, sampling lower-risk elements of the FCMS by random sampling for later subsequent verification. (**Input = 1.6 FTE days**);
- **January 15th – Pre-announced Reality Check.** Opening meeting, 'walking the line', verify the validity of PFDs sections electively sampled on a high-risk basis, verify the validity of the FCMS by cross-referencing the EPT and production records data. The Officers verify that the FCMS, on the basis of the objective evidence, is actually valid. (**Input = 1.6 FTE days**);
- **January 19th – Unannounced Reality Check.** Verify implementation of all SOPs for CCPs and verify implementation of ORPs on the factory floor. (The Officers split verification duties.) Officers discuss their findings and then cross-reference OPs against a random sample of 3 SOP production records for each CPP and OPP. They verify that the establishment is implementing critical controls – using the objective evidence available. Further documentation is requested in order to complete this verification off-site. (**Input = 1.6 FTE days**);
- **February 1st (1.00 a.m. to 2.30 a.m.) – Unannounced Reality Check.** Verify all SOPs for the Cleaning and Disinfection PRP applying the same general pattern as on January 19th above. (**Input = 1.6 FTE days**);
- **March 15th – Pre-announced Reality Check:** The officers use random sampling to select a high-risk product from the product range. One officer undertakes a Mass Balance from the production records and requires that the FBO simulates a product recall to be completed within 3 hours and makes observations. The other Officer conducts a Process Control verification of the entire process throughout the factory taking into account Master Manufacturing instruction, traceability, lot marking and provenance elements of the FBO's FCMS. The officers then meet and discuss their respective findings. They conclude that on the basis of the objective evidence, they have verified process control. (**Input = 1.6 FTE days**).

The officers conclude that they have verified the most critical elements of the FCMS and elect to undertake the verification of the remaining, less critical elements much later in the inspection cycle as follows:

- **July 15th Announced Reality Check:** The officers verify all remaining PRPs using random sampling to select three SOP records from each PRP. They verify with step 11 by referring to internal and external audit reports and to HACCP team minutes. They verify compliance of every product label. They conduct a close-out meeting with the Managing Director and the Technical Manger summarising their overall findings. (**Input = 1.6 FTE days**).

3.2 OCV DOCUMENT REVIEW AND INSPECTION PREPARATION

During the document review stage the officer gathers information, carries out the OCV Study and begins to compare and contrast this with the FCMS to identify those areas which require more or less attention during the subsequent reality check stage.

3.2.1 The Use of Forms

A suitable form or checklist should be used to enable a systematic and objective approach to verification. It also directs activities within the scope of the inspection.

Forms in Chapter 5 have been designed to reflect the inspection processes and tools in this guidance. Where alternative forms are used as the official record, these should be sufficient to demonstrate that the FCMS has been verified.

3.2.2 Business Profiling

The process should commence with the officer constructing a general profile of the business; and includes:

- Checking and cross-referencing information held on the business profile and risk profile;
- Identifying the general food safety hazards and authenticity vulnerabilities;
- Making an assessment of the general food safety risks associated with the business; and
- Documenting an overview of the FCMS.

Profiling ensures the officer has current information on the business. The officer can use Business Profile Form (Chapter 5 – Form B).

3.2.3 OCV Study and FCMS Review

The officer must acquire a sound working knowledge of the FBO's process and the FCMS and its validation status – prior to the on-site inspection. It is strongly recommended that current FCMS information relating to manufacturing establishments is retained in the establishment file. Ideally, the Competent Authority should be provided with updates and controlled amendments made to the FCMS by the business.

The review process constitutes a vital part of the overall inspection, establishing a broad risk profile of the business, to prepare and to inform the officer. Sufficient time resource must be devoted to the review and research, commensurate with the risk and/or complexity and size of the food business operation.

Officers may wish to supplement their understanding by undertaking additional research in order to inform themselves of relevant information that might not be held within the business file or database. For example, food hazards associated with the food products and processes and experience of these hazards in the past. The officer can use 'the staircase' (see Chapter 4), at this stage as a model to model and to represent the Controlling Factors/ Control Measures which the officer has identified as the controlling factors for the product. This can be used to inform the OCV Study for the product.

The officer may use Form C in Chapter 5 to help give direction to the review of the FCMS and as a guide to documenting the official record. Alternative methods of documenting the assessment (for example see Chapter 4), may offer a visual representation of the same information.

The officer should review and become familiar with product descriptions, including the vital product safety aspects, in order that the FCMS can be verified in relation to these underpinning descriptions.

3.2.4 Verification of the Hazard Analysis

Accurate verification of the hazard analysis is vital to the aims and objectives of the inspection.

Effective FCMS are founded upon accurate identification of the relevant hazards. Thus, if this vital early step within a FCMS is incorrect, a hazard or hazards can remain out of control throughout the entire FCMS. This can occur where a relevant hazard has been overlooked or discarded in error, during the hazard analysis process. Where this happens, it is possible that the necessary control measures will also be omitted.

These errors can be compounded by the inclusion of irrelevant hazards. In such cases irrelevant (and sometimes expensive) measures, intended to control a non-existent hazard, can be put in place, serving to distract the business from the real hazard.

Officers should be aware of the problems associated with generic groupings of hazards – such as 'microbiological, chemical and physical' etc. Bacteria, for example, have different physiological growth requirements which means that they are opportunistic contaminants under differing conditions. As a consequence, species-specific control measures may be required to control them. Officers should be prepared to undertake the appropriate, in-depth research on the process, its food science and technology, its microbiology and its epidemiological history. Particular attention may be required to new and emerging issues.

Allergens and additives are considered as types of chemical hazards.

The officer should research the history of the safety of the product (or like products) and apply systematic hazard analysis to the OCV Study.

Relevant literature may provide information on hazards associated with the products and inform upon key specific food science and technology aspects. In effect, preparation involves more than looking at the file and the FCMS. Verifying the hazard analysis often requires considerable research and experience.

HACCP Steps 5 – 6

There are three key considerations when verifying the Hazard Analysis:

1. Adequacy

   The adequacy of the hazard analysis is vital, particularly in relation to whether all significant hazards have been identified and that the analysis has been undertaken for all products and processes within the scope of the inspection.

2. Evidence

   When assessing the analysis of hazards, the officer may require access to supporting evidence from the FBO at this stage. This may take the form of, for example:

   - Records of the hazard analysis process;
   - Records of validation;
   - End product testing results;
   - History of the safety of the product;
   - Generic plans; and
   - Relevant and appropriate predictive models where they have been used.

3. Competency

   Officers will gauge the competence of the people identified as responsible for the FCMS study – in particular, those conducting step 6.

   One method of doing this is for the officer to take sections of the process flow diagram, preferably a high-risk section and, without reference to the HACCP control chart, carry out his/her own desktop study using their own knowledge and reference material.

   At this stage, the officer may also consider the following:

   - Have significant food safety hazards been included or have any been omitted?
   - Have hazards and control measures been precisely defined or are they vague and general?
   - Has the hazard analysis been carried out systematically, ideally using the contributory factors, i.e. using the PIIGS/PIIMS format (or alternative) to associate or map the hazards to process steps where it is relevant to do so in terms of epidemiology?
   - Have control measures been identified for each specific hazard, are they realistic and scientifically valid?

Consideration should also be given at this stage as to whether:

- Control measures eliminate or reduce identified significant hazards to acceptable levels (HACCP Steps 7 and 8);
- Monitoring activities at CCPs are sufficient to identify any loss of control (HACCP Step 9);
- Identified corrective actions will prevent unsafe food from entering the food chain (HACCP Step 10); and
- Verification procedures are adequate and effective (HACCP Step 11).

3.3 THE OCV REALITY CHECK

The purpose of the Reality Check main or 'on-site' inspection is to verify that procedures and practices described in the FCMS (including the prerequisites programmes) are adequate in order to protect the consumer – and are actually implemented in reality.

The scope of the inspection is determined during the preparation for OCV. However, the identified scope may change depending upon the findings of the Opening Meeting. The scope of the Reality Check should also be changed during the Reality Check if major deficiencies are found. OCV could identify an issue that requires immediate attention. This would constitute a 'break out' from the defined scope.

The Reality Check will consist of a combination of activities including:

- A review of the relevant documentation relating to the FCMS (including prerequisites) and an assessment of their adequacy and accuracy – particularly verified in the environment of production.
- A physical examination of the operations, processes, practices and records by means of observation, tests, measurement (e.g. checking the temperature of the products or sterilisers) and/or interview – to verify whether these aspects comply with the documented procedures and are valid in the production environment.

It is recommended that the officer use Form D (see Chapter 5).

In practice, the early stages of the Reality Check will naturally overlap with the Opening Meeting.

It is natural that officers focus upon Reality Checking. **However, no part of OCV is intended to be mutually exclusive.** Consequently, officers should take every opportunity to continue with the OCV Study and to continually triangulate between the cardinal points of OCV. **The production environment observed in reality affords opportunities to revisit earlier decisions.**

Officers may find it appropriate to address HACCP Steps 2, 3, 6, 7, 8 and 11 immediately following the Opening Meeting, where access to the office environment is conducive to the extensive paperwork references that will be required. Key areas of OCV include verification of the following:

- Description of the products and the identification of their intended use;
- Detail of hazard identification and analysis;
- Validation of the control measures and critical limits;
- Determination of the CCPs;
- Validation of monitoring procedures;
- Whether corrective actions are being undertaken;
- Whether the relevant record keeping is being undertaken; and
- Whether the records confirming controls are being maintained.

3.3.1 Verifying FCMS

At each step in the process flow, the officer should continue to conduct his/her own HACCP Study, comparing and cross-referencing that against the FCMS as it is written down and against how the business is actually operating and performing in practice.

Key areas of consideration include confirmation of the following:

- The flow diagram is consistent in detail with the way the business is actually operating;
- The hazard identification and the hazard analysis are comprehensive and are accurate within the environment of the operation;
- Control measures are being applied;
- The control measures in practice are capable of eliminating the hazard or reducing it to an acceptable level;
- All steps that are critical have been identified as such;
- CCPs have been applied in practice;
- Critical limits are in operation;
- Monitoring is being undertaken;
- Corrective actions are being undertaken; and
- Relevant documents are being referred to and records are being maintained.

Overall, the officer should be prepared to triangulate all elements of the FCMS to the operation in practice and to the OCV Study, in order to confirm the objective that the operation in practice will protect the consumer. The officer should observe practices in reality and make his/her own measurements as required.

It is critical that staff working at CCPs are interviewed in order to verify their understanding of the hazards they are controlling, that they can competently implement the control measures and the SOPs stated in the FCMS and that they can competently undertake monitoring, corrective actions and record keeping. Critically, officers will need to cross-reference their findings in terms of observations, assessments of understanding and assessments of competence to the OCV Study and to the FCMS.

Steps 1, 2, 3, 6, 7, 8 and 11

HACCP Steps 1, 2, 3, 6, 7, 8 and 11 are critical to any FCMS based on HACCP Principles, yet they are often overlooked by businesses. Errors in their application would undermine the entire FCMS/ HACCP Plan, however carefully it was implemented.

The officer must be prepared to continue to study and to verify underpinning documents within the FBO's HACCP Study which may not be referred to by the FBO on a daily basis. Examples include HACCP worksheets and minutes of HACCP team meetings, where available.

Perusal of these will enable the officer to verify the critical thinking of the FCMS to identify objective evidence, e.g. the accuracy of hazard identification and analysis, scientific validity of control measures and critical limits and the accuracy of CCP identification, within the realities of the production environment.

Officers must also actively challenge the thinking underpinning the FCMS – particularly assumptions or rules of thumb – by cross-referencing observations against their own knowledge, experience or research. These tasks are critical and must be allocated an adequate amount of time. **Officers should bear in mind that OCV does not accept an FCMS at face value.**

Steps 4 and 5 – The Process Flow Diagram.

The accuracy of the process flow diagram must be verified.

One approach to this verification is undertaken by 'walking-the-line'. This involves a step-by-step and meticulous verification of the process in reality – and also a check that the Process Flow Diagrams are congruent. Officers should bear in mind that in situations where the process and the process flow Diagram are not in agreement, this is potentially an early warning sign that the FCMS has not been verified frequently enough. New or modified process steps which are not reflected by the Process Flow Diagram and are, therefore, not considered by the FCMS, may entail uncontrolled hazards.

Verifying the Control of Product Disposition

Product disposition management is closely allied to considerations of the process flow. It relates to the control of and the position within the process of all components of the final product and the final product itself. The FBO must be in control of the position and the traceability of all product components throughout the manufacturing process. Tracking also extends to being able to account for the original provenance of all the components used in final product. Using these FCMS components, the FBO should be able to account for the disposition of all products, all ingredients and components, packaging, non-conforming product and waste product at all times. This is achieved by the dual processes of reactive tracking and proactive tracing of products and ingredients. The latter process is essential to eliminate mistakes in the production process and also to eliminate fraudulent substitution of ingredients. Figure 3.2 below summarises these concepts.

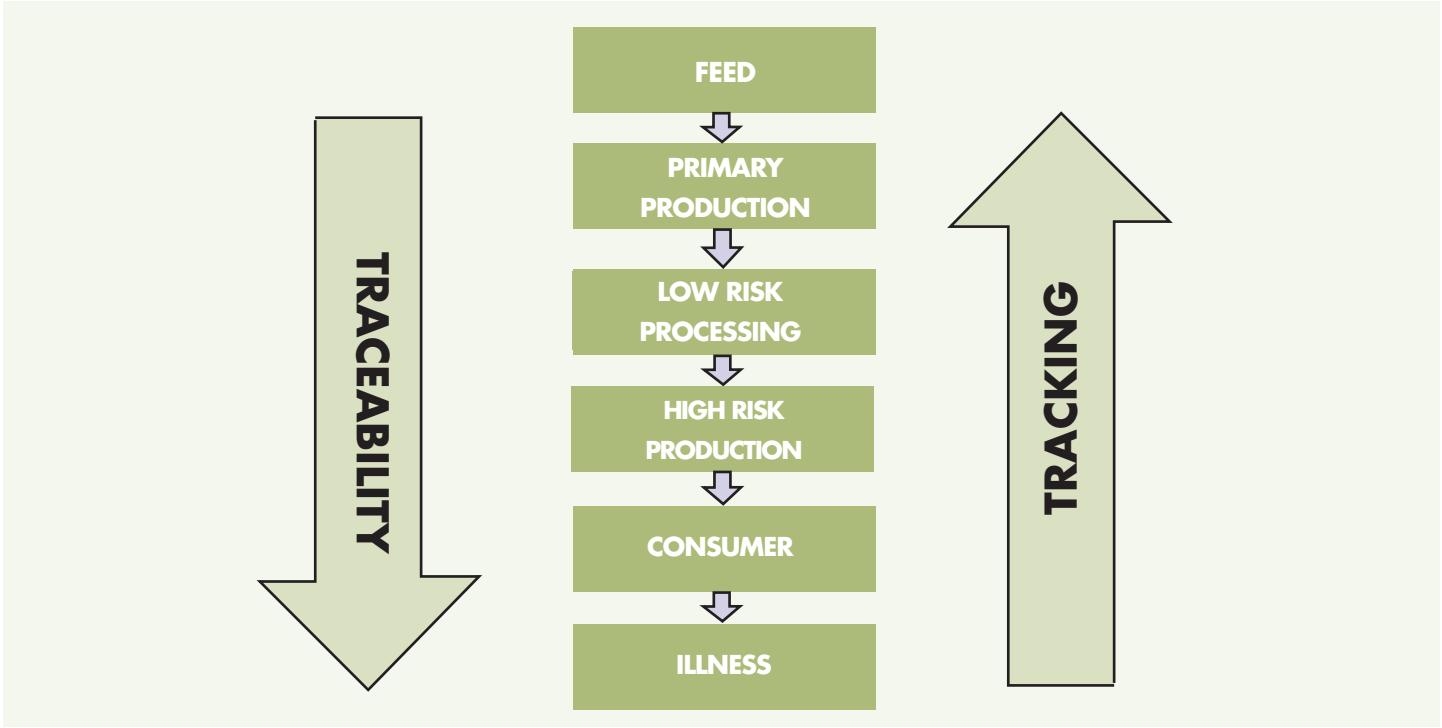
The control of the disposition of ingredients, products, waste products and packaging is essential to a FCMS. The FCMS cannot operate if product disposition is not known and is not under control. In the absence of disposition control, products and packaging cannot be verified as being subject to CCPs nor can they be adequately protected from contamination. Similarly, without disposition control, waste products could be recycled back into the human food chain and fraudulent adulteration and substitution may not be prevented.

Product Disposition Control

Product Disposition Control embodies a number of inter-relating elements as follows:

- Process management;
- Master Manufacturing instructions;
- Provenance/ Supplier Approval;
- Ingredients' specification;
- Traceability – Including systematic, comprehensive and accurate internal traceability;
- Production Coding;
- Lot Marking;
- Labelling;
- Approval Coding;
- Control of Non–Conforming product, ingredients and packaging, Including Re-Work procedures; and
- Waste Control.

Figure 3.2: The concepts of Tracing and Tracking



Similarly, OCV must also be applied to waste and non-conforming products and packaging. Waste products must be prevented from being returned into the process flows.

It is suggested that officers use the Business Profile Form (see Chapter 5 – Form B) to identify Competent Authorities responsible for Official Controls in the supplying establishments, in order that tracing can be undertaken in a continuous, joined-up manner. This practice may also assist in the identification of Food Fraud.

3.3.2 Reality Check Methods

A Mass Balance Approach

Mass balance is a reconciliation exercise, relating the quantity of products and ingredients entering the establishment with those leaving as product placed onto the market or as waste.

One suggested approach is to select a random sample of finished high risk product and, using the lot mark as a reference, systematically track the products backward from the end of the process flow diagram, throughout the entire process flows (including all ingredient and packaging process flows) eventually culminating in the receipt of all ingredients and packaging. This process should be conducted whilst verifying with reference to Process Management procedures, approved supplier and product specification etc.

The process of verification must also focus upon samples of re-worked products. (These will probably have to be selected from archival records.) Such products must be prevented from being returned into the main process flow(s).

If this is successful, all products should be able to be tracked back to the raw ingredients and packaging. The input quantities and output quantities should agree with the master manufacturing instructions (with wastage subtracted).

Verification of disposition control is completed when all samples have been found to conform to the FCMS (see also Chapter 4).

Example 3.4: Mass Balance Exercise

During the main inspection of a smoked salmon manufacturer, an officer randomly sampled three days of production and requested the following:

- Records for the purchase of all ingredients;
- All relevant production records;
- Records of finished product sales; and
- Records of waste products.

Where these did not reconcile to the satisfaction of the officer, further enquiries and verifications were necessary.

In practice, it is unlikely that exact reconciliation will be demonstrated, therefore, the officer should use his/her professional judgement to determine whether further investigation is required.

Product Recall/Withdrawal

Product recall/withdrawal relates to disposition control. FBOs must be able to implement an effective product recall or withdrawal in order that the consumer is safeguarded against a hazard that has not been eliminated or reduced to an acceptable level. Effective recalls and withdrawals are based upon robust disposition control. By applying effective disposition control, an FBO will be able to establish the following:-

- The quantitative and qualitative aspects of a batch that contains a hazard;
- The distribution of the batch that contains the hazard;
- How much of the batch has been or requires to be recalled or quarantined; and
- How much of the batch contains the hazard remains on the market, i.e. to how much is the consumer still exposed?

Similarly, it is critical that this is verified. One suggested approach is to select a batch as identified by its lot-mark and require the FBO to simulate a product recall or withdrawal supplying all of the objective evidence of distribution of the product and tracking the product retrospectively through the process flow to the point of provenance. Relevant processing records should be obtained in order to verify that control measures have been applied in relation to the batch.

The FBO must obtain evidence that the business can achieve effective product recall/withdrawal within a timeframe that minimises the exposure of the public to the hazard and allows for Food Standards Scotland to instigate a Food Alert and/or a press release as is required (see also Chapter 4).

Example 3.5: Product Recall (Reverse Trace) – Distillery

Prior to the inspection of a distillery producing Scotch Whisky and gin, an officer visited a retail establishment known to stock product produced on site and records details of one bottle offered for sale. Following the opening meeting of the inspection, the officer provided the FBO with the product details and requested a product recall be simulated for that batch of product.

The FBO produced the following documentation:

- Product Recall Procedure;
- Purchase records for the ingredients;
- Internal traceability and production records;
- Stock control records identifying the quantities distributed and remaining in storage; and
- Customer contact list.

The information provided demonstrated to the officer that the FBO could identify the quantity of product to be recalled, the location and recipients of the product and that they had the means to contact customers within an acceptable timescale to effect the recall.

Example 3.6: Product Recall (Forward Trace) – Mussels

An officer carried out an inspection of a dispatch centre for Live Bivalve Molluscs. The business purchases mussels from several harvesting areas and dispatch these to local restaurants as well as exporting to Europe and Asia. During the inspection, the officer proposed the following scenario:

A harvesting area for mussels has been closed following detection of high PSP levels. The failed sample was taken on 8th November (three days before the inspection). The previous sample – taken on 1st November – was satisfactory. Can the business identify the product which requires to be recalled and implement an effective recall? Incoming records indicate that the business received mussels from the closed site on 2nd, 4th, 6th and 7th November.

Scenario 1: The FBO produced:

- Registration documents for all incoming products and dispatch records for outgoing product. However, there was no internal traceability to demonstrate which incoming products were supplied to which customers.
- PSP toxin testing results, the most recent being for 25th October.

The FBO could not demonstrate that any products received since 2nd November were not affected and, therefore, would require to recall all mussels supplied since 2nd November.

Scenario 2: The FBO produced:

- Registration documents for all incoming products.
- Dispatch records which contained a traceability code to identify which batch of product was supplied to each customer.
- PSP toxin testing results, the most recent being for 25th October.

The FBO could demonstrate that some customers had been supplied with product unaffected by the recall, therefore limiting the recall to customers receiving mussels from the closed harvesting area since 2nd November.

In the above scenarios, the FBO would be required to demonstrate that they could effectively identify and contact immediate customers to effect the product recall.

Scenario 3: The FBO produced:

- Registration documents for all incoming products.
- Dispatch records which contain a traceability code to identify which batch of product was supplied to each customer.
- PSP toxin testing results for each incoming batch of product. These results were all negative for PSP and the results were stored in the test machine for officers to view (the correct use of the machine will be verified as part of the inspection process).

The FBO could demonstrate that all incoming batches of product are within acceptable limits for PSP and therefore no product requires to be recalled.

3.3.3 Evidential Triangulation

It is during the Reality Check that most of the objective evidence verifying the implementation status of the FCMS will be gathered and also recorded. The recording of the **positive and the negative aspects** of implementation is essential.

Evidential Triangulation is described and exemplified within Chapter 4.

3.4 THE CLOSING MEETING

A closing meeting should be held with the FBO and/or their representative to discuss and consider the findings. It is suggested that the personnel responsible for the development and verification of the FCMS are also in attendance.

The officer should represent the findings on the verification of the FCMS, i.e. Verification of the FCMS in terms of agreement between the OCV Study and the Reality Check. This should include the following points, although not exclusively:

- The validation status of the FCMS;
- Confirmation and description of any hazards identified by the OCV Study that are not in agreement with the FCMS.

At this stage, the officer will apply the relevant enforcement policy and other associated protocols.

4. OFFICIAL CONTROL VERIFICATION TOOLS

The application of OCV in practice is supported by a range of science-based practical tools which are the subject of this Chapter. These tools are as follows:

4.1 Business Profiling

4.2 OCV Mapping

4.3 The Staircase Model

4.4 Triangulation and Gap Analysis

4.5 Evidential Triangulation

4.6 Elective Sampling

4.7 Random Sampling

4.8 Random Number Generation

4.9 Work Breakdown Structure

4.10 PERT Chart

4.11 Gantt Chart

4.12 Structured Interview Techniques

4.13 5W 1H Analysis

4.14 Mass Balance and Product Recall/Withdrawal

4.15 Root Cause Analysis

4.16 Statistical Analysis and Predictive Modelling

4.1 VERIFICATION TOOL – BUSINESS PROFILING

Business profiling ensures that an officer has up-to-date, relevant information about an establishment in order to allow them to determine:

- Whether the scope of the FCMS is appropriate;
- Any research which may be required in relation to potential hazards; and
- Potential areas appropriate for elective sampling.

Figure 4.1: Components of a comprehensive Establishment Profile

Products

- Intended use
- New Products
- General hazards associated with products
- Extrinsic product safety factors e.g. packaging, MAP
- Intrinsic product safety factors e.g. a_w, salt content
- Potential for economically motivated food fraud

People

- Management commitment
- Composition of HACCP Team
- Experience and technical knowledge
- Customer Base and scale of distribution
- Vulnerable groups

Procedures

- FCMS and it's validity
- Pre-requisites
- Recall and traceability
- Sampling

Public Information

- Websites
- Social Media
- Companies House
- Advertisement of new products

Establishments

- Layout plans
- Process flows
- Alterations since previous inspection

Past

- History of complaints
- Previous formal action
- Response to previous inspections
- Allegations of food fraud

4.2 VERIFICATION TOOL – CONCEPT MAPPING

Function

A Concept Map can be used to organise and structure knowledge and generate ideas. A concept map will start with one concept and then go on to suggest relationships with subsequent concepts. Ideally, it should form a branching shape, leading radially from the initial concept.

When to use

It can be used at both the Planning and Managing the Inspection stages initially (see Chapter 3). However, a Concept Map can also be used for other, smaller projects during the inspection process.

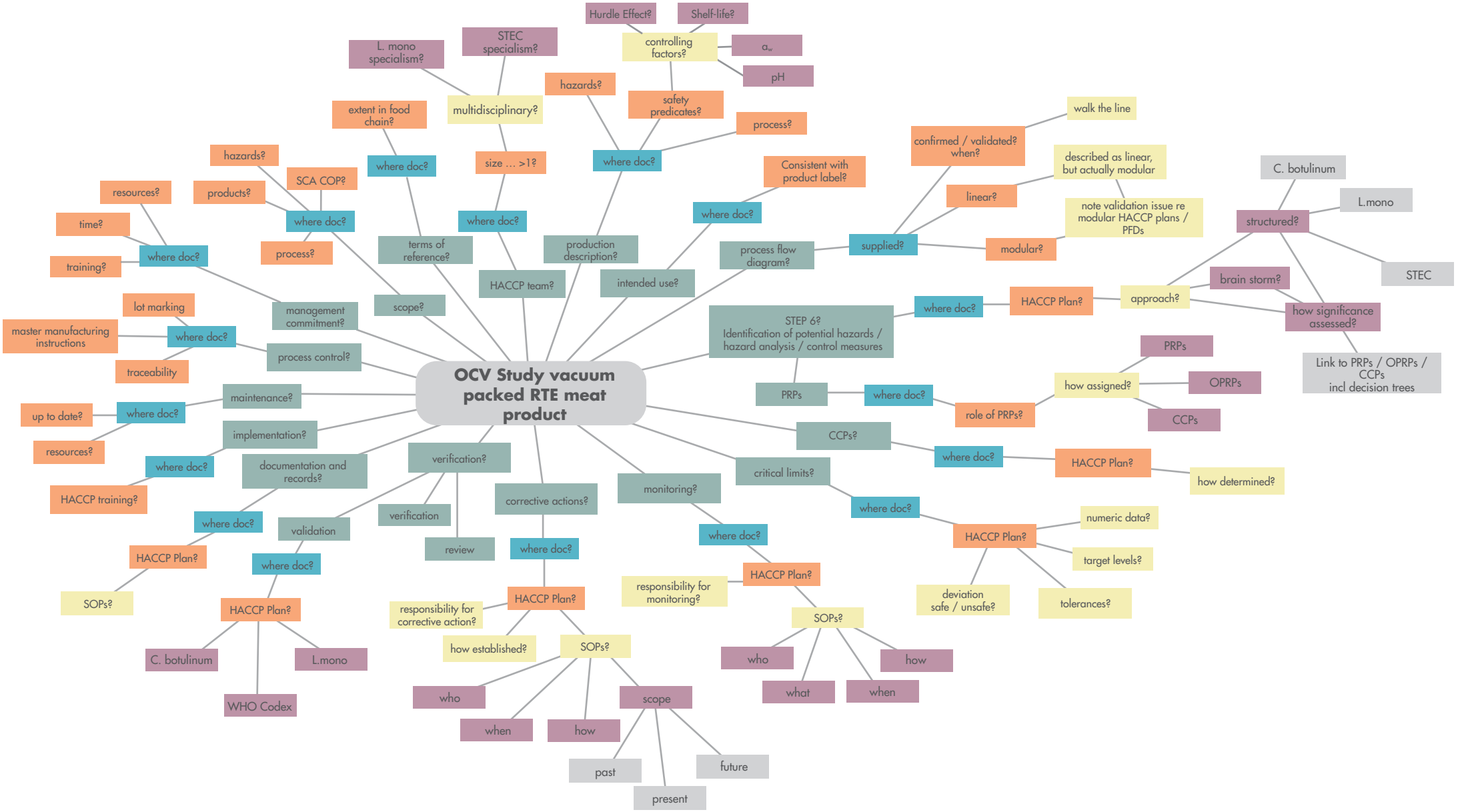
How to use

This technique can help to identify the main concept which must be one specific thing. All subsequent related concepts will then fall under the main concept. This must be done in a hierarchical format, getting more and more specific the further down the map goes. Once the nature of the business/task is mapped out it will help to determine how the overall inspection can be planned and performed.

Evidence

The Concept Map is an optional administration tool used prior to the commencement of the inspection cycle and amended as necessary based on any findings. As an administration tool, it is not expected that the officer will be required to document evidence in order to justify their planning – other than the completed Gantt chart itself, should the officer choose to use this tool (see Chapter 4).

Figure 4.2: Example of a Concept Map for an OCV Study for a vacuum packed RTE meat product



4.3 VERIFICATION TOOL – THE STAIRCASE MODEL

Function

The staircase is a tool which supports the OCV Study. In particular, it supports the officer's understanding of what the FBO's proposition actually is and what that proposition means in terms of food safety. The 'Staircase' can be envisaged as a model of the actual food safety requirements of the FBO's proposition.

The 'Staircase' is a schematic representation/ infographic of the controlling factors/measures available to control a specific hazard, usually a microbiological one, i.e. to eliminate a pathogen or reduce it to an acceptable level and also to increase shelf life.

FBOs frequently do not make their safety propositions clear in the form of comprehensive and systematic product descriptions, sometimes with serious consequences for the entire FCMS. Consequently, the officer may have to research and deduce what these propositions must actually be. Such a tool may assist in making the picture clear. The infographic form may assist in capturing these propositions and depicting them in an intuitive way. This is also useful as an infographic tool to identify what the FBO must validate.

Once the staircase has been completed, the officer will be provided with a model proposition relating to food safety. The Staircase Model will then help officers triangulate the FCMS by reference to the OCV Study and provide an early assessment on the ability of the FBO to prevent, eliminate or reduce hazards to acceptable levels.

When to use the Staircase Model

Although, the staircase can be used at any point during OCV, the principal application will be during the planning stages of the inspection and development of the OCV Study and informs the subsequent inspection steps and the triangulation process. When the officer is carrying out research and/or a literature review on the FBO's process, the Staircase Model may be used to capture and represent the essential features of a valid FBO proposition.

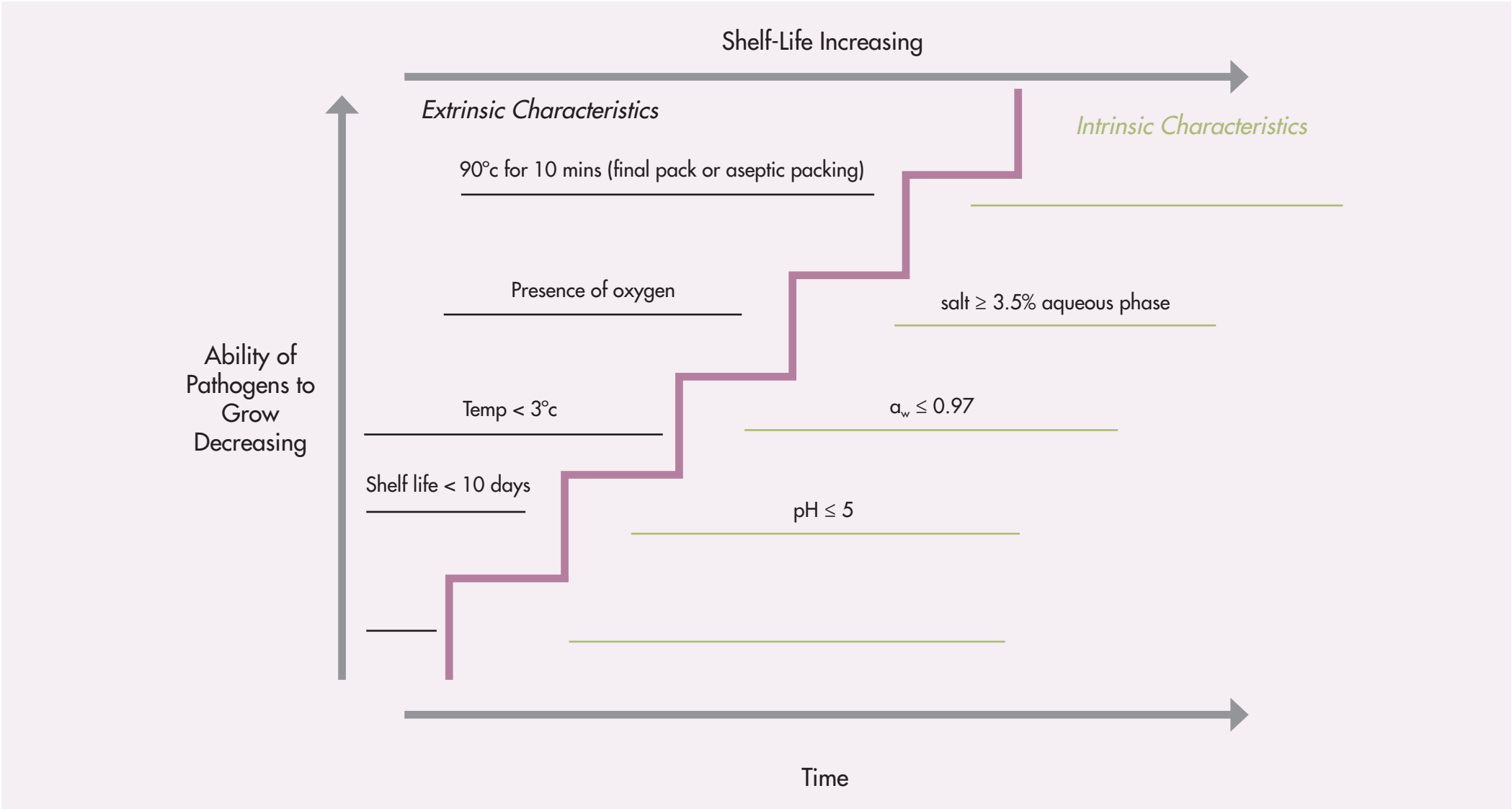
How to use

There is a clear need for the officer to conduct the research on both the relevant food science and technology and also the epidemiology of the process.

The officer will require access to academic and reliable sources of information and be able to confirm the critical parameters relating to controlling factors/control measures. In food microbiology, the controlling factors/control measures are typically divided into intrinsic and extrinsic factors and the Staircase Model reflects this. Based upon this research, the staircase can be populated and annotated. In practice, the more valid controlling factors/measures that are added the safer the process becomes. The staircase is intended to represent this in an intuitive way, in that food safety and shelf life increase commensurately with height and distance to the right-hand-side.

The staircase should always be annotated with academically rigorous references and citations.

Figure 4.3: Staircase Model applied to the control of Clostridium botulinum



Reference: The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non proteolytic Clostridium botulinum

4.4 VERIFICATION TOOL – TRIANGULATION AND GAP ANALYSIS

Function

Triangulation and Gap Analysis are the core principles of OCV providing for the overall, structured, systematic and scientific approach. They are also cognitive tools and enable a practical approach to applying OCV.

When to Use

Triangulation and Gap Analysis have general application throughout OCV. The other OCV tools should be integrated into Triangulation and into Gap Analysis.

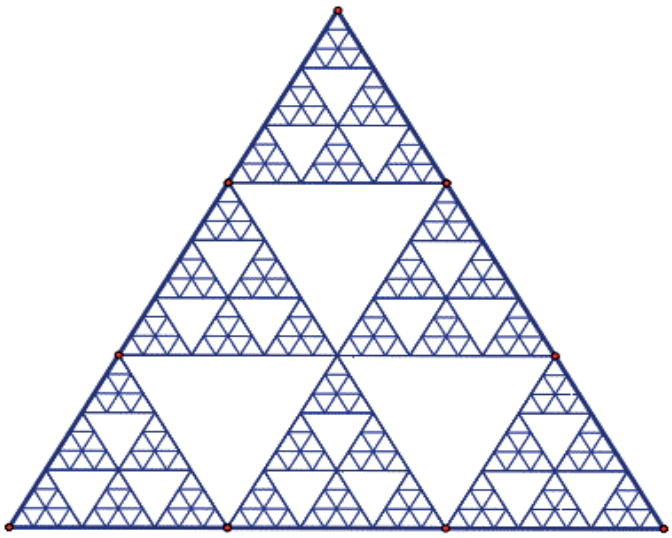
How to Use

Notwithstanding the principal importance of triangulation to OCV, triangulation of the entire FCMS – all at once – is impractical and potentially overwhelming – except in the simplest of FCMSs. This is because the proposition that the FBO makes in terms of Food Safety and in terms of Food Authenticity is, in fact, a multitude of component propositions. For example, when the FBO proposes that a food is safe, he/she is actually proposing that effective Process Control is in operation and that a HACCP study has been carried out. In turn, Process Control requires SOPs, Traceability and Lot-Marking, for example, and a HACCP Study itself is a complex proposition comprised of 12 main steps. Furthermore, particular processes imply a bespoke specific HACCP study.

A practical approach is to consider the entire FCMS as the sum of its component parts and to treat each component part as an individual triangulation in its own right, i.e. the verification of composites. This should, consequently, be viewed as a modular or bite-sized- chunks approach to identifying each individual component of the entire FCMS. The objective is to provide the officer with parts of the complex whole that are manageable and can be verified individually in a series of individual triangulation exercises. Once each component has been verified, the entire FCMS has been verified in total.

Analogies can be helpful when representing and explaining this technique. For example, a Russian Doll can be opened and inside is found a smaller copy of itself and so on. The last and the smallest part of the entire doll is analogous to a component of the FCMS that would be subject to verification by a specific triangulation. A further analogy that has proved to be helpful is 'Sierpienski's Triangle' represented by Figure 4.4 below.

Figure 4.4: Sierpienski's Triangle



Sierpienski's Triangle is an example of fractal and recursive relationship in geometric form. This means that the total is composed of smaller and smaller versions of itself.

The outer-most triangle is analogous to the overall OCV triangulation exercise. Looking inside this triangle is analogous to perceiving how complex the overall FBO's proposition is in reality and just how challenging that would be to verify in one attempt. The inner triangles are analogous to more manageable bite-sized-chunks. These can be verified in a series until all of the outer triangle representing the overall FCMS has been verified.

This requires a systematic and comprehensive approach to breaking down the overall FBO proposition in terms of the FCMS. A practical approach is to apply deduction, reasoning from the research that the officer has carried out on the product, the process, its hazards and its epidemiological history. This is best represented by a practical example.

Example 4.1: A Practical Demonstration Applied to Verifying Vacuum-Packed Cold-Smoked Salmon.

The officer was working in the planning phase of OCV and was interested in identifying which aspects to triangulate.

From research applied to this process, the officer knew that the contaminating microflora included Clostridium botulinum (C. bot) and that vacuum packing creates the anaerobic conditions required for the outgrowth of this pathogen – while the epidemiological history of the process confirms that this has been the case.

From the review of the FCMS, the officer knew that the FBO intended to control this hazard (i.e. the outgrowth of C. bot. spores) via the controlling factors of a_w <0.97 and/or aqueous phase salt >3.5%. The officer is also aware that the OCV Study has confirmed that this is a sound proposition. The officer deduces that a drying process is required and from reviewing the FCMS the officer verifies that the FBO intends to do so via two steps, i.e. curing and cold smoking. These steps must, therefore, be verified in terms of individual triangulations. The FBO's components propositions for the control of the outgrowth of C. botulinum have been broken down into subjects of specific individual triangulations.

4.5 VERIFICATION TOOL – EVIDENTIAL TRIANGULATION

Function

Evidential Triangulation is a technique for enhancing the certainty of verification by cross-referencing two or more independent sources of objective evidence. In effect, corroboration is being sought. Since much of OCV is founded on the use of a single source of evidence and, as such, may suffer from limitations associated with that method or from the specific application of it, triangulation offers the prospect of enhanced confidence.

When to Use

Evidential Triangulation has general application throughout OCV. The other OCV tools should be integrated and used in combination.

How to Use

When verifying any aspect of the FCMS, three or more sources of independent evidence should always be sought. Typical examples include:

1. Observations of a Standard Operating Procedure (SOP) in operation;
2. Interviews with personal responsible for carrying out SOPs;
3. Records relating to the same SOPs.

The attributes of Objective Evidence are as follows:-

- Scientific – Can the evidence be evaluated by independent observers to reach the same conclusions?
- Scientific – Are the data documented in a manner to allow re-creation of the data or the events described?
- Scientific – Does the documented evidence provide sufficient data to prove what happened, when, by whom, how, and why?
- Legal – Was the documentation completed concurrent with the tasks?
- Legal – Is the documentation attributable, i.e. is the person responsible for the evidence identified?

Evidential triangulation can be recorded as a simple triangle with the three sources of evidence annotated at each corner. This makes clear which sources of objective evidence are being cross-referenced. The representations of the person being interviewed should be noted in summary and that person should be attributed. Observation should similarly be noted in summary and the person or persons being observed also attributed. The identity of records should be noted.

All sources of objective evidence should be recorded contemporaneously and referenced with a time and a date.

Evidential triangulation is most effectively carried out in combination with sampling, e.g. elective sampling of high-risk SOPs and random sampling of persons responsible and of the related records.

4.6 VERIFICATION TOOL – ELECTIVE SAMPLING

Function

It is inefficient to try and verify all of the FCMS directly, therefore, elective sampling allows for sampling with bias. The officer should decide where and what to sample. This is a technique in which the officer relies on his or her own judgment when choosing what processes/procedures to sample.

When to use

Elective sampling is used for critical and high risk elements of the business, e.g. HACCP Steps 1-6, HACCP Steps 7-10, Validation, certain OPPs, Process flow diagrams for high risk areas, rework following corrective actions, labelling of allergens and traceability. Elective sampling should be used in the early stages of verification.

How to use

Elective sampling must be planned and integrated into the general plan of the inspection cycle and used along with random sampling (see Chapter 4). Elective samples can be chosen based on risk or as a reaction to previous findings during triangulation or gap analysis.

Evidence

At the conclusion of elective sampling, depending on the subject matter chosen, the officer should have evidence to show that the FBO is doing what they said they were doing.

Example 4.2: Reality Check Elective Sampling of the FCMS

While planning an intervention in a sous-vide ready-meal manufacturer, and before the random sampling of elements of the FCMS are selected, the officer considers the elements of the FCMS that address high risk products and elects to sample the following elements of that FCMS:

- All critical control points, including HACCP Steps 6-12;
- The validation study supporting the control measure and the critical limits for cooking (i.e. time/temperature regime, mass of product and cooker loading parameters);
- The calibration status of the sous vide cookers;
- The process flow diagram relating to the high risk zone; and
- The training status of all personnel working within the high risk zone.

4.7 VERIFICATION TOOL – RANDOM SAMPLING

Function

It is inefficient to try and verify all of the FCMS directly therefore random sampling allows for sampling without bias. With random sampling, every element has an equal chance of being sampled. This is a technique intended for sampling large groups of products or documents.

When to use

Random sampling should be used for lower-risk elements of the business, e.g. a Prerequisite Programme (PP). It can be used when carrying out unannounced verification visits.

How to use

Random sampling must be planned and integrated into the general plan of the inspection cycle and used along with elective sampling. It is vital that the elements selected are sufficient in number and range to be representative of the whole FCMS. It is best practice to change the testing day and products selected, therefore, the use of a Random Sample Generator would be advantageous. The random sample generator, generates a number which can then be allocated to a day of production. Random sampling can be performed for a person, a product, a machine, a process or a date.

Example 4.3: Reality Check Random Sampling of the FCMS

During an inspection, an officer attempts to verify that corrective actions are being undertaken by the FBO and that the FCMS is 'live' – i.e. that the FBO is learning from any mistakes that are made. Whilst reviewing the ATP records, the officer notes that since the last inspection, there have been 26 instances where the ATP-based verification of cleaning and disinfection has indicated a potential cross-contamination hazard.

Rather than verify each and every instance through an audit trail, the officer decides to select a sample of the ATP assays through random sampling. A random number generator is accessed on a calculator and is used to select a representative sample of the total assays. The officer selects the samples with reference numbers that correspond to the random number generator, dividing the random number appropriately where it is greater than 26. Such a process allows the Officer to select without introducing bias and represents a sound basis for making deductions relating to corrective actions more generally.

4.8 VERIFICATION TOOL – RANDOM NUMBER GENERATION

Random numbers for the purposes of making random sampling selections can be generated in a number of ways:

- Random number generation function on scientific calculators; and
- Random number generation applications available on the internet.

Week																				
1	88	22	87	58	39	82	13	51	4	29	36	92	85	17	69	37	11	70	55	02
2	52	49	94	07	83	16	15	80	75	93	81	61	62	41	28	77	35	63	19	48
3	07	26	93	35	54	51	05	60	28	94	12	23	24	62	36	64	69	88	40	10
4	46	73	97	80	32	71	01	09	48	87	67	65	99	95	08	85	04	06	55	37
5	94	53	43	96	16	49	88	61	93	71	34	48	50	59	62	40	55	01	23	67
6	98	25	68	75	57	52	28	54	73	58	19	81	37	56	09	92	07	90	84	42
7	29	78	14	89	60	97	77	87	85	70	30	27	22	18	10	32	69	21	51	44
8	71	39	03	66	80	47	05	13	72	20	31	02	91	35	95	46	15	36	33	04
9	63	41	86	83	65	17	79	99	64	08	24	76	45	38	74	26	82	11	12	06
10	39	53	37	67	54	36	73	84	15	99	88	68	58	60	55	06	23	10	09	96
11	27	72	13	91	97	02	28	85	30	64	48	98	24	31	95	35	63	83	49	57
12	32	01	07	90	26	03	65	80	87	74	76	25	04	20	79	45	46	05	34	66
13	61	77	14	40	12	52	71	81	93	29	99	75	51	50	18	86	08	92	94	33
14	22	16	42	38	17	62	47	78	41	89	82	44	43	70	56	11	59	21	69	19
15	19	17	34	41	29	92	12	22	89	05	18	71	93	47	99	85	69	20	57	87
16	67	08	72	73	91	60	49	13	06	58	15	87	16	54	78	11	66	33	46	39
17	07	88	48	75	30	59	36	14	32	40	51	97	24	44	80	01	52	04	84	71
18	27	98	43	74	21	23	70	86	79	56	09	65	96	26	61	28	68	42	02	92
19	95	77	25	35	45	62	76	86	39	50	55	90	31	63	10	81	94	82	53	87
20	64	20	95	17	49	97	50	58	55	14	56	54	29	69	71	74	33	12	42	82
21	80	08	39	79	24	75	19	57	02	94	28	18	67	81	91	84	31	30	86	49
22	77	35	82	48	13	72	34	52	92	65	96	90	06	38	63	85	51	32	27	13
23	41	04	45	66	46	68	15	83	10	61	01	03	21	99	47	88	09	05	60	32
24	62	93	76	07	98	73	70	44	26	23	16	97	40	25	11	36	59	37	87	48
25	19	51	43	46	68	40	88	33	26	27	21	58	60	90	34	30	52	07	65	73
26	18	53	48	05	28	01	80	42	25	89	59	66	77	64	15	38	57	31	91	42
27	94	16	23	73	32	83	71	17	76	63	49	10	61	06	98	47	70	22	82	18
28	79	84	67	74	72	56	55	87	09	94	96	12	75	95	29	41	08	44	50	23
29	78	93	39	99	97	81	85	86	37	62	14	02	20	24	45	54	35	04	03	36
30	36	38	52	79	15	73	71	66	01	67	03	53	70	99	07	57	29	75	27	45
31	96	84	92	81	61	89	43	35	11	24	91	63	26	55	74	23	46	68	54	98
32	64	95	04	06	94	17	78	42	56	80	25	16	69	83	09	33	34	12	87	77
33	72	28	62	86	31	22	65	40	10	90	85	13	41	47	97	60	37	51	59	14
34	19	05	02	30	21	76	44	29	49	93	32	58	08	82	18	39	20	88	50	48
35	09	86	11	65	92	32	23	19	20	61	33	75	69	82	35	84	14	59	17	58
36	90	99	79	97	54	02	06	44	37	07	10	52	60	24	63	22	45	98	43	47
37	68	66	36	42	27	28	29	94	93	91	40	31	71	80	30	37	62	49	96	25
38	85	21	81	51	57	01	13	16	34	08	73	18	72	26	76	95	87	74	64	55
39	39	56	04	48	70	67	05	53	03	78	41	38	77	83	12	50	88	15	89	46
40	75	25	32	05	10	82	07	52	06	13	38	80	91	44	39	04	72	19	22	76
41	27	28	78	23	03	02	73	30	42	95	29	77	65	88	94	90	53	63	97	81
42	61	70	67	17	93	45	59	24	35	79	16	14	21	26	64	46	19	69	86	20
43	66	50	92	51	96	08	84	12	36	62	55	01	68	58	56	47	40	31	71	60
44	99	41	54	37	83	89	43	15	34	57	18	11	49	87	09	74	98	33	85	48
45	68	58	23	32	73	75	40	91	29	20	27	63	05	13	72	98	59	03	71	66
46	87	33	44	37	80	61	86	45	11	47	48	15	60	88	55	76	09	34	67	17
47	51	26	94	82	28	65	41	90	70	01	39	74	62	43	42	12	38	69	92	93
48	21	81	49	35	57	84	08	89	77	53	83	16	97	99	04	18	06	54	14	19
49	52	22	96	56	07	24	85	10	36	10	64	95	78	31	25	79	02	30	50	46
50	41	17	25	81	18	45	83	96	15	92	58	84	75	12	29	59	56	91	98	49
51	77	30	66	90	20	68	50	82	57	78	27	22	89	34	03	53	70	16	11	86
52	47	72	33	43	76	42	63	79	44	14	21	61	13	39	38	31	02	52	74	19

4.9 VERIFICATION TOOL – WORK BREAKDOWN STRUCTURE (WBS)

Function

A WBS is, as its name suggests, a break-down of an OCV into its constituent elements. It is used to identify those individual elements – enabling them to be assembled into a PERT chart and a Gantt chart (see Chapter 4). Thus, the WBS is a decomposition of a complex OCV task. A WBS defines all the things OCV needs to accomplish and also organises them into multiple levels or hierarchies which show the 'parent' tasks which are broken down sequentially into their components. This process is displayed graphically in order that its individual elements can be identified and understood visually and intuitively. The outcome represents the basis for systematically incorporating them into subsequent project management tools such as the PERT and the Gantt chart.

A simple WBS is represented in figure 4.6.

A WBS should be used flexibly and in sufficient detail, as is sufficient to support the planning of OCV.

When to Use?

A WBS is used in the early stages of planning OCV – following the Concept map of the FCMS to which the WBS will refer — and supporting the production of subsequent PERT and Gantt charts.

How to Use?

The concept map of the FCMS serves as a useful reference point for developing a WBS.

Developing a WBS in OCV is a simple process of dividing the overall OCV task into its principal elements, e.g. Business Profiling, OCV Study, Triangulation and Reality Check. These can then be broken down further, e.g. via Concept Mapping, OCV and interviews with personnel at CCPS. This process of decomposition continues until it is neither useful nor possible to break components down any further. The initial stages of this process will be generic to all OCVs, however, it will become progressively more specific and bespoke to individual FBO FCSMs as the process progresses.

WBS can simply be developed by hand or using a template such as represented in Figure 4.6.

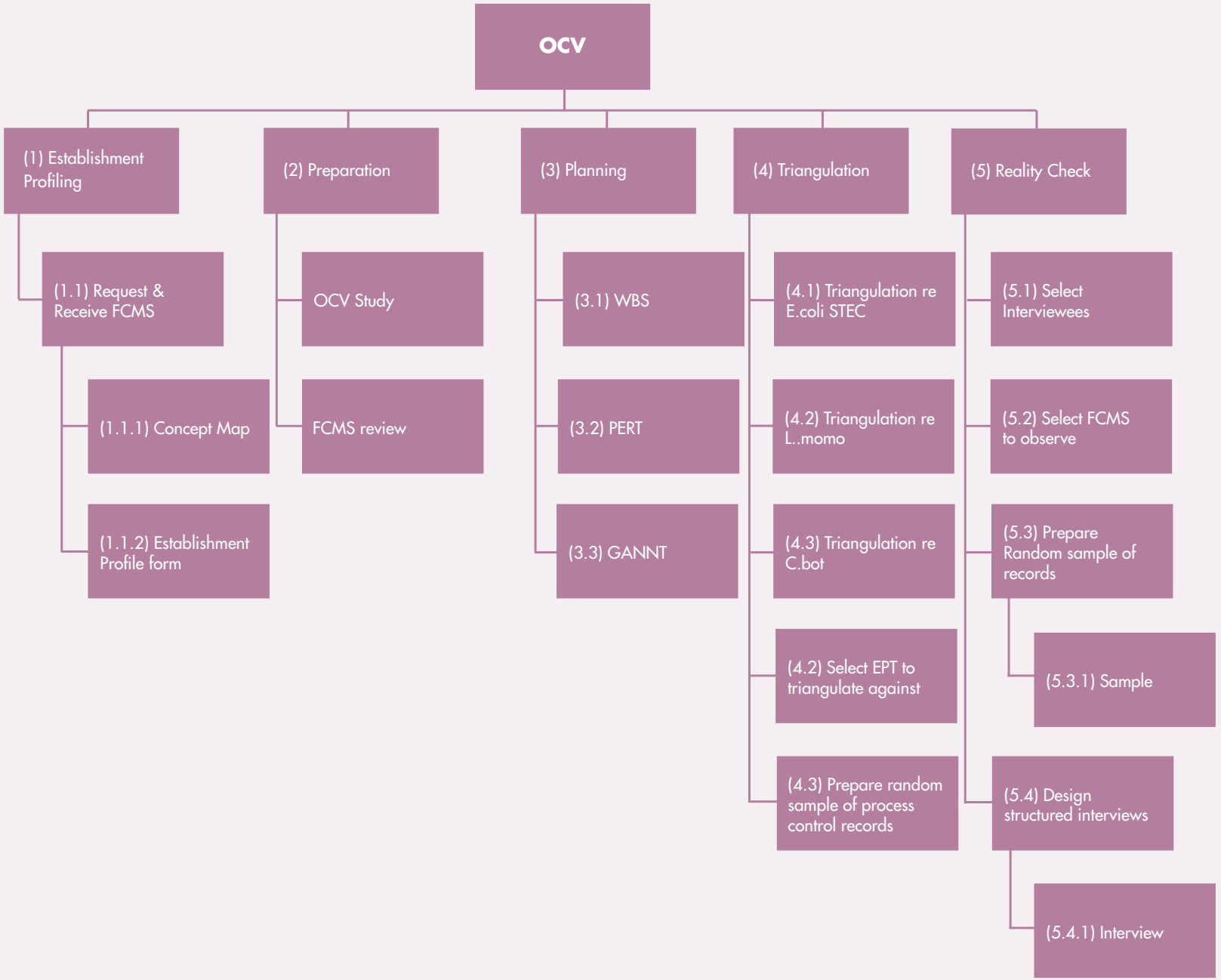
Evidence

At the conclusion of the WBS, depending on the subject matter chosen, the officer should have evidence to demonstrate that the grounds for an OCV plan have been established.

What is the evidence that the task has been done?

Completion of a WBS by hand or using a template. It should be borne in mind that the level of detail required is commensurate to the complexity and the risk of the FCMS.

Figure 4.6 – Example of Work Breakdown Structure for a Vacuum-Packed RTE Meat Product



4.10 VERIFICATION TOOL – THE PERT CHART

Function

PERT, which stands for Programme Evaluation Review Technique is a project management tool to assist the officer in planning the inspection cycle. It documents the 'critical path' of events or activities associated with Official Control Verification and the tasks necessary to complete them.

When to Use

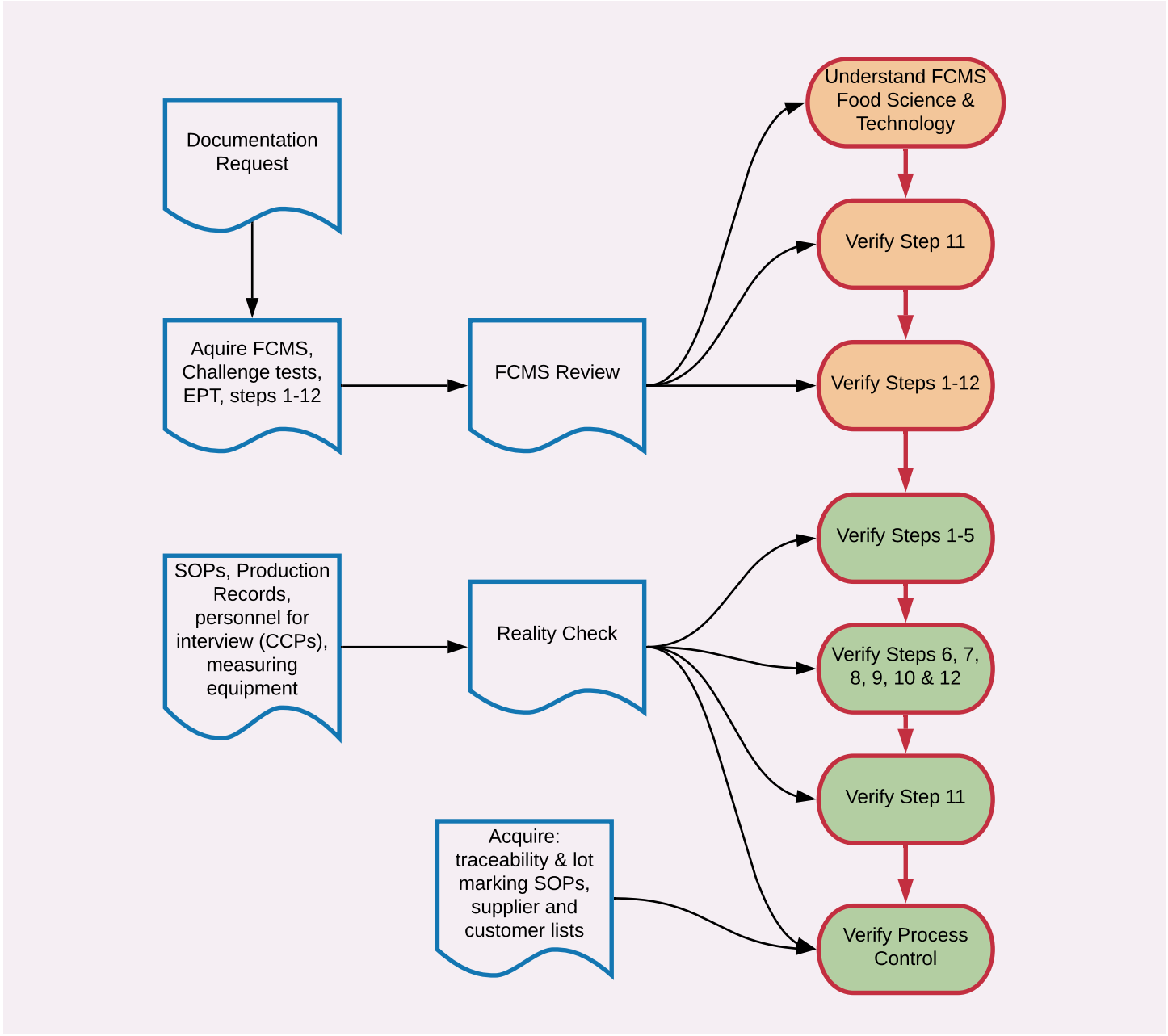
The use of the PERT Chart is most appropriate at the planning stage (see Chapter 3).

How to Use

Each activity should be identified. Activities are then outlined (in red in the example given below) and represent an example of a critical path in completing an Official Control Verification inspection cycle.

The chart is then developed to include tasks which require to be completed for each activity (as highlighted in blue in the example). As with Gantt Charts, the PERT chart clearly identifies whether activities and tasks are parallel or sequential.

Figure 4.7: Example of a PERT Chart



4.11 VERIFICATION TOOL – THE GANTT CHART

Function

The Gantt chart is a commonly used project management tool which can assist the officer in planning the inspection cycle. It documents the different stages involved and when each stage will take place.

When to Use

It is most effective when implemented at the planning stage (see Chapter 3), however, it may be necessary to adapt the chart throughout the inspection cycle.

How to Use

The officer should, primarily, identify the key stages of the inspection cycle. Certain aspects are likely to feature for all establishments, e.g. Documentation Request and Documentation Review. Other stages will vary depending on the establishment – in particular the number and focus of announced and unannounced visits.

Once the key stages of the inspection cycle have been determined, the officer should consider the appropriate timescale for these and detail them on the Gantt chart, indicating the estimated start date and duration of each stage.

The chart shows the relationship between the stages within the inspection cycle. Some will require to be completed before subsequent stages can be begun, and others can't end until preceding ones have ended. These dependent activities are called "sequential" or "linear" stages. Other stages will be parallel or contemporaneous, i.e. they can be carried out at the same time as other stages.

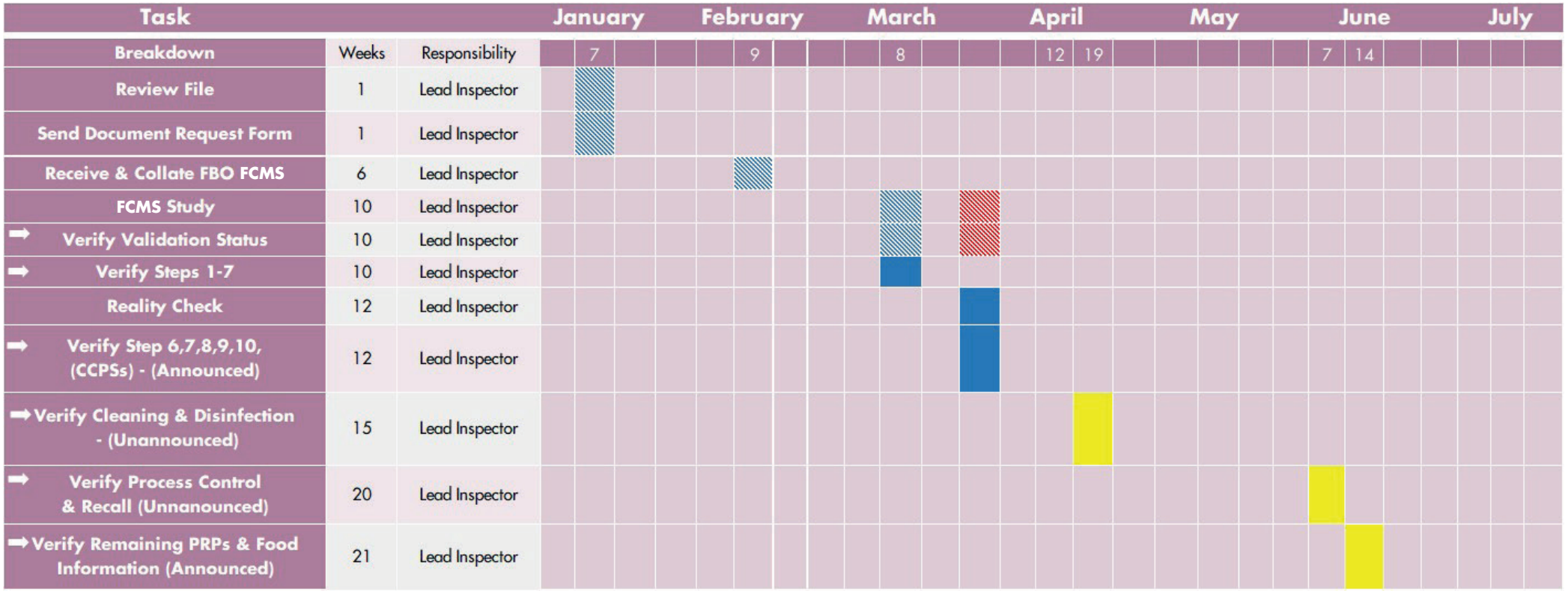
The officer may choose to use colour-coding or other means to differentiate between unannounced inspections and announced inspections, office-based work and onsite visits etc.

The chart will almost certainly evolve during the inspection cycle. For example, an officer may not be able to identify the most appropriate elements of the FCMS to electively sample during the reality check until the document review stage has been completed.

Evidence

This is an optional administration tool used prior to the commencement of the inspection cycle and can be amended as necessary based on any findings. It is not expected that the officer will be required to document evidence to justify his/her planning – other than the completed Gantt chart itself.

Figure 4.8: Example of a Gantt Chart



- The blue elements denote announced verifications and the yellow denote unannounced verifications.
- The striped elements denote critical tasks in terms of timing – Such tasks must run to time because subsequent tasks depend on them (i.e. they are contingencies of subsequent tasks. This is exemplified by the verification of validation status – There is little point in a reality check of an FCMS that is clearly invalid.
- The red striped elements also denote verification milestones. It can be seen that the end of the FCMS Review constitutes such a milestone.

4.12 VERIFICATION TOOL – STRUCTURED INTERVIEW TECHNIQUES

Function

These tools have a number of functions:

1. To promote awareness of the critical importance of interviewing in eliciting key information;
2. To support officers undertaking interviews, by providing structure, whilst integrating open and closed questions whilst applying inductive and deductive logic to reach valid conclusions; and
3. To provide the basis of a plan to prepare for complex interviewing situations. The tools are intended to be used flexibly at an officers own discretion.

When to Use

At any point during OCV when considered appropriate to do so.

How to Use

The key aspects of almost anything can be clarified by using a series of questions commencing with What? Why? Where? When? Who? and How? This is known as a 5W-1H approach (see Chapter 4). Open and closed questions have different applications and the choice of open and closed questions is frequently a trade-off between their respective strengths and weaknesses. The officer can draw inferences from the evidence obtained.

Three models are represented in the form of the 'Pyramid', the 'Funnel' and 'Diamond'.

The Pyramid

The pyramid is the simplest version and progresses from closed questions to open questions. The officer then expands the topics by allowing open-ended questions and more generalised responses. The officer might optimally use the pyramid structure where they judge that the interviewee needs to warm up to the subject.

Using a pyramid structure for question sequencing is also useful when the officer requires an ending determination about the subject.

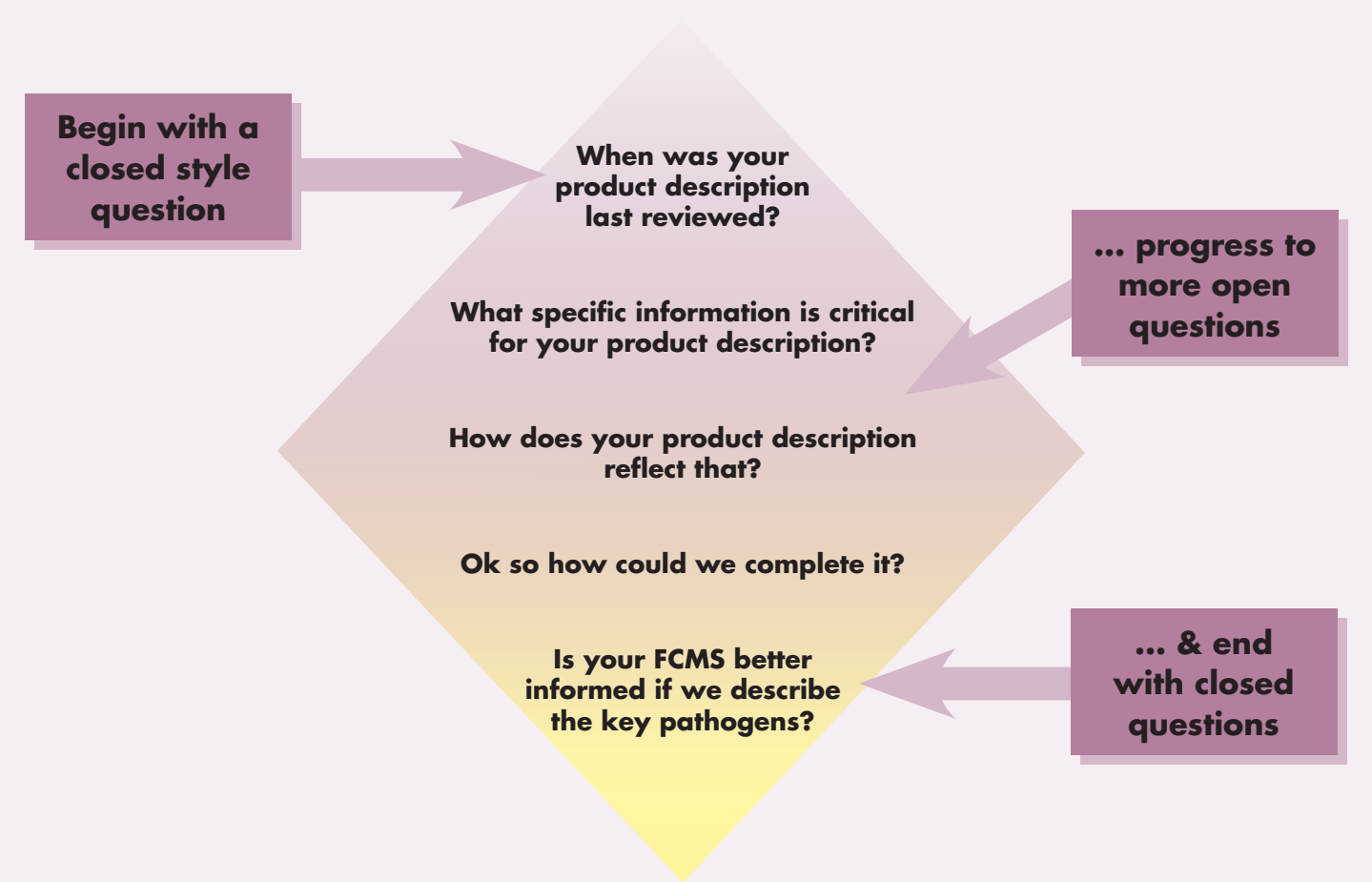
The Funnel

The Funnel is slightly more complex. The officer begins with generalised, open-ended questions and then narrows the possible responses by using closed questions. Subsequent questions are developed from the preceding questions. This interview structure can be thought of as funnel shaped. Using the funnel structure method provides an easy, non-threatening way to begin an interview. A funnel-shaped question sequence is also useful when the interviewee feels emotional about the topic and needs freedom to express those emotions.

The Diamond

Often a combination of the two structures, resulting in a diamond-shaped interview structure, is optimal. This structure entails beginning in a very specific way, then examining general issues, and finally coming to a very specific conclusion, as shown in the picture. The officer begins with easy, closed questions that provide a warm-up to the interview process. In the middle of the interview, the interviewee is asked for opinions on broad topics that obviously have no "right" answer. The officer then narrows the questions again in order to get specific questions answered, thus providing closure for both the interviewee and the officer. The diamond structure combines the strengths of the other two approaches but has the disadvantage of taking longer than either other structure.

Figure 4.9: The Diamond



4.13 VERIFICATION TOOL – 5W 1H ANALYSIS

Function

5W 1H Analysis enables a structured approach to support the verification of the FCMS. It comprises a set of questions whose answers are fundamental to establishing the truth of a situation or to problem solving. According to the underlying principle known as the 'Five-Ws', a conclusion or an inference can only be considered complete if it answers key questions starting with an interrogative word which can be asked in a past, present or future tense according to circumstances.

When to Use

The technique has general application to any stage of OCV, including the processes leading to the OCV Study and during the Reality Check. 5W1H can also be integrated into other OCV tools as well as Triangulation and Root-Cause Analysis.

Not only does 5W1H Analysis support verifying fundamental truths, it supports and guides the officer in challenging situations, such as dealing with situations of seemingly overwhelming complexity and/or of rapidly-changing situations where 5W1H helps to keep the officer on track and in control.

How to Use

Typically, questions are constructed taking the following forms for example:

- **Who?** – Is involved or who was involved?
- **What?** – Is intended to happen or what happened?
- **Where?** – Does it take place or where did it take place?
- **When?** – Will it happen or when did it take place?
- **Why?** – Why will that happen – or why did that happen?
- **How?** – Will that happen or how did it happen?

Each question should have a factual answer, i.e. facts necessary to establish a truth. Importantly, none of these questions can be answered with a simple "yes" or "no".

5W1H is closely linked to the concept of 'Objective Evidence', i.e. both the analysis and the objective evidence of the answers to the questions are required to establish a truth and must both be recorded.

Example

5W1H Analysis is exemplified in Chapter 3, i.e. to guide and to simplify step 6 of the OCV Study.

4.14 VERIFICATION TOOL – MASS BALANCE & PRODUCT RECALL

4.14.1 Mass Balance Exercise

Function

A Mass Balance Exercise is a multi-function tool which aims to reconcile incoming ingredients with finished product (and wastage) by verifying a particular product or ingredient. Consequently, it can be used to test internal traceability, assess adherence to process control documentation and identify potential food fraud.

The tool focuses heavily on internal traceability which is often closely linked to product recall procedures. The officer may, therefore, choose to extend the scope of the mass balance exercise to assess the effectiveness of the product recall procedures.

When to Use

The product selected for exercise may be identified prior to the inspection, e.g. by identifying a product on sale, or during the inspection, perhaps by selecting from records or finished products observed in storage during the inspection.

How to Use

When selecting a product or ingredient for Mass Balance Exercise, the officer should consider the need for elective and/or random sampling. Conducting a Mass Balance Exercise on all component ingredients and packaging associated with a product could be a lengthy and unnecessary process. Consequently, the officer may choose to focus the mass balance exercise on specific component ingredients after selecting a finished product. Examples may include ingredients which are linked to a CCP, e.g. salt used for curing or where there is an incentive for substitution or adulteration.

Once the product has been selected, the officer should attempt to track the product or ingredient backwards through the production process flow to the receipt of incoming ingredients. This should allow the officer to compare input and output quantities and identify any discrepancies which may require further investigation.

This tool may also be used by selecting an incoming ingredient and tracing it forward through the production process.

Example 4.4: Mass Balance Exercise

During the main inspection of a small-scale pie manufacturer, the officer selects a Free Range Chicken and Mushroom Pie in the finished product chill to verify. She takes a photograph of the product (including labelling) and notes that there are 24 of the batch remaining in the finished product chill.

The officer requests the following:

- Production records for the relevant batch;
- Product recipe;
- Records and invoices for incoming ingredients; and
- Wastage records.

A review of the production records demonstrates that 100 pies were produced. (Photo taken of records for file).

The recipe for the product indicates 9kg of chicken is required for a batch of 50 pies. Consequently, in this instance, the recipe was doubled. (Photo of recipe taken as evidence). It is assumed that the officer has verified separately that this achieves the declared chicken content.

The FBO advises that the free-range chicken is not used in any other products (this is reflected in the product list) and is delivered the day before production. The chicken and mushroom pies are produced once per week and there is no rework associated with the product.

The Goods-in Record (photograph taken) includes the incoming delivery of chicken from a supplier on the FBO's approved supplier list and the invoice (photograph taken) includes the description 'Free Range Chicken Thigh – skin on' with a weight of 20kg. The FBO advises that the skin is removed and the product trimmed prior to processing.

Records of wastage are not retained other than waste transfer notes. Category 3 Animal By-Products are stored in a 240l bin and uplifted weekly and a waste transfer note for the relevant week is produced (photograph taken). The officer is satisfied that the quantities are representative based on the throughput of the business and that no further investigation is required.

The officer documents a brief summary of the findings to file with the supporting evidence obtained.

4.14.2 Product Recall/Withdrawal Test

Function

The Product Recall/Withdrawal Test is a means of challenging the ability of the FBO, in the event that a product recall/withdrawal is required, to effectively identify the quantity and location of potentially affected stock and recall/withdraw this efficiently.

When to Use

The optimal opportunity is usually during the reality check stage of the inspection cycle.

How to Use

The officer should propose a scenario whereby either an ingredient or a product requires to be recalled or withdrawn. The officer should request that the business identifies the quantity and location of potentially affected product.

As traceability is a key factor in both mass balance and product recall/withdrawal, it is recommended that rather than carrying out separate traceability checks for both, the mass balance exercise be used as the basis for the product recall/withdrawal test.

Example

As in the example discussed for Mass Balance Exercise (see Chapter 4), the officer has established that 76 pies have been distributed. The officer proposes a scenario whereby the chicken used in this batch is being recalled by the supplier and requests that the business identify which customers have received all relevant pies.

The FBO advises that there is generally a small quantity of stock remaining when a new batch is produced. As they do not record the batch issued to each customer, they will require to contact all customers supplied with chicken pies since the date of production. Even though some customers will have received product from the previous batch, the FBO's traceability system does not allow this to be established without contacting the customer.

The FBO advises that each product has a unique code. When entered into the FBO's electronic system this quickly identifies that 85 pies have been sold to 15 customers since the day of production. The officer randomly selects three customers from the list and asks the FBO to provide the corresponding invoice for the sale and contact details for the customer.

On completion of the exercise, the officer is satisfied that the FBO can quickly identify and contact potentially affected customers if required.

4.15 VERIFICATION TOOL – ROOT CAUSE ANALYSIS (RCA)

Function

RCA is a collective term that describes a wide range of similarly structured and cognitive approaches, tools, and techniques used to uncover the actual root causes of problems. RCA is a set of troubleshooting approaches based on the fact that the most effective way to solve a problem and prevent it from happening again is to determine its root cause and to take action to eliminate it.

In RCA, it is useful to consider factors and root-causes. A factor is considered a root cause if its removal from the chain of events leading to food borne illness prevents the final undesirable outcome, i.e. food-borne illness or prejudice to the consumer from recurring. On the other hand, a causal factor is one that affects the chain of events, but is not an actual root cause. Causal factors can be numerous and can act to mask the actual root-cause that the officer is trying to identify. RCA supports the officer in identifying the actual root-cause.

RCA can also be used to support triangulation and Gap Analysis.

When to use

RCA will be most often applied during the OCV Study and during the Reality Check when a Gap is identified.

How to use

RCA can be used in conjunction with other OCV tools, such as Triangulation, Gap Analysis and the evidential triangulations during the Reality Check. The basic materials for an RCA are a Fishbone Diagram. Reference is made to Figure 4.10.

The basic procedure for RCA is described below:

Brainstorm the major categories of causes of the problem. If this proves difficult, then the generic headings can be used:

- Methods;
- Machines (equipment);
- People (manpower);
- Materials;
- Measurement; and
- Environment.

The factors are annotated as branches from the main and central arrow in the Fishbone Diagram.

The factors are considered as possible causes of the problem. The question: "Why does this happen?" is reiterated. Sub-factors are added as sub-branches. This pattern is repeated and experience has shown that within five iterations of this process, a Root-Cause is identified.

RCA is perhaps most powerfully used as an adjunct to Triangulation and to Gap Analysis.

In the former, the cardinal points of OCV actually reconcile. This is the desirable outcome. If triangulation is carried out cross-referencing a passed EPT sample, i.e. cross-referencing all of the FCMS elements that relate to this passed sample, then OCV has associated a safe product with what the FBO has proposed to do and is, in fact, doing. Similarly, this is the desirable situation.

RCA is usually applied to situations of failure. However, RCA can be also applied to help confirm the Root-Cause of success. The relationship between an FBO proposition and the FCMS with safe food is not always clear or established. Examples of this are processes which propose to use hurdle-technology. Examples of such products are unpasteurised cheese and vacuum-packaged cold smoked salmon with extended shelf life. Repeated iterations of triangulation and RCA over time will strengthen an inference that the pass EPT results are actually the result of the agency of the FBO's proposals and the FCMS – and not the result of some other unidentified agency which the FBO cannot manage – or are not the result of some probabilistic situation which could fail to danger over time.

RCA can also be used in its more traditional application, i.e. to help identify the root cause of a failure to reconcile the cardinal points of OCV.

Example 4.5: Root Cause Analysis

During the reality check, an officer identifies a problem in relation to the storage temperature of minced meat. Staff are monitoring the temperature of the chiller and only take corrective action when this rises above 3.5°C. This constitutes a hazard and a risk in term of the multiplication of for example, enterobacteriaceae and listeria spp. The OCV Study – FCMS review for this establishment did not reveal any issues, as, according to the FCMS, the chiller should always be kept below 2°C.

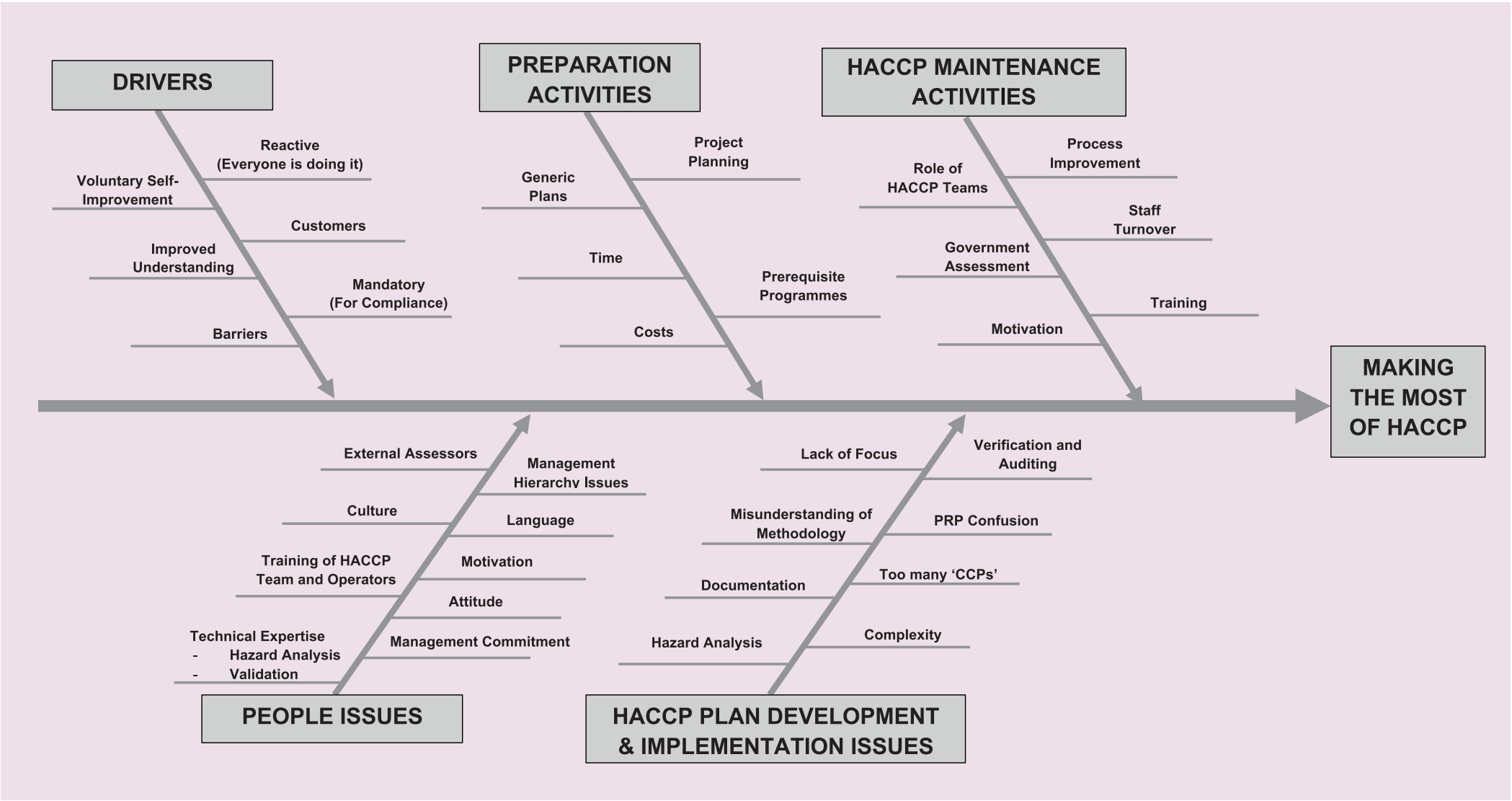
Rather than merely verifying the incorrect corrective action (i.e. a causal factor), the officer undertakes RCA and interviews relevant establishment staff to try and identify the root cause. Using a 5W1H analysis the officer records the following findings:

Initial interviews point to inaccurate instructions given to members of staff via their training. Examining the training programme it is clear that the roll out amongst staff has been poor, training records are not signed off, and the programme has not been reviewed in 4 years.

Further questioning established that the company lost a major contract 3 years ago, after which the training manager was made redundant. The RCA established that in fact the problem could be attributed to lack of resource committed to training by the company due to financial pressure. This was a clear example of lack of higher management commitment to the FCMS, for which training was a PRP.

Senior management were informed of the findings and undertakings given to resource staff training. The training programme was separately addressed, hence ensuring future staff members performing these duties in future will receive adequate training and take the correct corrective action.

Figure 4.10: Example of a Fishbone Diagram



4.16 VERIFICATION TOOL – STATISTICAL ANALYSIS AND PREDICTIVE MODELLING

Function

Statistical analysis is a science which deals with the collection, presentation and analysis of data. It is recognised as one of the most powerful tools of all in OCV and is a means whereby Official Control Verification applies a truly quantitative approach. FBO data may be underused during in Official Controls and Statistical Analysis represent one of the most effective approaches available to an officer.

Statistical analysis goes far beyond reviewing data in terms of pass/fail criteria, by opening up the possibility of far more detailed analysis. This way, raw data is processed into useful information from which much deeper insights and inferences (potentially of critical importance) can be drawn. These may not otherwise be evident or manifested. Statistical analysis also paves the way for long-term, real-time and dynamic verification of FBO performance.

In OCV, statistical analysis takes two principal forms:

1. Descriptive statistics; and
2. Inferential statistics.

A detailed consideration of these approaches is beyond the scope of this document. Moreover, the techniques are already well established and will have been covered in the academic aspects of professional training. The following is an overview.

Descriptive Statistics

Descriptive statistics is the term given to the analysis of data that helps describe, show or summarise data in a meaningful way such that, for example, underlying patterns and trends emerge out of the raw data.

Descriptive statistics frequently constitute the first steps in statistical analysis during OCV.

A simple review of raw data is unlikely to reveal the underlying meaning of that data – particularly when there is a lot of data. Descriptive statistics, therefore enables OCV to present the data in a more meaningful way, supporting easier interpretation. For example, if the FBO had provided 300 EPT results, the officer would be very interested in the overall performance of the process. There would also be great interested in the distribution or spread of the EPT values. Descriptive statistics supports Official Controls in pursuing these interests.

These approaches do not, however, support inferences beyond the raw data analysed, nor do they enable the reaching of conclusions about any hypotheses that might be made or need to be tested. Descriptive statistics remain simply a way to describe the data.

Typically, there are two general types of statistics that are used to describe data:

1. Measures of central tendency are techniques for describing the central position of a frequency distribution for a group of data. In the example above, the frequency distribution is simply the distribution and pattern of the EPT results from the lowest to the highest. In OCV, the central position can be described using a number of statistics, principally,
    - The arithmetic mean;
    - The geometric mean (This mean indicates the central tendency or typical value of a set of numbers by using the product of their values (as opposed to the arithmetic mean which uses their sum));
    - The median; and
    - The mode.

2. Measures of spread are techniques for summarizing a group of data by describing how spread out the values are. For example, the mean score of 100 EPT results may be 65 out of 100. However, not all batches of the product will have the same EPT value. Rather, their scores will be spread out. Some will be lower and others higher. Measures of spread assist in OCV by illustrating and summarising how spread out such values are. To describe this spread, a number of techniques are available to OCV, including:
    - Graphs, charts and frequency distribution plots – Visual and intuitive;
    - The standard deviation – Quantitative;
    - Six-Sigma – Quantitative;
    - The range;
    - Quartiles;
    - Absolute deviation; and
    - Variance.

Calculating the mean, median, minimum, maximum, mode, and standard deviation along with producing an appropriate chart will, for example, identify outlying data points and skewed data. A large difference between the mean and median indicates skewed data or influential outlying data points. Such outlying data points and skewed data are of potentially great significance to OCV.

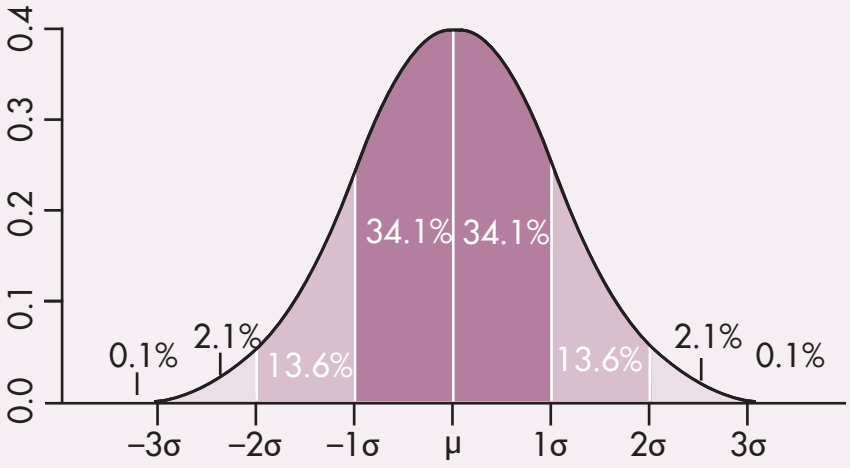
Measuring spread is a very powerful tool underpinning inferences about the capability of a process to consistently perform within specified parameters. For example, a constantly small value of standard deviation with all data occurring within specified parameters is indicative of a process that is capable in terms of food safety.

Statistical approaches to process capability are now well established. In particular, the Six- Sigma approach is becoming commonplace in the manufacturing of goods. The significance of various levels of confidence that result is highly informative: 1σ = 84.13% 1.5σ = 93.32% 2σ = 97.73% 2.5σ = 99.38% 3σ = 99.87% 3.5σ =99.98% 4σ =100%, where σ denotes standard deviation.

Thus when all data occurs either side of the mean within 3 standard deviations and all of that data is within acceptable parameters it can be inferred that if there are no changes to the process, there is 99.87% confidence that all data will continue to fall within that range of variation.

This is significant to OCV in terms of verifying process capability. Figure 4.11 below depicts the relationship between the level of confidence and the value of σ either side of the mean.

Figure 4.11: The relationship between confidence and the value of σ either side of the mean



Inferential Statistics

Inferential Statistics comprises a very wide range of techniques which are concerned with the analysis of a subset of data leading to inferences or predictions about the entire set of data. Inferential statistics may be used in OCV to infer from sample data more general attributes of the entire population of data. They can be used to make judgments of the probability that an observed difference between two groups of data is a dependable relationship or one that might have happened by chance.

This is significant in particular to the emergence within the food sector of minimally processed foods where there is not an established and transparent cause-and-effect relationship between the process and outcomes in terms of food safety. Inferential statistics can also be used to verify the strength of the relationship between two established cause and effect variables such as cooking times and bacterial EPT levels.

Inferential Statistics are frequently the next step after Descriptive Statistics.

Before undertaking inferential statistics, it is frequently necessary to identify and to quantify the degree to which the data fits with established frequency distributions, the normal distribution being an example. Techniques for this process include:-

- Shapiro-Wilk; and
- Kolmogorov-Smirnoff tests.

In OCV, hypothesis testing will be the principle relevance test of the strength of relationship between parameters. Hypothesis tests are statistical tools widely used for assessing whether or not there is an association between two or more variables.

Examples of such variables in OCV are potentially highly varied and include the following, for example:

- The EPT level of E. coli STEC spp;
- The pH level in cheese making;
- The concentration of brine;
- The EPT level of salt in the aqueous phase in smoked fish or meats;
- The level of fat in chocolate (which has been shown to exert a protective effect against heat treatments during chocolate making);
- The level of salmonellae in the finished product;
- The level of EPT listeria spp;
- The results of ATP cleaning verification activities and supplier audit scores; and
- The level of adulteration with non-species DNA.

It should be emphasised that data on all of these variables should already be recorded by FBOs but has not been utilised to optimum effect either by FBOs nor Official Controls.

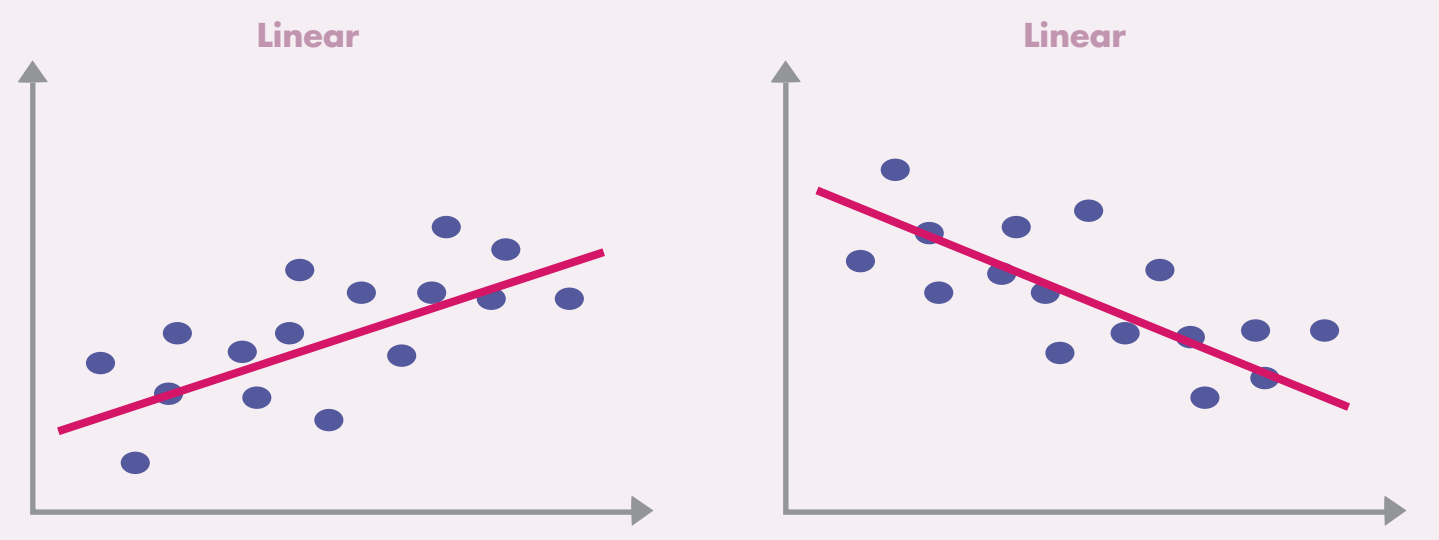
Hypothesis tests provide a probability of the type 1 error (p-value), which is used to accept or reject the null hypothesis. In OCV, the null hypothesis will frequently be that there is no association between two variables and the Alternative Hypothesis is that there is an association between the variables.

Examples of Hypothesis Tests of Association that are frequently used in combination are:

Pearson's Product Moment Correlation Coefficient: Used to measure the strength of association between two variables and ranges between -1 (perfect negative correlation) to 1 (perfect positive correlation).

Linear Regression: Provides a numerical explanation of how variables relate or might relate to one another. Regression enables prediction of the value of the dependent variable (y) given a value of the independent variable (x) and can be used to control for confounding factors when describing a relationship between two variables.

Figure 4.12: Linear relationships between dependent and independent variables



When to Use

Statistical Analysis may be applied at any stage of OCV. Particular applications are as follows:-

- During the OCV Study – when verifying validation, particularly process capability;
- During the process of approval of an establishment and modifications of approval;
- Whenever a more long-term dynamic picture of FBO performance would be informative;
- When a process does not have causal-transparency and a measure of the degree of association between the process and its outputs would be informative; and
- Continuously – where FBO data is shared with the Competent Authority and a dynamic picture of performance is maintained and kept under review over time. This implies a new relationship between the FBO and Competent Authority, but one which is potentially powerful in terms of protecting public health and preventing incidents in the first place – in that trends and other indications toward loss of control can be identified earlier.

How to Use

Modern statistical computer applications are readily available. Many of these are inexpensive, automated and intuitive to use. Most of them provide guidance on the statistical techniques to apply and provide some measure of the interpretation of the results.

Statistical Analysis implies the absolute requirement for data. Competent bodies have the statutory powers to acquire such data. Modern computing techniques and ICT can provide for the establishment of new relationships with FBOs, whereby data is periodically shared and updated – allowing for long-term, real-time and dynamic verification of performance to be maintained.

Inferential Statistics and Predictive Modelling

The use of inferential statistics can be used to make predictions, for example of the effect on changing a parameter on another parameter, frequently a controlling factor value on an EPT value. Predictive modelling is in fact a specialist form of Statistical Analysis informed by microbiological expertise and challenge testing.

5. FORMS

Form A	Inspection Cycle Summary Sheet
This form is to be used by the officers during the planning stages and throughout the inspection cycle, taking into consideration various aspects of the establishment and facilitating an estimate of the resource required.	
Form B	**Business Profile Form**
This form is used to record the relatively static business details, general risk profile in terms of processes, products, FCMSs, supply and distribution etc. In the event of no changes, this should be confirmed on the form. This form is to be used when conducting the initial approval inspection/application of OCV and reviewed at subsequent official controls. In the event of no changes, this should be confirmed on the form. This form will incorporate information gathered at all stages of the inspection cycle.	
Form C	**FCMS Review Form**
This form captures a summary of and potential gaps in the FCMS. Gaps are identified when the FCMS is compared with the Official Control FCMS Study. This form is intended for use at Stage 1 of the Inspection, i.e. Document Review.	
Form D	**Physical and Prerequisites Inspection Check**
This form captures the FBO's implementation of prerequisites as well as the officer's observations on the physical condition of the establishment. It is anticipated that the officer will use this form during Inspection Stage 3 – Main Inspection. This form is to be used when conducting the initial Approval inspection/application of OCV and reviewed at subsequent official controls.	
Form E	**Reality Check**
This form captures officer observations in relation to the implementation of the FCMS and will be used to highlight gaps between the FCMS, its implementation and the officer's Official Control FCMS Study. This form should be used by the officer during Inspection Stage 3 – Main Inspection. This form is to be used as a cover page to which officers should attach all relevant tools and evidence used during the reality check.	
Other Forms	
Including; CCP assessment form, Non CCP assessment form, Traceability/Product Recall/Mass Balance Form.	

FORM A – Inspection Cycle Summary Sheet

Business Information

Business Name:

Approval Number:

Address:

Completing Officer:

Resource Calculation

Resource Requirements: (Refer to Annex 1 Calculation)		
		Justification/Comments
Process Code		
Factor	**FTE Days**	
Document Review Time		
Additional Document Review Time (for each additional process requiring a HACCP Study)		
On-site Time		
Additional On-site Time (for each additional process requiring a HACCP Study)		
Factor for Absence of FCMS		
Additional Factor for Number of Employees		
Other Resource Demands (e.g. research)		
Total Resource (FTE days)		

Inspection Cycle Plan

Inspection Cycle Plan:	
Proposed Date of Inspection	Proposed Scope (E.g. announced/unannounced, activities, processes or aspects of FCMS being verified)

Inspection Cycle Outcomes

Summary of Interventions				
Date	**Officer(s)**	**Scope**	**Announced/ Unannounced**	**Outcomes**

Inspection Cycle Documentation

Inspection Documentation	**Date Completed**
Pre-Inspection Documentation Schedule Issued	
HACCP Assessment Checklist Reviewed/Updated	
Establishment Profile Completed/Updated	
Physical and Pre-requisites Inspection Form	
Reality Check Inspection Form	
Establishments Specific Inspection Form	
END OF FORM	

FORM B – Business Information and Profile Form

Business Information

Business Name:	
Full Address:	
Telephone Number:	
E-mail Address:	
Approval Code:	
Main Contact:	
Details of FBO (Include Name(s) of Partner((s)):	
FBO's Address (If different to above):	
Registered Office Address (if different to above):	
Registered Office Tel No. (if applicable):	
Name of Company Secretary:	

Out of Hours Contact Details

Name:	
Telephone:	
Mobile:	
Email:	

Premises Profile

Scope of Approval:

Product	Establishment Type	Select Appropriate
Red Meat	Abattoir	
	Cutting Plant	
Poultry and Lagomorphs	Abattoir	
	Cutting Plant	
Farmed Game	Abattoir	
Wild Game	Game Handling Establishment	
Minced Meat, Meat Preparations and Mechanically Separated Meat	Processing Plant	
Meat Products	Processing Plant	
Live Bivalve Molluscs	Dispatch Centre	
	Purification Centre	
Fishery Products	Factory Vessel	
	Freezing Vessel	
	Processing Plant	
	Fresh Fishery Products Plant	
	Auction Hall	
Raw Milk & Dairy Products	Collection Centre	
	Processing Plant	
Eggs and Egg Products	Packing Centre	
	Processing Plant	
	Liquid Egg Plant	
Frogs Legs and Snails	Processing Plant	
Rendered Animal Fats and Greaves	Storage	
Treated Stomachs, Bladders and Intestines (Processing Plant)	Processing Plant	
Gelatine	Processing Plant	
	Collection Centre/Tannery	
Collagen	Processing Plant	
	Collection Centre/Tannery	
General POAO	Cold Store	
General POAO	Wholesale Market	
General POAO	Re-wrapping and Re-packaging Establishment	
General POAO	Re- packaging Establishment	

Type of foods produced/manufactured/processed: (indicate type and note use of raw meats & ready to eat foods. Use of raw eggs and shellfish products for high risk foods).

Type of process – e.g. thermal processing of low acid foods, pasteurisation, hot holding, re-heating/ regeneration, minimally processed foods cook chill/cook freeze, brining, smoking, vacuum packing, modified atmospheric packing: (Officer to describe all elements of processing).

Description of establishments (layout, facilities, general suitability): (Officer to attach/Link to establishments plan).

Suppliers and supplied products: (Alternatively attach suppliers list).

Supplier Name	**Supplier Address**	**Products**

Types of Incoming POAO Used:

POAO class	Species	Carcase Meat/ Wholesale Cut	Boxed/ Packed /Vac-Pack Meat	Minced Meat/ Meat Prep	Meat Product	Blood	Fat/ Offal	Milk (Raw)	Milk (Pasteurised)
Domestic Ungulates	Beef, Lamb, Sheep, Pork, Goat, Buffalo								
Solipeds	Horse								
Ratite	Ostrich Other								**Eggs**
Poultry	Chicken Turkey Geese Duck Other								**Eggs**
Wild Game	Venison Small Wild								
Farmed Game	Venison Other								
Lagomorphs									
Shellfish				Live/Dead/Processed					
Fish				Wild/Farmed					
Honey									
Other									

Scale of distribution (nature – e.g. local retailers/caterers and number):

(include identity of customers, details of chain and extent of supply i.e. local, regional export etc).

Production quantity (throughput):

Officer to record the verified weekly throughput:

Vehicles – Officer to detail number, refrigeration, list of registration details to be obtained:

Special considerations (trading hours, production times, PPE requirements language, etc):

Employees (Detail number of food handlers):

Is the business subject to a system of:

Audit	**Details**
Internal	
External	
Third Party Accredited	

Officer Notification/Recommendations

Officer to record other observation(s) as appropriate (i.e. advice to next inspecting officer: issues for consideration, advice on format of next intervention, notification of any particular guidance or codes of practice applicable etc.)

Inspecting Officer:	
Review Record:	

Date of Review	**Officer Name**	**Officer Signature**
END OF FORM		

FORM C – FCMS Review Form

Business Name:	
Approval Number:	
Officer:	
Date of Initial Completion:	

PREPARATION AND PREREQUISITE PROGRAMMES

What evidence is there of management commitment to the FCMS?	
What is the scope of the FCMS? **Has a linear or modular approach been taken?** **How many HACCP studies are there?** **Are all products covered by the FCMS?**	
Does the FCMS include a documented prerequisite programme?	
Does the FCMS include process controls? E.g. master manufacturing instructions, traceability, and product recall.	

HACCP Step 1: HACCP Team

Who was on the team?	
Are all appropriate disciplines represented?	
What is the level of knowledge? (Evidence of training, qualifications, experience, etc)	
Do any processes require specialist knowledge?	
Has external expertise been sought where necessary?	

HACCP Steps 2 and 3: Product Description and Intended Use

Are all products and processes covered by product descriptions?	
Has the product been described in safety terms? E.g. does it cover composition, characteristics (e.g. a_w, pH), processing (drying, heating, freezing etc.) packaging (e.g. MAP), storage conditions (e.g. chilled, frozen), shelf-life, intended customers and use etc, micro/chemical criteria? Has the epidemiological history of the product/process been referenced? Have the principle hazards been specified? Have the controlling factors/measures been identified in general terms?	

HACCP Steps 4 and 5: Process Flow Diagram

Is the process flow diagram (PFD) accurate and adequate?	
Has the PFD been verified for accuracy and by whom? **How was it verified? Is this documented?**	
Are inputs, process/ storage activities and outputs included in the flow diagram? (Including Rework). (The PFD should be verified by 'walking the line' during the reality check inspection.)	
Have CCPs been mapped onto the PFD?	

HACCP Step 6: Hazard Identification and Analysis

It is suggested that elements of the PFD are sampled on both an elective and random basis and the officer carries out and documents Step 6 according to the structured approach in the guidance.
A chart for recording is included at the end of this form.

Have all relevant hazards been identified? **Have the hazards been specifically identified by type/source or have they been generalised?** **What method was used to identify the hazards?** **Were the contributory factors considered used i.e. P.I.I.M.S/P.I.I.G.S?**	
How did the team assess the likelihood of occurrence and severity? (Rating system?)	
What information sources were utilised? (e.g. legislation, industry guidance, scientific data, trade associations, own experiments/ data)	
Have appropriate control measures been identified for each hazard?	
Will the control measures control the hazards and how was this validated?	

HACCP Step 7: Determine the Critical Control Points

How were the CCPs identified? By expert judgement? By the use of a decision tree? (Has the decision tree been used correctly?) By the use of consultants?	
Have all necessary CCPs been identified?	
Have any controls been incorrectly identified as CCPs?	
How are the hazards which are not controlled by CCPs addressed? Prerequisites, Operational Prerequisites, Standard Operating Procedures etc.	

HACCP Step 8: ESTABLISH CRITICAL LIMITS (ALL CCPs)

Have critical limits been established for each CCP? How do they differ from operational limits/target levels?	
How were the critical limits established? (Experimental data, legal requirements, literature references, etc)?	
Are the critical limits realistic, measurable or observable? (E.g. time, temperature, pH, a_w, visual appearance etc.)	
What validation exists that the critical limits control the identified hazards?	

HACCP Step 9: ESTABLISH MONITORING SYSTEM

Do monitoring procedures cover all CCPs?	
Has the reliability of monitoring procedures been assessed where appropriate?	
Is monitoring frequent enough to detect loss of control?	
Do procedures ensure monitoring equipment calibrated appropriately?	
Is monitoring restricted to appropriately identified and trained personnel? **Do monitoring procedures specify who/what/when/how?**	

HACCP Step 10: ESTABLISH CORRECTIVE ACTIONS

Have the corrective actions been properly defined such that control is regained?	
Do the corrective actions prevent all non-conforming product entering the food chain? (Including production since last satisfactory CCP check if appropriate)	
Has the authority for corrective action been assigned? **Do corrective actions address past, present and future loss of control?**	

HACCP Step 11: VALIDATION, VERIFICATION AND REVIEW PROCEDURE

How has the HACCP system been validated? E.g. process capability studies, product testing etc.	
What verification procedures are in place? E.g. management checks, internal audits, external audits, sampling, calibration etc.	
Who is responsible for verification?	
Are all CCPs covered by the verification programme?	
What review arrangements are in place for the HACCP? (All Steps to be considered)	

HACCP Step 12: ESTABLISH DOCUMENTS AND RECORDS

Are the FCMS procedures adequately documented? E.g. Hazard analysis, CCP determination, CL determination, sampling plans etc.	
How is the documentation controlled with regard to update and issues, etc.?	
Are records adequate to demonstrate that CCPs/OPPs are being effectively monitored and under control (including corrective actions)?	
Are validation, verification and review procedures documented?	

Record of Review

The FCMS review should be reviewed at each inspection cycle and updated electronically – a record of the review and summary of any changes should be detailed below. In the event of significant changes to the HACCP system a new checklist should be completed.

Date of Review	Summary of Amendments
END OF FORM	

FORM D – Physical and Pre-Requisites Inspection Form

Business Name:

Approving Number:

Officer:

Date of Initial Completion:

Establishments Design and Layout

Assessment	Objective Evidence
Equipment in good repair and capable of being cleaned and disinfected (where necessary)	
Structure in good repair and capable of being cleaned and disinfected (where necessary)	
Maintenance Arrangements	

Cleaning & Disinfection

Assessment	Objective Evidence
Procedures Specify: Agents Dilution Rates Contact Times Temperature Time **Consideration of positive release of high risk equipment**	
Cleaning Schedules	
Verification by FBO e.g. swabbing plan	

Pest Control

Assessment	Objective Evidence
Pest Control Arrangements (Note contractor details where applicable)	
Evidence of Activity/Proofing issues	

Waste Management

Assessment	Objective Evidence
Waste Disposal Arrangements (including ABP)	
Observations on waste control, including in food rooms and waste awaiting uplift	

Personnel & Personal Hygiene

Assessment	Objective Evidence
Changing Facilities	
Protective Clothing Provision	
Hand Washing Facilities and Procedure	
Sickness Procedure	
Visitors and Contractors Arrangements	

Training

Assessment	Objective Evidence
Training of Food Handlers	
No. of Food Handlers	
No. Trained to Elementary	
No. Trained to Higher Level (specify)	
Training Format e.g. in-house/ on-line etc.	
CCP/OPP/PRP/Task Specific Training	
HACCP Training	

Product and Environmental Testing

Assessment	Objective Evidence
Sampling Plan (include details of laboratory and UKAS accreditation)	
Validation and Verification sampling	
End Product Micro sampling (including EC 2073/2005 where applicable)	
Environmental Sampling	

Process Control

Assessment	Objective Evidence
Control of Incoming Product – supplier approval, certificates of conformance etc.	
Master Manufacturing Instructions/Recipes	
Standard Operating Procedures for control of recipes, ingredients, labelling etc.	

Complaints, Traceability & Product Recall

Assessment	Objective Evidence
Traceability Procedure	
Internal Traceability	
Product Recall procedure, including arrangements for testing **Date and outcome of last test**	
Complaints	

Labelling and Documentation (Copies to be taken for file)

Assessment	Objective Evidence
Approval Code Applied	
Validated Durability Date applied (with appropriate storage conditions specified)	
Invoices Compliant with EC 931/2011 (where applicable)	
Declarations/Claims	

Allergens

Assessment	Objective Evidence
Allergen Policy	
Allergen Cross Contamination Procedures	
Declarations	

Review Record

Date	Officer
END OF FORM	

FORM E – Reality Check Record

Business Name:	
Approving Number:	
Officer:	
Date of Initial Completion:	

Reality Check

This form is to be used as a cover page to which officers should attach all relevant tools and evidence used during the reality check.

FCMS element(s) being assessed:	
Justification:	
Tools/Methods to be used:	
Observation on the validity of HACCP for element assessed:	
Future considerations:	

Other Observations

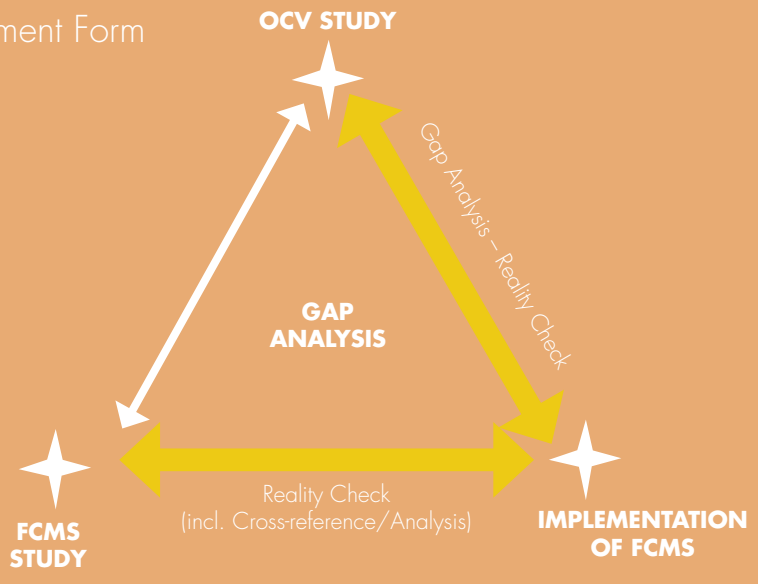
Officers Notes:	

(Attach all other relevant tools and evidence as required.)

END OF FORM

Other forms

Reality Check – CCP Assessment Form



Business Name:

Officer:

Date of Reality Check:

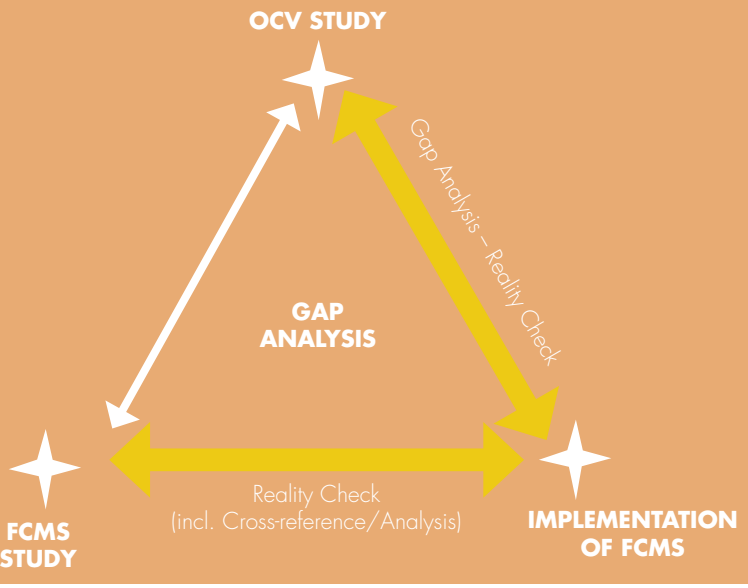
Product:

CCP:

	Record Sources of Evidence
Has the CCP been correctly identified?	
Critical Limits (Appropriate, achieved in practice)	
Monitoring (Appropriate frequency, trained staff, consistent with written procedure)	
Corrective Actions (Are these being actioned when required, consistent with written procedure)	
Records (Accessible, correct version, completed correctly)	
Is the CCP under control? Evidential Triangulation – record sources of evidence.	

Other forms

Reality Check – Non – CCP Assessment Form



Business Name:

Officer:

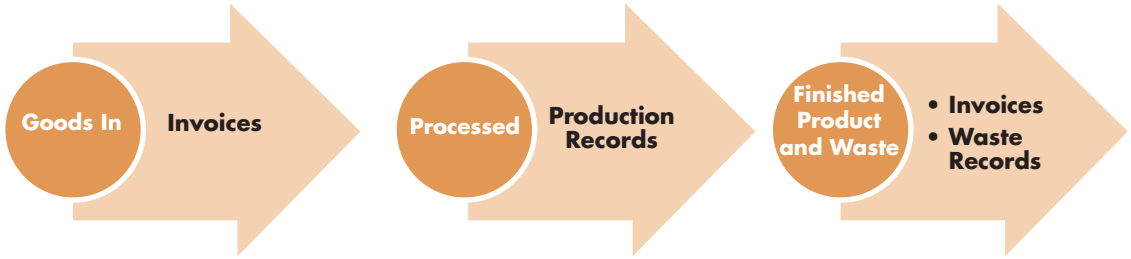
Date of Reality Check:

Product:

CCP:

	Record Sources of Evidence
Has the Step been correctly identified? (PRP/OPP etc)	
Controls and Limits (Appropriate, achieved in practice)	
Monitoring (Appropriate frequency, trained staff, consistent with written procedure)	
Corrective Actions (Are these being actioned when required, consistent with written procedure)	
Records (Accessible, correct version, completed correctly)	
Is the CCP under control? Evidential Triangulation – record sources of evidence.	

Traceability/Product Recall/Mass Balance



Business Name:

Officer:

Date of Reality Check:

Product:

CCP:

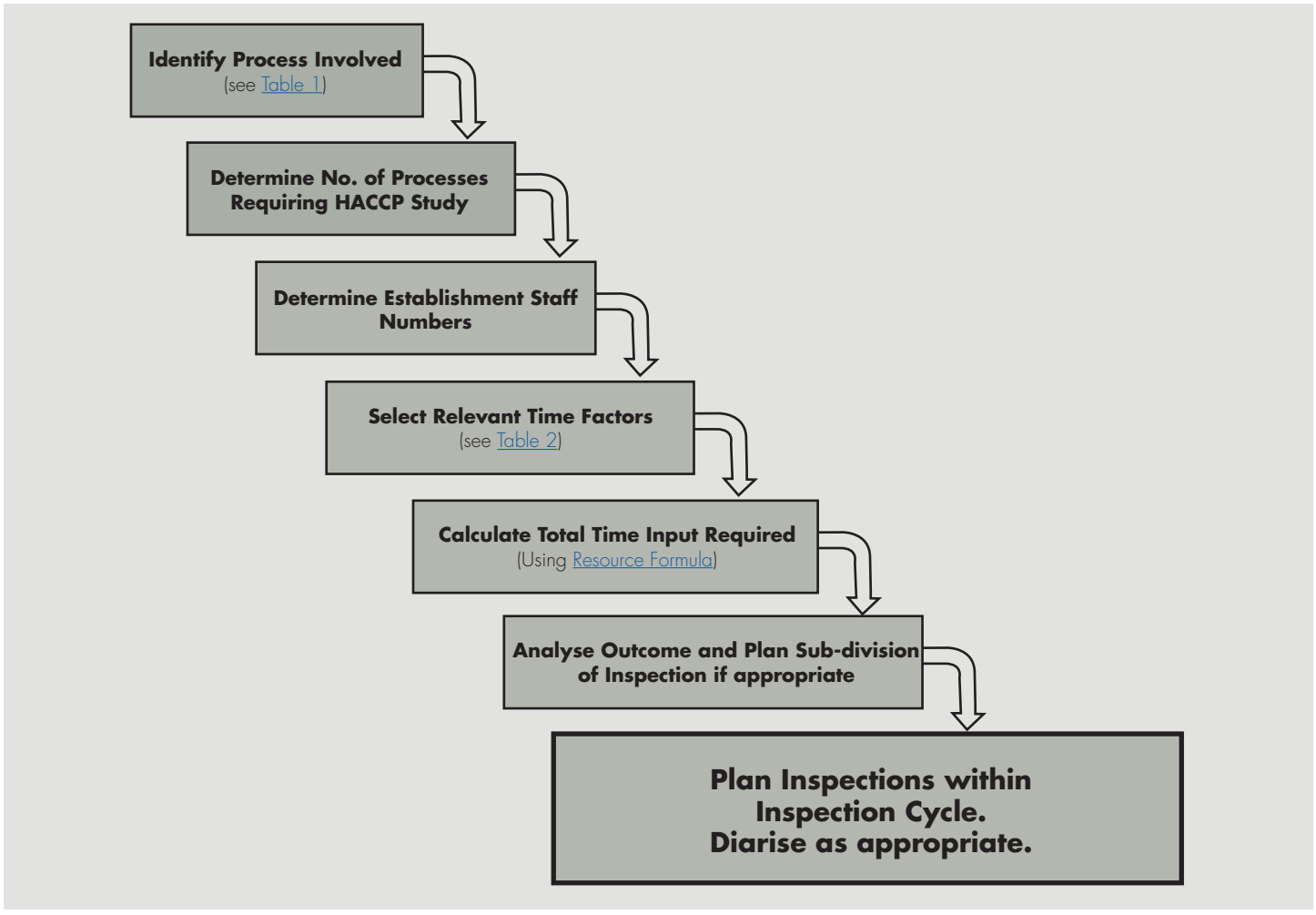
	Record Sources of Evidence
Can ingredients be traced back to intake and supplier (reverse trace) **or can all products produced with affected product be identified?** (forward trace)	
Can the FBO identify all product which requires to be recalled?	
Mass Balance	
Ability to effectively identify and contact customers	
Recommended improvements to system	

6. ANNEXES
ANNEX 1 – RESOURCE CALCULATION

Chapter 3 of this guidance refers to the planning of inspections in approved and manufacturing establishments. It is essential that a Competent Authority is able to determine the resource demands relating to each individual establishment and, by extension, to the entire inspection programme. It is vital, therefore, that the Authority is able to estimate the time likely to be involved in each inspection.

The undernoted calculation methodology is based upon the principles of ISO 22000 and may be used to predict the amount of time which should be allocated to each inspection or "Inspection Cycle" (see Chapter 3).

Figure A.1: Resource Calculation Process



Calculation of Estimated Time Required for Inspection – The Resource Formula

The estimated time (i.e. "ET") required for an Official Control Verification inspection shall be calculated using the Resource Formula as follows:-

Resource Formula:

ET = DRT + ADRT + OST + AOST + FFCMS + AFTE + ORD

Where:

DRT =	**Document Review Time** (for Document Review stage contributing to Official Control Verification, including Official Control OCV Study)
ADRT =	**Additional Document Review Time** for each additional process requiring a HACCP study
OST =	**On-site Time** (for Reality Check stage contributing to Official Control Verification, including OCV)
AOST =	**Additional On-site Time** for each additional process requiring a HACCP study
FFCMS =	**Factor for Absence of FCMS**
AFTE =	**Additional Factor for Number of Employees**
ORD =	**Other Resource Demands**

Process Categories

The length of time devoted to the inspection process should reflect the nature of the establishment. Consequently, the officer should determine the category of process or processes undertaken within the establishment in order to apply the Resource Formula accurately. Table 1 lists a range of process types and groups these into Categories.

Table 1 – Process Categories

Process Code	Product/Technology	Example of Product/Process
A	Non-RTE POAO Handling/re-wrapping of FTE foods only	Abattoir Shellfish dispatch Fishmonger
B	RTE POAO shelf-life extended by established validated heat treatments (e.g. ACMSF 6 log reduction 90OC for 10 minutes etc. Composite products made from RTE POAO	Cooking of POAO Bakery (Composite products containing POAO e.g. pies and pasties) Hot-smoked POAO Pasteurisation of dairy products by established batch or HTST processes Cheeses, pates and terrines etc.
C	Cook-chill	Ready meals preserved by chill holding & intended for regeneration at point of consumption
D	RTE POAO preserved by canning, vacuum and MAP Products with shelf life extended by minimal thermal processing Products containing critical ingredients, Including the use of 'Hurdle-technology' Products subject to minimal processing in combination with critical hygiene controls Shellfish depuration POAO placed upon the market untreated Products subject to allergen claims	Canned POAO and composite products Cold-smoked POAO, Vacuum and MAP preservation POAO not subject to a thermal process validated to achieve 6 log bacterial reductions (e.g. rare burger manufacture) Sushi and sashimi 'Very Low Gluten', 'Dairy Free' etc.

"Additional" HACCP Studies

The Resource Formula takes into consideration the fact that many food establishment operations involve more than one process which requires a HACCP Study. This applies to both the estimation of Document Control Time and the On-site Official Control Time.

While food products may be identical or very similar, the associated food science and technology may involve different hazards and/or different levels of risk and complexity. Officers should exercise professional judgement when determining the true nature of the overall operation – in relation to the processes which demand a separate HACCP Study.

The following examples demonstrate where it should be considered that "additional" HACCP Studies are applicable. This list is not definitive or exhaustive – officers should use professional discretion when reviewing both the FBO's and their own product descriptions (i.e. Inspection Stage 1). By doing so, the officer can discriminate between FBO HACCP Studies that require to be considered as "Additional" and those that may not:

Examples of where HACCP Studies should be viewed as "different" or "additional"

a) Where a FBO HACCP Study refers to the inclusion of particular allergenic ingredients – where other HACCP Studies either refer to different allergens or none at all. For example, where peanut flour is used in one process – wheat or soya flour being used elsewhere.

b) Where two or more FBO HACCP studies entail the use of ingredients with differing hazard profiles. For example, the distillation of single malt whisky may simply involve the use of barley, whereas production of artisan Scottish gin might include a range of wild-foraged botanicals with unique toxicological profiles and/or requiring Novel Food licensing.

c) Where a FBO HACCP Study relates to new or emergent food science and technology (requiring specific validation) while the other FBO HACCP Studies do not. For example, burger production intended for the rare burger market or high- pressure (non-thermic pasteurisation) of fruit juices.

d) Where a FBO HACCP Study relates to substantively different science and technology from other FBO HACCP Studies. For example, hot smoking being carried out at the same establishment as cold smoking or pasteurised cheese production at the same establishment as unpasteurised cheese production.

e) Where a FBO HACCP Study relates to preservation techniques that are substantively different from others applied within the establishment. For example, where a product shelf life is extended by vacuum packaging or curing whereas the shelf life of other products are controlled by chilled temperature only.

f) Where FBO HACCP Study or Studies involve different species of fish or shellfish and/or shellfish derived from category A and B classified waters. For example, a fish ready-meal containing scombroid species and another containing whitefish. Alternatively ready-to-eat mussels are derived from both Category A and Category B classified waters with different processing requirements.

Time Factors

The estimated time to be allocated to aspects of inspection will vary in accordance with the nature of the Category of Process or Processes carried out (see also Table 1).

Table 2 lists the key components of the Resource Formula and designates appropriate time factors applicable to each dependent upon Process Category.

Table 2 – Time Factors

Process Code	**DRT** (FTE days)	**ADRT** (FTE days)	**OST** (FTE days)	**AOST** (FTE days)	**FFCMS** (in FTE days)	**AFTE – Number of Employees** (in FTE days)	**ORD** (FTE Days)	**For each Additional Site Visited**
A	0.25	0.25	0.75	0.25	0.5+	1 to 19 = 0 20 to 49 = 0.5 50 to 79 = 1.0 80 to 199 = 1.5 200 to 499 = 2.0 500 to 899 = 2.5 900 to 1299 = 3.0 1300 to 2999 = 4.0 3000 to 5000 = 4.5 >5000 = 5.0	Determined by officer	50% of minimum on-site official verification time
B	1.00	0.25	1.00 – 1.50	0.50				
C	1.00	0.25	1.00 – 2.0	0.50 – 1.00				
D	1.0-1.5	0.50	2.0 – 3.5	0.50 – 1.00				

Worked Example

An officer planning an inspection of a smokery establishment begins by reviewing the Business Profiling information and the product descriptions. The establishment is engaged in both hot and cold smoking of salmon and trout and extends the shelf life to 42 days by a combination of chill holding and vacuum packaging. The establishment also manufactures terrines and pates using fish trimmings and cream cheese. There are 43 employees. The establishment has been verified as achieving greater than broad- compliance for 5 years and holds a recognised food safety accreditation.

The officer recognises that hot and cold smoking of salmon and terrine manufacture etc constitute three distinct processing categories necessitating three distinct FCBO HACCP studies and therefore proceeds as follows:

The officer must apply the Resource Formula:

ET = DRT + ADRT + OST + AOST + **FFCMS** + AFTE + ORD

Inspection Component	Description	Time Allocated (Days)
DRT	Document Review Time	1.0
ADRT	Additional Document Review Time (2 additional HACCP Studies)	0.5
OST	On-site Official Control Verification	2.0
AOST	Additional On-site Official Control Verification (2 additional HACCP Studies)	1.0
FFCMS	Factor for Absence of FCMS	0.0
AFTE	Additional Factor for Number of Employees (43)	0.5
ORD	Other Resource Demands	t.b.c
ET	**Total Time Allocated to Inspection[1]**	**5.0[2]**

1 This calculation does not include travelling time or time allocated to report writing or enforcement activity.

2 For the purposes of this document, 1.0 officer-day equates to 5 FTE Hours. This may be different depending upon Authority/ Organisation.

Planning the Inspection

The officer should consider how the 5 days allocated to the inspection should be allocated. It is unlikely that any inspection will be undertaken over 5 consecutive days. Consequently, the officer should take a modular approach and plan a series of partial inspections over the period of the inspection cycle. The inspection cycle should be planned and scheduled. The Project Management tools within this document provide for such an approach.

ANNEX 2 – PRE-INSPECTION DOCUMENTATION SCHEDULE

To: Name and address of FBO

Your food business is due to be inspected shortly. To save time during the inspection and to reduce disruption to your business on the day, it would be helpful if you could provide the information indicated below in advance. Requested information should be sent to:

Officer's business address:

For the Attention of: Officer's name

The information requested should be provided no later than: Date information required

If you have any questions, please contact the aforementioned officer at:
Officer's phone number:

Officer's email address:

1	**COMPANY PROFILING**	
1.1	**Identity and contact details, name, address, telephone number(s), email address and details for:**	
1.1.1	Food business operator (the legal person conducting the business):	☐
1.1.2	Managing Director:	☐
1.1.3	Company Secretary:	☐
1.1.4	Quality/Safety Assurance Manager:	☐
1.1.5	Person responsible for authorising conformance with food safety management procedures:	☐
1.2	List of current product range:	☐
1.3	List of current customers:	☐
1.4	List of current suppliers:	☐
1.5	Master manufacturing instructions:	☐
1.6	Current site layout/plan:	☐

2	**HACCP-ASSOCIATED DOCUMENTATION**	
2.1	**HACCP Plan**	☐
2.2	Current HACCP Plan	☐
2.2.1	Including current process flow diagrams	☐
2.2.2	Including standard operating procedures for each CCP/Operating manuals for equipment at each CCP	☐
2.2.3	Including monitoring records for each CCP since [date]	☐
2.2.4	Including corrective action records for each CCP since [date]	☐
2.3	**Verification Activity**	☐
2.3.1	Operating instruction manuals for HACCP control measurement	☐
2.3.2	Documentation from last review of HACCP Plan	☐
2.3.3	Minutes of last 3 meetings of the HACCP Team	☐
2.3.4	Documentation in relation to the last process flow diagrams review/validation	☐
2.3.5	Documentation in relation to new product design (from the date of the last inspection)	☐
2.3.6	Documentation in relation to the last 3 internal audits of the HACCP Plan	☐
2.3.7	End product sampling and assay plan	☐
2.3.8	Results of end-product assay(s) from the date of the last inspection:	☐
	• Microbiological	☐
	• Chemical	☐
2.4	Documentation associated with validation: process capability assessment	☐

3	PREREQUISITE PROGRAMMES	
3.1	**Training**	☐
3.1.1	Training policy	☐
3.1.2	Records in relation to training:	☐
	• Induction training	☐
	• HACCP training	☐
	• CCP/SOP training	☐
	• Food hygiene training	☐
3.2	**Staff Hygiene**	☐
3.2.1	Policy on staff hygiene (e.g. protective clothing)	☐
3.2.2	Staff Exclusion Policy	☐
3.3	**Cleaning and Disinfection**	☐
3.3.1	Cleaning and disinfection procedures	☐
3.3.2	Cleaning and disinfection schedules	☐
3.3.3	Specifications for all cleaning and disinfection agents	☐
3.3.4	Environmental cleaning and disinfection assays e.g. swabbing	☐
3.4	**Water Supply**	☐
3.4.1	Results from microbiological assay of the water supply	☐
3.4.2	UV light renewal records	☐
3.4.3	Filter renewal records	☐
3.4.4	Procedure for chemical dosing	☐
3.5	**Pest Control**	☐
3.5.1	Pest control policy/contract	☐
3.5.2	Results of pest control inspections since the date of the last LA inspection	☐

4	**OTHER GOOD MANUFACTURING PRACTICES**	
4.1	**Foreign Body Control**	☐
4.1.1	Policy procedure on foreign body control	☐
4.1.2	Glass/Perspex control procedure	☐
4.1.3	Results from glass/Perspex audits undertaken since last LA inspection	☐
4.1.4	Results from foreign body control measures e.g. metal detection/scanning	☐
5	**TRACEABILITY, PROVENANCE AND LOT MARKING**	
5.1	**Traceability procedure**	☐
5.2	Lot marking procedure	☐
5.3	Records in relation to last traceability test/challenge	☐
5.4	Procedures for product recall conforming	☐
5.5	Records in relation to last product recall test/rehearsal	☐
5.6	**Procedure(s) for managing non-conforming product e.g. disposition, control, quarantine, re-working etc**	☐
5.7	Records in relation to non-conforming product since the last LA inspection	☐
5.8	Procedure for supplier approval	☐
5.9	Last supplier approval	☐
5.10	Last supplier audit for each supplier	☐
6	**CALIBRATION**	
6.1	**Procedure for calibration of HACCP control measure and monitoring equipment**	☐
6.2	Calibration records	☐
7	**ALLERGEN MANAGEMENT AND CONTROL**	
7.1	**Policy on allergen control**	☐
7.2	Method for informing customers in relation to allergenicity of product	☐
7.3	Procedure for procurement in relation to allergen control	☐
7.4	Procedure for controlling cross contamination in relation to allergens	☐

GLOSSARY

Cardinal Points of Official Control Verification

The three main reference points contrasted and compared by the officer when verifying the Food Safety Management System of a food establishment, when conducting official control verification. These Cardinal Points are:

1. An official control FCMS Study conducted by the officer;
2. The FCMS created by the FBO;
3. A reality check of the implementation of the FCMS and of the OCV study *in situ*.

These cardinal points in the official control FCMS and the FCMS reflect the FBO's proposition that he or she intends to do the right things and in the FCMS and the reality check that he or she has been doing those things.

Cognition

The mental action or process of acquiring knowledge and understanding through thought, experience, and the senses.

OCV is a scientific, structured and systematic cognition for Official Controls based upon gap analysis and triangulation referencing the three cardinal points of OCV.

See also cardinal points of official control verification, gap analysis and triangulation.

Contributory Factors

These factors derive from the work of Dr. Frank Bryan, formally of the USFDA, on the epidemiology of foodborne illness, particularly the causation of food borne illness. Hazards associate themselves with particular process steps. Application of this knowledge of association actually supports 'mapping' the hazards to process steps where it is relevant to do so in terms of the epidemiology of foodborne illness.

Epidemiology

The study of how often diseases occur in different groups of people and why.

Evidential Triangulation

A technique whereby two or more sources of evidence are used to corroborate each other and to enhance the certainty of an inference or conclusion – Frequently an induction.

Food Control Management System (FCMS)

The interrelated elements that are designed and applied by a food business operator to prevent foodborne illness and/or prejudice caused by the consumption of food.

These elements include aims, objectives, policies, procedures, practices, processes, methods, controls, roles, responsibilities, relationships, documents, records and resources.

In practice, a FCMS may combine the following 4 main components:

- Prerequisite Programmes;
- Process control (Product Disposition Plans);
- HACCP Studies; and
- Incident Management Plan.

The ambit may include food safety, food standards, food defence, food fraud and crime, traceability and provenance.

Gap Analysis

The key, underpinning concept of OCV. It is the process whereby the Officer compares and contrasts the aspects of the three cardinal points of OCV.

The term somewhat overlaps with Triangulation.

Inspection

This is the term applied by this document in relation to official control interventions conducted within approved/manufacturing establishments.

It means the examination of any aspect of food or food production in order to verify that the process will deliver safe food and that relevant aspects comply with the legal requirements of Food Law.

Inspection applies to the entire food establishment, i.e. the FCMS, the physical establishments, the FBO and the workforce.

Inspection Cycle

The period of time between programmed interventions as determined by Annex 5 of the Food Law Code of Practice Scotland.

Food Standards Scotland advocates that the favoured intervention applied in relevant establishments should be the Inspection informed by the Official Control Verification process. Consequently, the term "Inspection Cycle" is favoured instead of the more technically-correct "Intervention Cycle".

In OCV, the Inspection Cycle refers to the period within which the FCMS must be fully verified by the Competent Authority.

Non-destructive testing (NDT)

A wide group of analytical techniques used particularly within safety critical science and technology applications, in order to evaluate the properties of a material, component or system without causing damage. It is sometimes used as an approximate metaphor for describing the process of OCV. OCV can be used as an analogue of NDT in official controls.

Objective Evidence

Information based on facts that can be proved through analysis, measurement, observation, and other such means of research.

OCV Study

The application of the WHO-Codex defined steps and principles of HACCP and of other FCMS elements to a product and/or process, undertaken by the Competent Authority.

The outcome of the process is one of the cardinal points of OCV, providing a key reference that is both external and independent of the FBO's own FCMS.

As part of the wider official control FCMS study, the official control step 6 Study in fact deduces and induces the pattern of food borne disease that would occur in an establishment, if the FBO did not take effective control measures.

Official Control Verification

The overall process of verification of the FCMS which is carried out by the Competent Authority. It is a scientific, structured and systematic cognition for the officer.

Operational Prerequisite Programmes (OPPs)

(See also Prerequisite Programmes)

Operational prerequisite programs (OPRPs) are prerequisite programmes (PRPs) that are essential. They are essential because a hazard analysis has shown that they are necessary in order to control specific food safety hazards.

OPRPs are used to reduce the likelihood that products will be exposed to hazards, that they will be contaminated, and that hazards will proliferate. OPRPs are also used to reduce the likelihood that the processing environment will be exposed to hazards, that it will be contaminated, and that hazards will proliferate in that environment.

P.I.I.M.S and P.I.I.G.S

Mnemonics relating to microbiological…

P. – Presence
I. – Introduction (By Cross Contamination)
I. – Introduction (By Direct Contamination)
M. – Multiplication
S. – Survival

P. – Presence
I. – Introduction (By Cross Contamination)
I. – Introduction (By Direct Contamination)
G. – Growth
S. – Survival

See also Contributory Factors

Prerequisite Programmes (PRPs)

Prerequisite v (PRPs) are the conditions that must be established throughout the food chain and the activities and practices that must be performed in order to establish and maintain a hygienic environment. PRPs must be suitable and be capable of producing safe end products and providing food that is safe for human consumption. PRPs support HACCP plans.

Process Control (Product Disposition)

A critical and an integral aspect of any FCMS. It relates to the quantity of all components of the product, their location and their progress through the entire process. Product disposition encompasses the master manufacturing instructions, traceability and lot marking for example.

Proposition(s) of the FBO

Propositions that the FBO makes, either explicitly or implicitly, when he or she places food upon the market. This is that the food is both authentic and safe and will not prejudice the consumer. In the context of FCMS, further deductions become (i) the FBO intends to do the right things and (ii) the FBO has or is doing those things.

(See also cardinal points of Official Control Verification)

Reality Check

The process of verification of the FBO's implementation of his or her own FCMS and a confirmation of the Official Control Verification Study in situ. OCV and the FCMS in the actual production environment i.e in situ.

Subjective

Generally considered to be a single person's opinion, thoughts or feelings. It has a viewpoint, or possibly a bias, regardless of the information it provides.

Examples are adjectives such as 'satisfactory', 'of high- standard' and 'compliant'.

Official Control verification seeks to minimise subjectivity in official controls.

Triangulation

The process of reconciliation of the cardinal points of official control verification. The term overlaps with gap analysis, but tends to be used in the positive i.e. where there are no gaps and the cardinal points are reconciled.

Not to be confused with Evidential Triangulation.

Food Standards Scotland © Crown copyright 2019