Food Standards Scotland
Inbhe Bìdh Alba

sfelc
Scottish Food Enforcement Liaison Committee

OFFICIAL CONTROL VERIFICATION

HACCP STUDY GUIDE

Version 1

Acknowledgment

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Introduction

A key component of the approach outlined in the Official Control Verification Guidance (OCV Guidance) is the OCV Study. This is intended to provide an external reference point or standard with which the FCMS is compared and contrasted. The creation of this external reference point is critical to the analysis of the FCMS and it is only through the process of Gap Analysis between these two points that the validity of the said FCMS can be verified. Officers should refer to the OCV Guidance for further detail on this process.

It is acknowledged that the scope of a Food Control Management System (FCMS) is more comprehensive than that of a HACCP and also relates to authenticity and process control etc, however, the scope of this document is specific to the HACCP study which encompasses the management of generic food safety hazards within the pre-requisites programmes and the management of food specific hazards within the HACCP Control Chart

This guidance outlined below represents a methodology for conducting a HACCP study from the standpoint of a food law enforcement officer. This involves the use of algorithms which are intended to represent the officer's thinking, although this should not unduly restrict natural thought processes. The aim is to gauge the adequacy of the FCMS in terms of food safety.

The table below summarises the Steps and the Principles of a HACCP Study.

Verifying Steps 1 to 12 – The steps of the Official Control HACCP study are as follows:

HACCP Step	Task	HACCP Principle
Step 1	Assemble HACCP Team	
Step 2	Describe Product	
Step 3	Identify Intended Use	
Step 4	Construct Flow Diagram	
Step 5	Confirm Flow Diagram	
Step 6	List all potential hazards; Conduct a hazard analysis; Consider control measures	Principle 1
Step 7	Determine CCPs	Principle 2
Step 8	Establish Critical Limits	Principle 3
Step 9	Establish Monitoring	Principle 4
Step 10	Establish Corrective Actions	Principle 5
Step 11	Establish Validation, Verification and Review	Principle 6
Step 12	Establish Documentation and Records	Principle 7

Verifying HACCP Step 1 – Assembling the 'HACCP Team'

Relevant Inspection Stages: Preparation and Opening Meeting

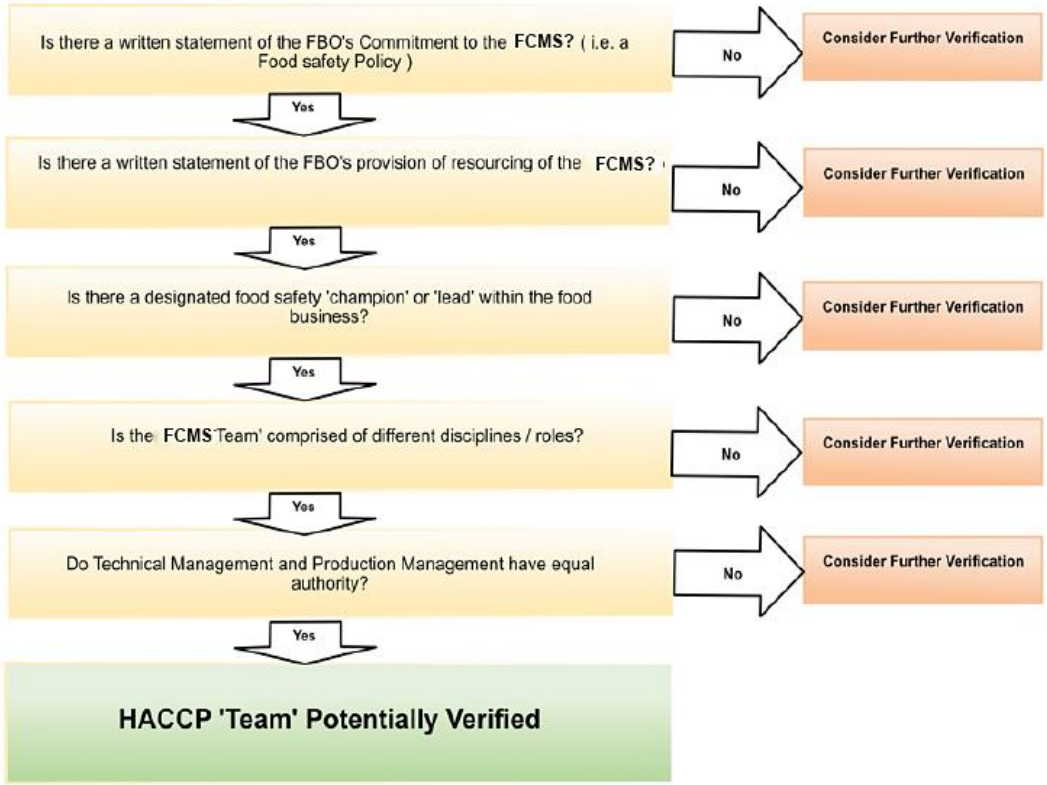
Two key issues at this point are the commitment of the FBO and the competency of the team. Without FBO commitment, the HACCP is significantly undermined. The commitment of the FBO is often considered to be an essential prerequisite in its own right.

The 'HACCP team' must also be competent. Ideally, the team should be multidisciplinary in order to bring specific knowledge and expertise appropriate to the product, the process and the processing environment.

It is acknowledged that the terms 'HACCP team' and 'multidisciplinary' reflect an idealised situation – one that does not often occur in reality, particularly within SMEs. However, these principles remain valid even where there is a degree of scaling applied in terms of the size of the HACCP team in proportion to the size of the business. In effect, competence of the 'HACCP team' is critical, regardless of the scale of the business. (See also OCV Guidance Chapter 5, Form C – FCMS Review Form)

Figure 1 below represents the process, which may be followed when verifying the 'HACCP Team'.

Figure 1: Verification of the HACCP Team



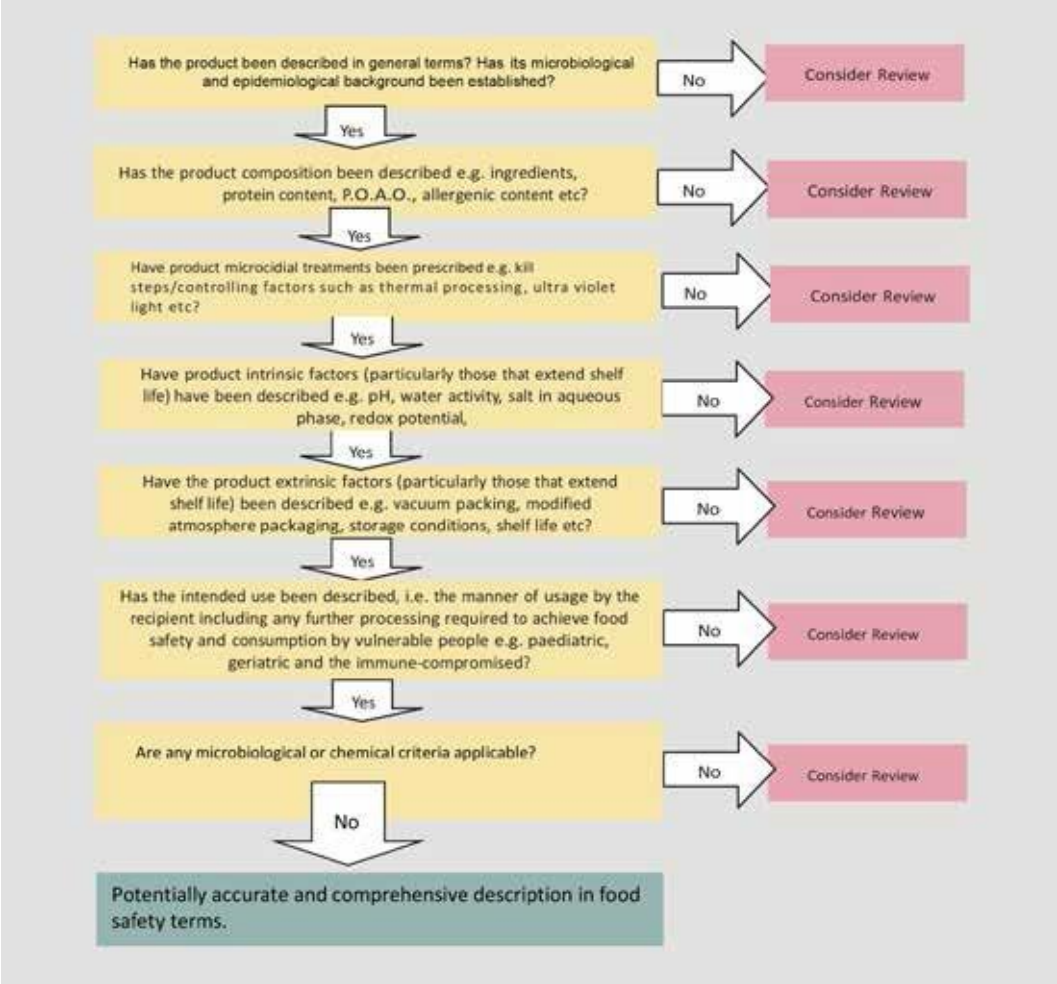
Verifying HACCP Steps 2 & 3 – Description of the products and their intended use

Relevant Inspection Stages: Preparation

The verification of product descriptions is essential as these descriptions represent the foundation of the HACCP. In effect, the design of the HACCP is informed by the product descriptions – and the system must accurately reflect these. The two must be compatible if the HACCP is to be fit for purpose.

Figure 2 below represents the process which may be followed when verifying the description of the product and the definition of intended use. This needs to be supplemented by knowledge of the relevant food hazards and the food science and technology involved. The Officer should conduct research at this stage into the epidemiological history of the product and process. (See also OCV Guidance Chapter 5, Form C – FCMS Review Form).

Figure 2 : Verifying the Product Description



Product descriptions do not need to be extensive or complicated. Concise descriptions need contain only the information relevant to the product in food safety terms as in the following example:

Example A.1 – Product Description

1. Pasteurised Fresh Milk.
2. Composition - Raw bovine milk, origin UK.
3. Rendered safe for human consumption through pasteurisation.
4. Intrinsic Properties – pH 6.5, Aw 0.997
5. Extrinsic Factors – Packaged aseptically in Polybottle with cap
6. Requires chilled storage refrigerate < 5°C, with a shelf life of 14 days and consume within 3 days of opening.
7. RTE suitable for consumption by all.
8. Allergens, Milk.
9. Free from pathogens, <100 cfu/ml. No chemical additives.

Verifying Step 11 – Verification Procedures

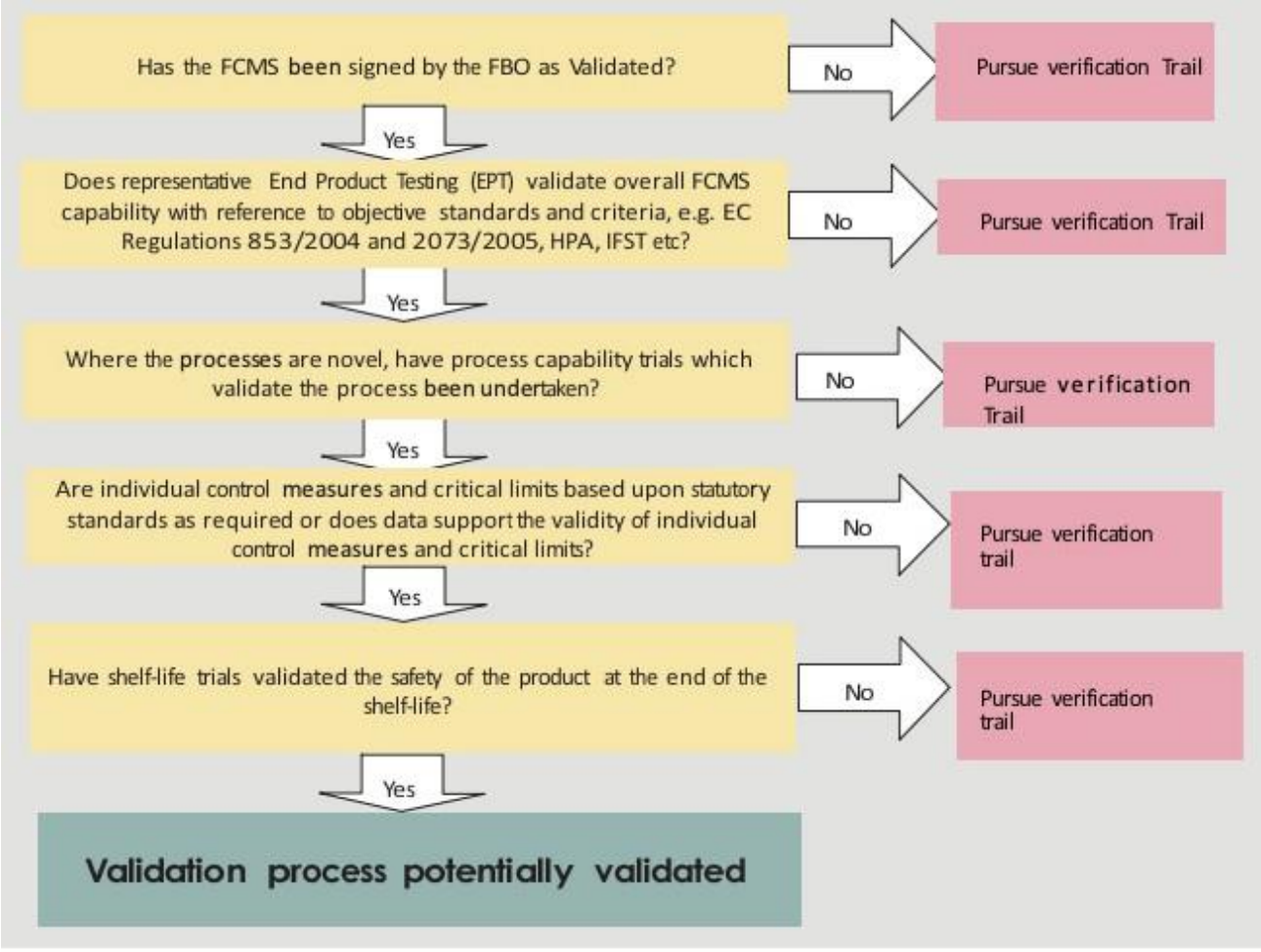
Relevant Inspection Stages: Preparation and Opening Meeting

Verifying Validation

Validation relates to proving the efficacy of the entire FCMS. This must be conducted prior to production (in terms of placing food on the market). Of particular importance is the validation of control measures and of critical limits.

Validation is often, incorrectly, carried out after production has commenced – based upon post-production data. This should not be accepted on safety grounds. The botulism outbreak associated with hazelnut yoghurt described in Example 2.1 of the OCV Guidance illustrates the dangers of inadequate validation. Figure 3 below represents an algorithm which may be used to verify the validity of the FCMS. (See also Chapter 5, Form C – FCMS Review Form).

Figure 3: Verifying Validation



The WHO-Codex document 'Guidelines for the validation of Food Safety Control Measures CAC/GL 69-2008' provides a useful reference.

The Difficulties of Verifying Validation

Verifying validation, particularly in relation to the identification and control of critical points, is a challenging activity and is one area where the officer may require specialist assistance.

Verifying Verification

The verification status of the HACCP itself requires verification during the early stages of the inspection process.

In order to do so, the officer should assess the validation data, end product testing results, internal and external audit documentation as well as the frequency and thoroughness of all verification activities.

The officer should consider whether changes or deficiencies in the HACCP plan, new emerging hazards, etc., are adequately addressed. The officer should also consider what actions are taken as a result of inadequacies in the HACCP (including its prerequisites) or any other non-conformity.

Verifying HACCP Steps 4 and 5 – The Process Flow Diagram

Relevant Inspection Stages: Opening Meeting and Main Inspection

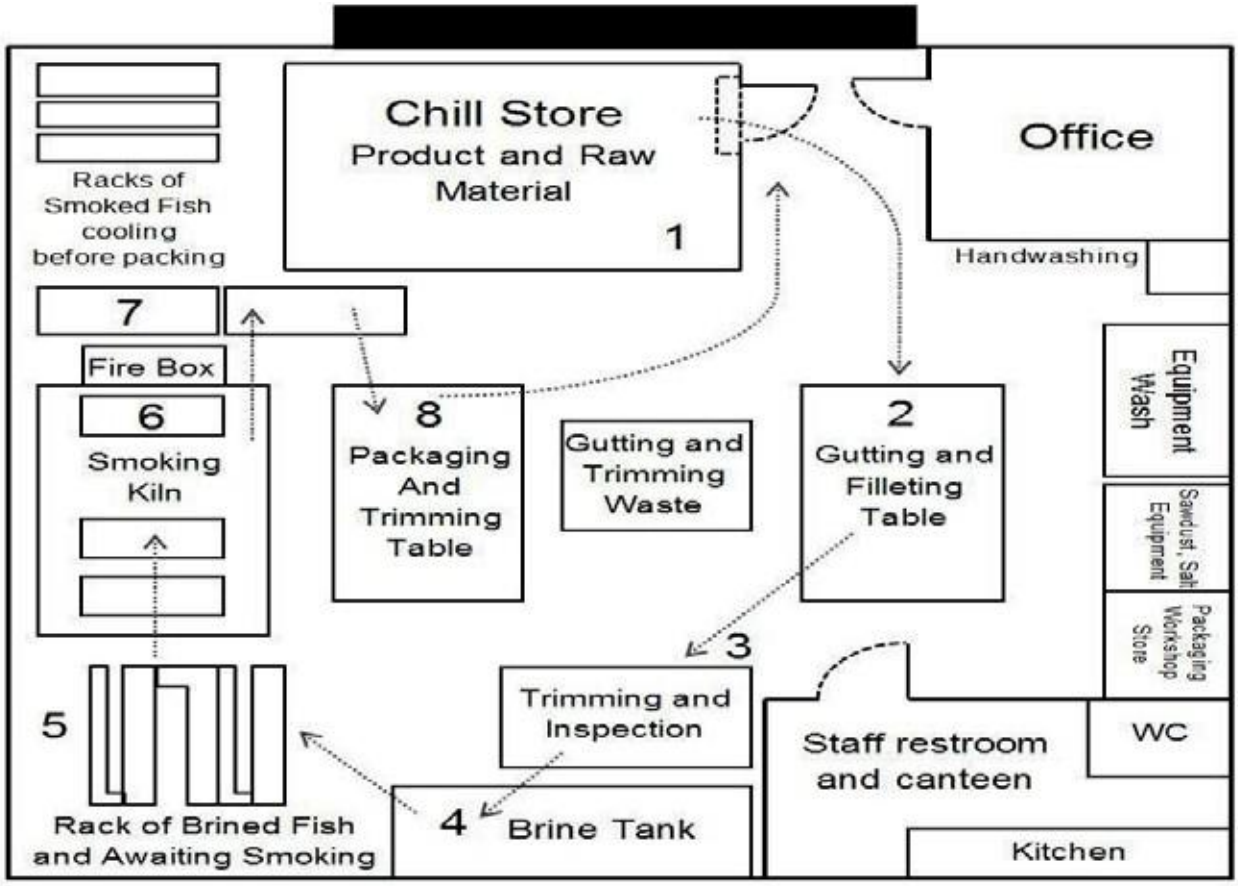
OC Verification of the Process Flow Diagram is vital as deviation from the process flow is frequently the first sign that the actual operation is deviating from the HACCP itself, i.e. the HACCP is becoming invalid. This process will also assist the officer in determining whether the CCPs are correctly identified and also if there is potential for post-process contamination.

Once the validity of the Process Flow Diagram been established, the focus may shift toward verification, i.e. “are they doing what they say they say they are doing?” This involves the same HACCP principles, but with more focus on their practical application.

Verification of the accuracy of the Process Flow Diagram is an essential component of the Official Control HACCP study and of the process of cross- referencing with the FBO HACCP Study. Inaccuracy or error at this stage will have a knock-on effect throughout the subsequent steps of the FBO’s HACCP study, possibly rendering them and the overall FCMS invalid.

Verification is undertaken by a detailed ‘walk of the line’ and careful cross-referencing of the actual operating sequence to the Process Flow Diagram. The officer should systematically and sequentially track the product(s) throughout the entire process flow(s); beginning at the point where raw materials are received and ending at the point where thefinished product is packed or dispatched. Subsidiary processes flows, e.g. staff flows and waste flows may then be subsequently verified. Figure 5 represents the systematic process of tracking the process flows.

Figure 5: Systematic/Sequential Tracking of the Process Flows



The Process Flow Diagram – A Framework for the Remainder of the Official Control FCMS Study

The Process Flow Diagram represents the essential framework for the FBO's HACCP study as well as for the Official Control HACCP (OC HACCP) Study.

The remainder of the OC HACCP Study is undertaken using the verified Process Flow Diagram(s) as its framework. The officer should track the process/packaging/personnel and waste flows applying the following steps of the OC HACCP Study to each step and to the prerequisite programmes.

Verifying Step 6 – List all potential hazards; conduct a hazard analysis; consider control measures

Relevant Inspection Stages: Preparation

Introduction to Step 6 – Listing Potential Hazards, Conducting Hazard Analysis and Considering Control Measures

Step 6 presents perhaps the greatest challenge to the FBO and the officer during an inspection. If the potential hazards and their nature cannot be recognised and understood, the official control process will be compromised.

Despite this, reference to this process in the WHO Codex is quite abstract:

"The HACCP team… … should next conduct a hazard analysis to identify, for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

- *In conducting the hazard analysis, the following should, wherever possible, be included:*
- *The likely occurrence of hazards and the severity of their adverse effects;*
- *The qualitative and/or quantitative evaluation of the presence of hazards;*
- *Survival or multiplication of micro-organisms of concern;*
- *Production or persistence in foods of toxins, chemicals or physical agents; and*
- *Conditions leading to the above.*
- *Consideration should be given to what control measures, if any exist, can be applied to each hazard."*

[WHO Codex 2003]

Step 6 constitutes perhaps the most frequently misunderstood and misapplied element of any HACCP study. A generic approach involving a simplistic requirement to produce process flow diagrams and apply very broad categories of hazards (e.g. biological, chemical and physical) at each step is likely to lead to inadequate controls being applied.

Manufacturing processes are often highly complex, involving multiple product lines as well as numerous production, personnel, packaging and waste process flows. Many of these afford the opportunity for the introduction, multiplication and survival of food hazards. There is also the additional human factor which can lead to pressure to achieve just in time production for high-risk, short shelf-life products.

However, if the underlying science is represented and Step 6 is broken down into bite sized- chunks, the process can be made easier to apply and the outcomes can be more successful.

The approach described here is based upon the science of epidemiology, an approach aligned to OCV and is based on a number of precedents:

- Bryan (WHO Codex ('Epidemiological Contributory Factors concept')) – 1992.
- LACORS (Relevance approach to 'Hazard Mapping') 1993.
- Structured Approach' to Step 6 formulated by Mortimore and Wallace 1998.
- 'Hazard mapping' – Food Law Code Practice Guidance Food Standard Scotland 2014 and antecedents (Note the terms 'Hazard Mapping' is not elaborated upon and must be inferred).

Officers are provided with inspection tools in the form of a Step 6 hazard identification and analysis form (Annexes 1 and 2) and a structured algorithm (Figures 15 and 16) which may be used at any point during the inspection.

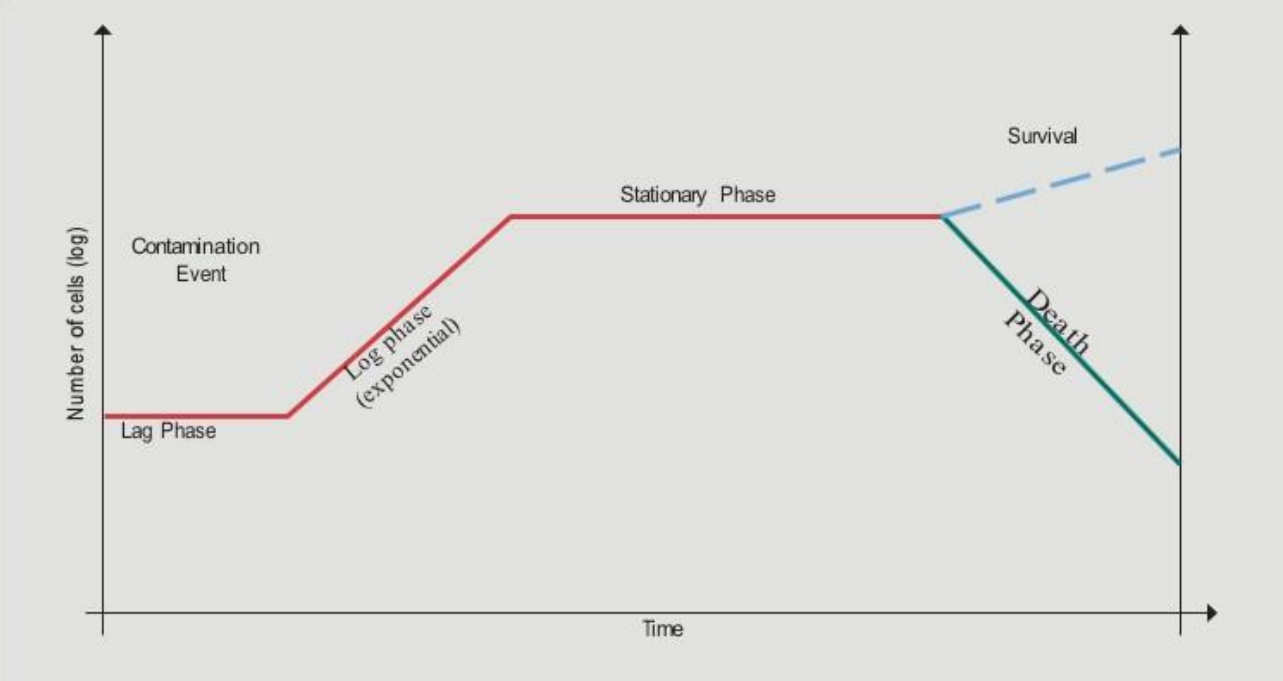
This approach leads to the analysis of the linkages between the process being inspected and the actual causes of food borne disease as confirmed by microbiology and epidemiology.

The Microbiological and Epidemiological Basis of Step

The Microbiological Dimension

Food-borne illness is a predictable natural process that has been described by science. This is represented by the Bacterial Growth Curve in Figure 6 below.

Figure 6: Bacterial Growth Curve



Microbiology confirms that the introduction of a bacterial pathogen by contamination to a suitable growth medium, may exceed an infective dose.

Alternatively, suitable conditions will lead to exponential multiplication of the hazard, eventually exceeding an infective dose, even where the initial contamination level was significantly lower. That said, the hazard may be eliminated or reduced to an acceptable level (i.e. below an infective dose) by the application of conditions designed to achieve that specific aim. Conversely, the hazard may persist if the relevant conditions are not applied. This insight represents the starting point for Step 6.

These relationships can be mapped onto process flow diagrams.

Figure 7 - This diagram represents a key to symbols within the subsequent figures.

	High level of contamination in raw materials	Process cannot reduce hazard to an acceptable level (risk of health adverse effect)
	Incorrect Parameters of Heat Treatment	Legal Limit is exceeded

Introduction of Hazard	Status Quo	Multiplication of Hazard	Elimination of Hazard or Reduction to an acceptable Level

Figure 8 represents the relationship between the process flow and the level of a bacterial hazard relative to an infective dose and a legal limit where the HACCP effectively eliminates the hazard or reduces it to an acceptable level.

Figure 8

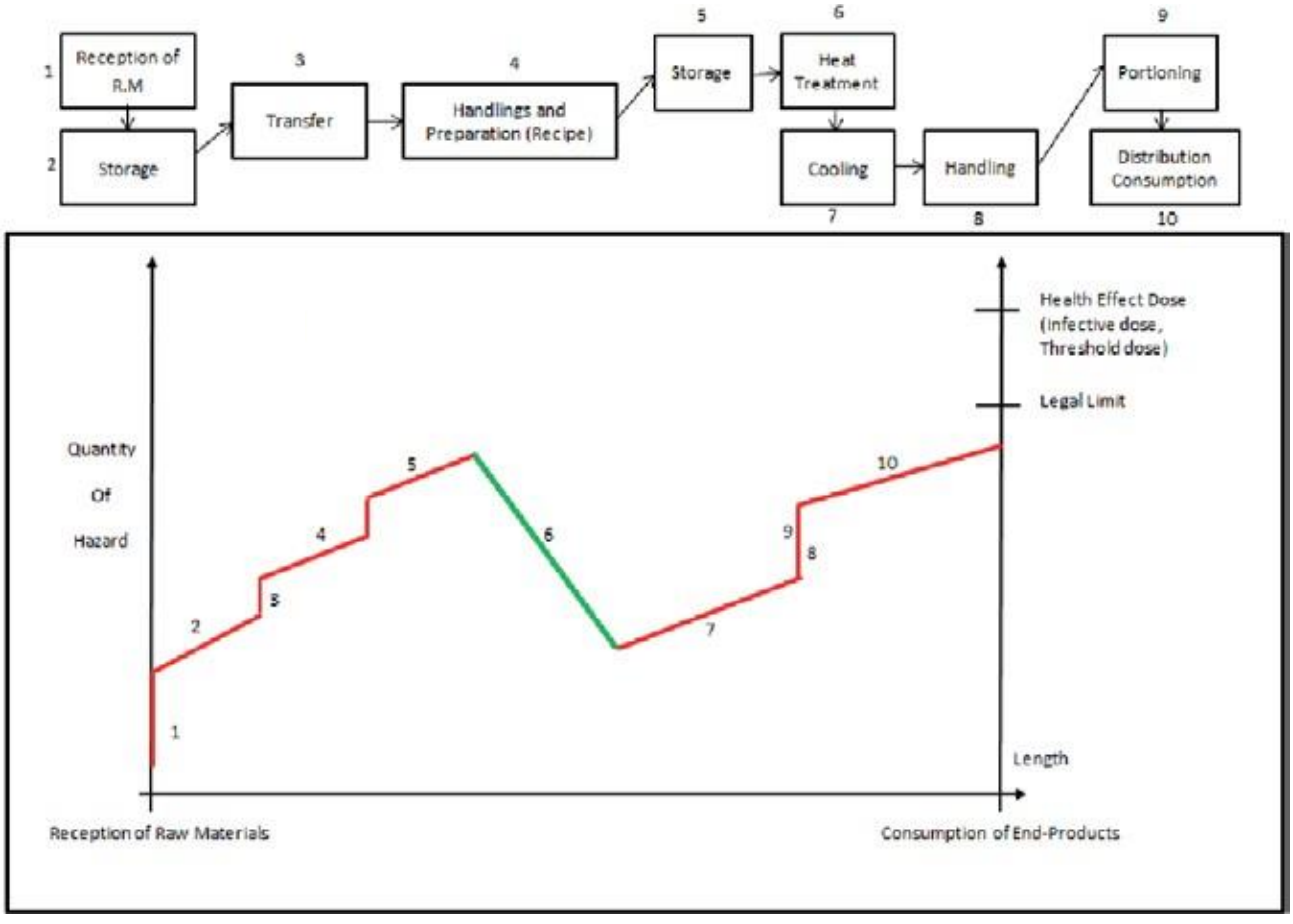
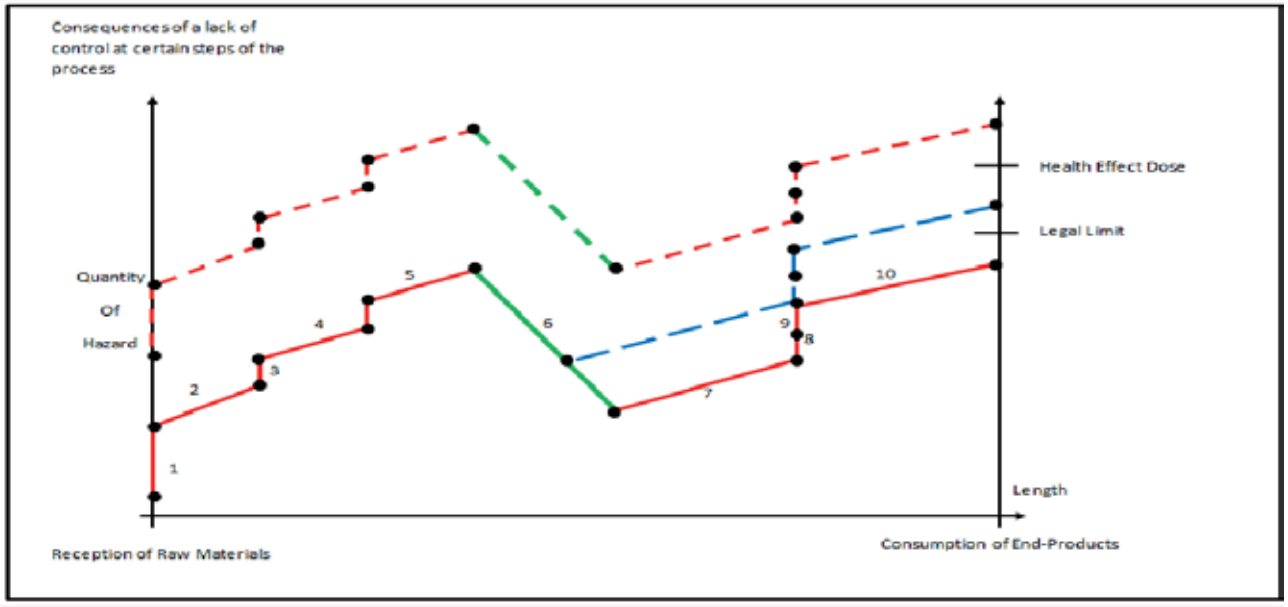


Figure 9 represents a relationship between the process flow and the level of the bacterial hazard relative to the infective dose and a legal limit in a situation where the HACCP has failed to eliminate the hazard or reduce it to an acceptable level.

Figure 9



This is, in fact, what happens in an outbreak of foodborne disease.

The Epidemiological Dimension

Epidemiological data on those factors that are known to have contributed to outbreaks of foodborne disease or practices or situations that have led to outbreaks have been termed as **'contributory factors'**. These 'contributory factors' have been found to be remarkably similar over a range of incidents. Summarised here are the most common 'contributory factors' of outbreaks of food borne disease:

Presence of hazards as inherent contaminants of foodstuffs at the outset of a process;

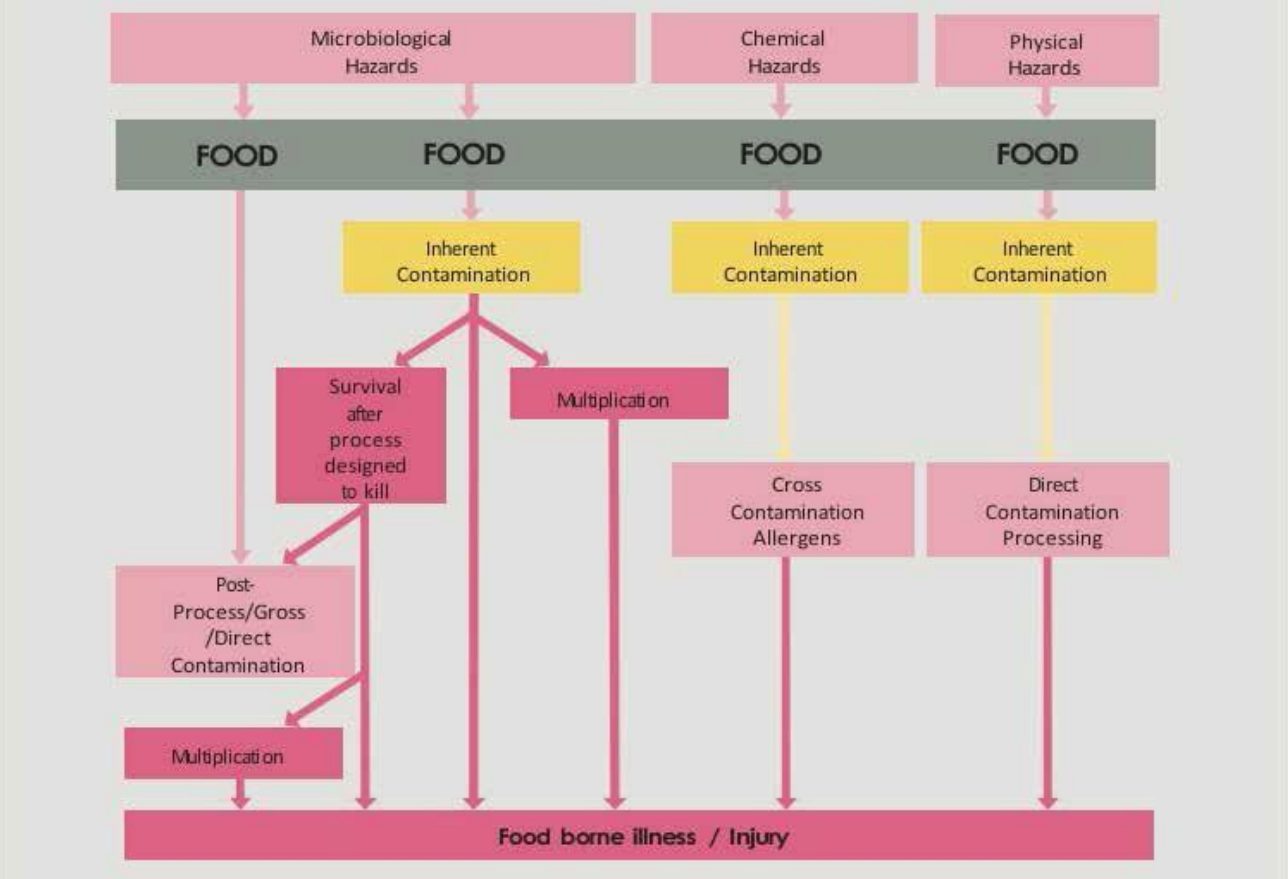
Introduction of hazards by direct contamination or by cross contamination;

Multiplication of hazards; and

Survival of hazards of a process intended to eliminate the hazard or reduce it to an acceptable level.

Epidemiology has confirmed that food-borne illness is the culmination of a predictable 'chain of events' wherein the contributory factors act alongside the hazards to cause foodborne illness. Figure 10 below summarises such a chain of events leading toward food-borne illness.

Figure 10: Food Borne Illness as the Culmination of a Chain of Key Events



The Outcomes – An Officer's Tool for Step 6

These insights lead to outcomes that make a critical contribution to the practice of Official Control HACCP Study:

1. The contributory factors and the chain of events, as demonstrated, reduce the inherent complexity of a manufacturing process and render it more amenable to understanding, thus easing the Step 6 of an Official Control HACCP Study.

2. Considering the list of hazards in terms of the contributory factors concept provides the officer with a practical tool whereby they can **'map'** the hazard onto the process flow diagram where it is relevant to do so. This creates a direct link between the hazard and the process flow diagram in terms of microbiology and epidemiology. The Process Flow diagram and the Hazard Map actually becomes descriptive and predictive of the chain of events that would occur if the FBO did not apply control measures.

3. The key steps within the chain of events renders the chain amenable to interventions (Control Measures on behalf of the FBO and Enforcement on behalf of Official Controls) which prevents the chain of events unfolding i.e. prevent food borne illness, thus being founded on epidemiology – Official Control verification is effective as an Official Control as is required by Regulation (EC) 882/2004.

This practical approach is further elaborated upon below.

A Structured Approach to Step 6

Addressing the problem of Step 6 can be eased by reducing the issue to basic questions, i.e. what, where, when and how etc (see Annex 2). Issues of significance and relevance can then be assessed using the process flow diagram as a framework or map. This approach breaks down step 6 into the following inspection skills:

- Hazard identification, i.e. **what** are the hazards?
- Hazard analysis, i.e. **what** are the significant hazards?
- Hazard mapping, i.e. **when** and **where** the hazards are relevant at process steps?
- Hazard causation, i.e. **why** the hazards are relevant at a process step?
- Hazard control, i.e. **what** needs to be done to eliminate the hazard or reduce it to an acceptable level?

This approach is founded in the microbiology and the epidemiology represented above. The answer to each question is a consequence of the answer to the preceding question. This logical approach ensures that the correct hazard is identified, analysed, mapped and its causation understood. Similarly, the outcome is a logically derived Control Measure that will actually eliminate the hazard or reduce it to an acceptable level.

Hazard Identification (What are the hazards?)

This aspect is relatively straightforward. A gap analysis is undertaken between the FBO's own hazard identification and validated sources of information which define and describe the hazards associated with the same or similar products and processes. Examples of such sources include:

1 Published epidemiological data;

2 Food microbiological textbooks; and

3 Advice from relevant specialist sources.

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 in turn mean that they are opportunistic contaminants under differing conditions. Consequently, species-specific control measures are sometimes required to control them. Officers should be prepared to undertake the appropriate research. Control measures for each hazard specific to more than one contributory factor are frequently required at the same process step.

Allergens and additives are considered as types of chemical hazards.

Hazard Analysis (What are the Significant Hazards?)

The WHO Codex defined hazard analysis as follows:

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

[WHO Codex 2003]

These considerations relate to risk factors associated with the identified hazards – the purpose being to identify the significant hazards. In practice, considerations will always include a combination of the following:

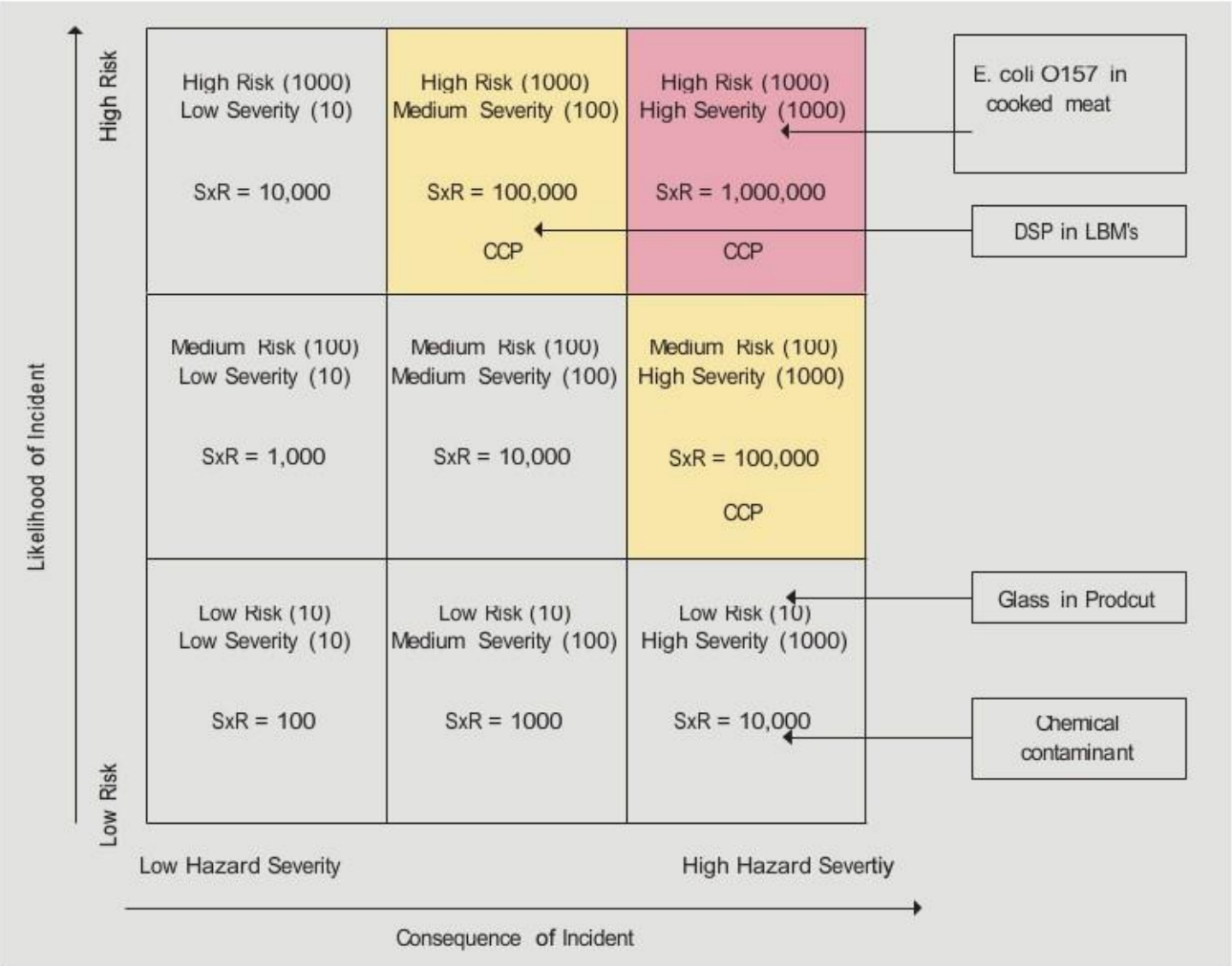
- The likelihood of the hazard occurring and its consequent effects – e.g. previous
- company/industry experience or complaints, epidemiological data;
- The severity of the hazard – e.g. life-threatening/ mild; chronic/acute;
- Numbers potentially exposed to the hazard –
- e.g. lot size; distribution;
- Age/vulnerability of those exposed – e.g. young/elderly; allergies;
- Survival or multiplication of micro-organisms of concern;
- Production or persistence in foods of toxins, chemicals or physical agents; and
- Source or cause of the hazard or conditions leading to the above.

The Practical Problems of FBO Risk Assessment

Since the WHO-Codex guidelines on HACCP were revised and with the advent of BRC and ISO2203 accredited FCMSs, it has become common place to introduce a measure of quantification (i.e. Risk Assessment) to step 6.

Figure 11 below, which summarises this process, is presented in the form of a 'Risk Quadrant' which is a simple formulation of the Risk Assessment Process, where risk is plotted as some function of the likelihood of an incident and the consequences of an incident.

Figure 11: The Risk Quadrant



This process should be approached with caution as errors at this step can lead to significant hazards not being subject to HACCP Principle 2, i.e.Critical Control Point determination. A common error is for such Risk Assessments to be undertaken by unqualified personnel and/or on the basis of incomplete information.

Where officers come across this approach, they are advised to verify the process in sufficient detail to determine whether or not significant hazards have in fact been discarded from HACCP Step 7, i.e. Determination of Critical Control points.

Hazard Mapping (Where and When are the Hazards Relevant at Process Steps?)

The relevance of a hazard to a step in the process flow or prerequisite programme is identified by identifying the relevant contributory factor:

Presence – A hazard which is likely to be an inherent contaminant of the food at the outset.

Introduction – A hazard introduced by contamination at a particular step of the operation, either via direct or indirect cross contamination.

Multiplication – A hazard may increase, e.g. by microbiological growth or toxin production, at a particular step.

Survival – A hazard might survive a particular step designed to eliminate it or reduce it to an acceptable level.

N.B. This is applicable to both generic hazards (prerequisite programmes) and to food-specific hazards (HACCP Control Chart).

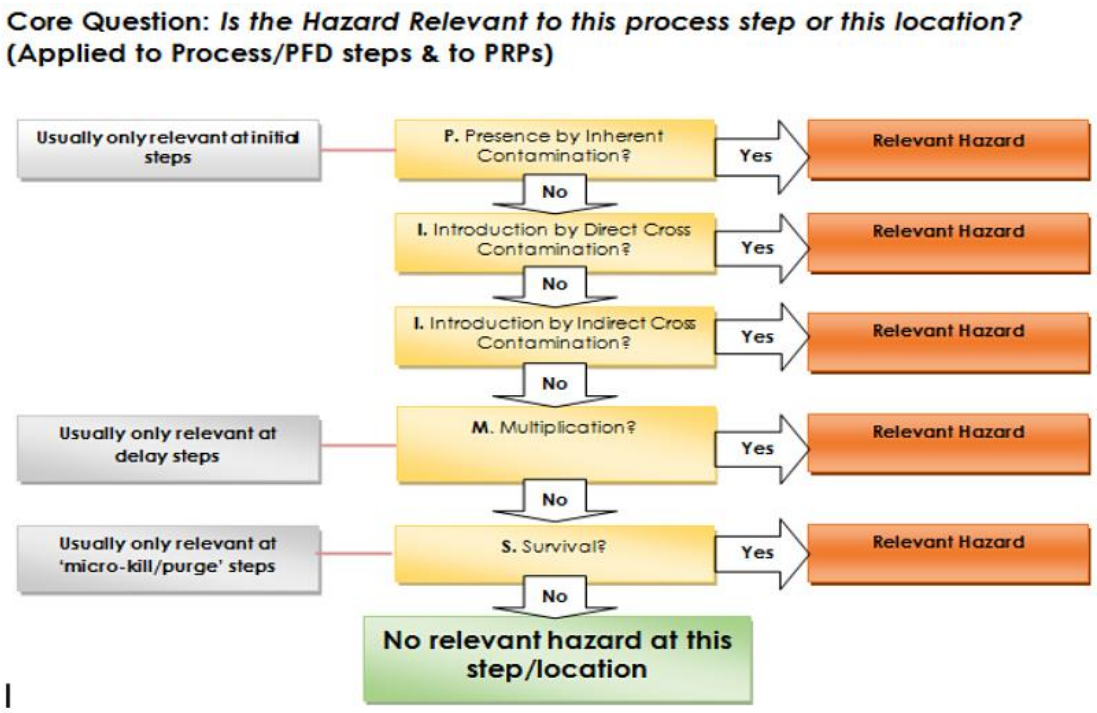
These 'contributory factors' have been condensed into the mnemonic of P.I.I.M.S.

These 'contributory factors' can also be integrated into a structured algorithm. This practical tool for officers can be applied to the process/personnel and waste flows and/or prerequisite programme, in order to identify whether the hazards are relevant at the process step or prerequisite in question.

The algorithm in Figure 12 below may be used to verify the relevance of a hazard at any step in the process flow(s).

Figure 12 Algorithm for Considering the Relevance of Hazards at Process Steps and Prerequisite Programmes

Core Question: Is the Hazard Relevant to this process step or this location?
(Applied to prerequisites or the process flow)



The outcome of this process is the Hazard Map which identifies the hazards in terms of the contributory factor at each process step.

Figure 13 demonstrates the process of hazard mapping.

Figure 13: Hazard Mapping (Microbiological)

Hazard Mapping (Microbiological)	
Manufacturing	Fish Products Smokery
Delivery (a)(b)(c) | Storage (b)(c) | Preparation (b)(c) | Processing (b)(c)(d) | Post Process (b)(c) | Storage (b)(c) | Distribution (b)(c) | Customer (b)(c)(d)	Delivery (a)(b)(c) | Storage (b)(c) | Fillet and De-bone(b) | Brine/Cure(c)(d) | Smoke (d) | Chill (c) | Vac Pack (b)(c) | Store (c) | Distribution (b)(c) | Customer (b)(c)(d)

Key: (a) Present (b) Introduction (c) Multiplication (d) Survival

Using hazard mapping the officer is able to verify exactly where the significant hazards are relevant within an establishment in terms of a potential chain of events leading to food borne illness.

Hazard Causation (How relevant are hazards at a process step?)

It is recommended that hazard causation is conducted as a relatively straightforward process of deduction, where the starting point is the hazard mapping of the position of the hazard in the process flow diagram and the relevant contributory factor used as the basis for deducing the causation. It is recommended that this is confirmed during the inspection reality check.

Hazard Control Measures. (What needs to be done to eliminate the hazard or reduce it to an acceptable level?)

Control measures must eliminate the identified significant hazards or reduce them to acceptable levels. Processes that do not achieve this objective are invalid as control measures.

Verification is a deductive process and an extension of the HACCP Step 6 process outlined above. By considering the relevant and significant hazards together with their Contributory Factors in the context of causation, the control measure can be logically and accurately deduced. Figure 14 below exemplifies this process.

Figure 14: Contributory Factors and Controls

Contributory Factors	Causation	Control Measure
Inherent Contamination	Contamination at Source	Elimination or reduction to acceptable Levels at Source
Direct or Cross Contamination	Process whereby hazard is transferred directly or indirectly from a contaminated sources to a RTE product	Spatial or temporal Separation of source or vehicle and RTE product and/or cleaning and disinfection
Survival	Failure of a process step to kill the hazard	Process step that kills the hazard
Multiplication	Time and/or temperature promoting multiplication	Time and/or Temperature arresting multiplication

A structured Form for Step 6.

The template Form that officers may use to verify an FBO's own approach to step 6 during an official control HACCP study is included at Annex 1 (See also Chapter 5, Form C – FCMS Review Form)

Chemical and Physical Hazards

The above approach is also used to address Step 6 in terms of chemical and physical hazards. Such categories of hazards are also addressed according to the same process, i.e.

1 Hazard identification, i.e. what are the hazards?

2 Hazard analysis, i.e. what are the significant hazards?

3 Hazard mapping, i.e. when and where the hazards are relevant at process steps?

4 Hazard causation, i.e. why the hazards are relevant at a process step?

5 Hazard control, i.e. what needs to be done to eliminate the hazard or reduce it to an acceptable level?

It should be noted that both chemical and physical hazards must contaminate products for there to be a food safety issue. With physical hazards, there often is an inherent contamination. Typical examples of chemical cross contamination include allergenic residues on machinery and biotoxin accumulation where shellfish are transferred into contaminated waters. These hazards can survive processes intended to eliminate them or reduce them to acceptable levels. Examples include the sieving of flour to remove stones and the separation of product lines containing allergens. Such hazards can actually also multiply, e.g. a metallic foreign object being splintered into multiple shards within a reversing dough breaker, or marine biotoxins increasing where shellfish are conditioned while exposed to direct sunlight.

Verifying Step 6 – Addressing Hazards via Prerequisite Programmes or CCPs

Relevant Inspection Stages: Preparation for inspection

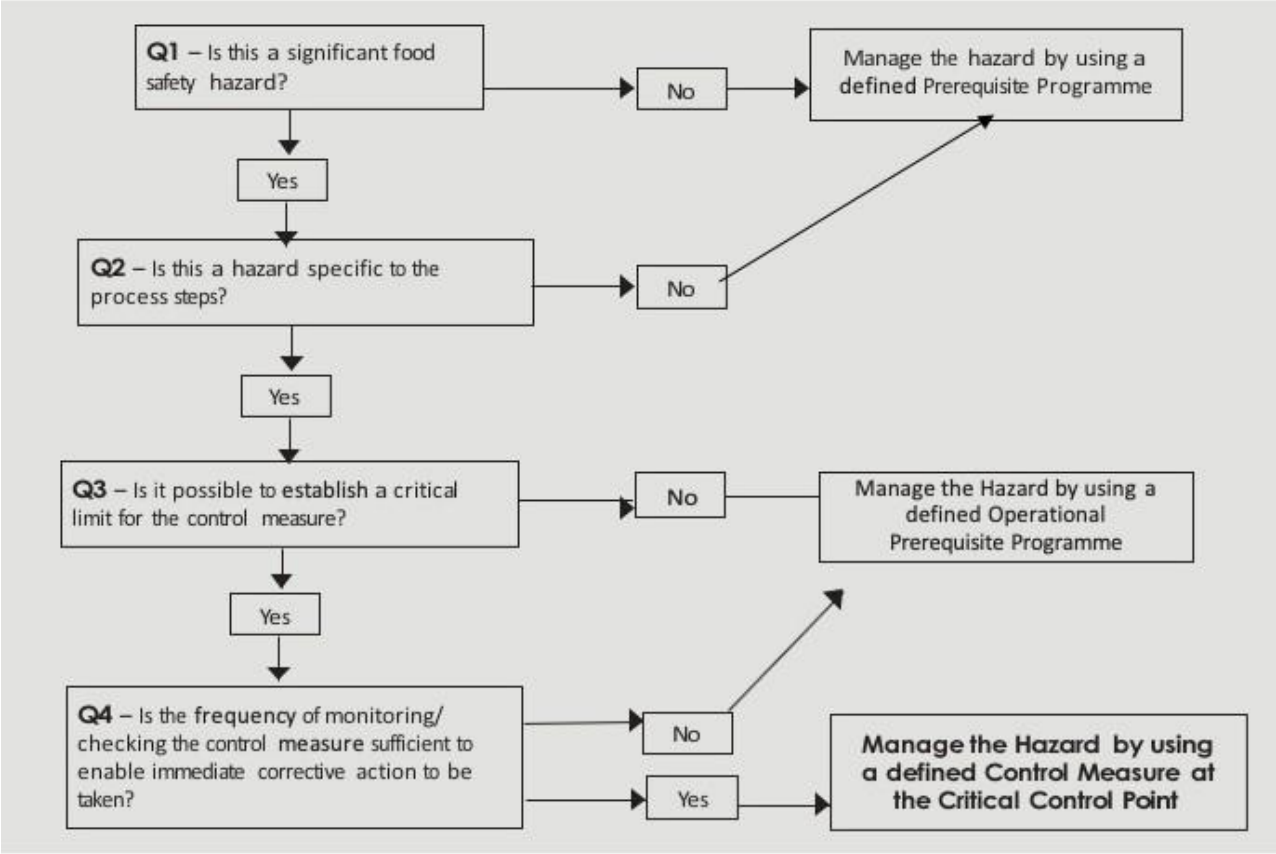
With the advent of ISO 22003, the concept of operational prerequisite programs (OPPs) is now commonplace. In some food manufacturing establishments, OPPs have completely replaced CCPs. One consequence is the need to depart from the established structure of a WHO Codex- based HACCP study which progresses from step 6 to step 7, by the insertion of a new step relating to OPPs before progressing onto step 7. At the time of writing there is no settled, industry-wide conception of OPPs. However, OPPs are intended to embody the control measures for significant hazards that are not amenable to control at specific points in space and time, i.e. at critical control points. Such hazards may be mapped onto the process flow diagram as being relevant at a number of process steps, i.e. they may be "site wide" hazards. It has also become appropriate to consider whether the hazards at the various process steps can be amenable to on- line continuous monitoring (i.e. in real time) and by reference to a discrete, i.e. numeric type critical limit.

Figure 15 below is suggested as a practical tool for officers to verify an FBO's decision to address a hazard as being controlled by a PrP an OPP or via a CCP.

Questions 1 and 2 focus on hazards at each process step.

Questions 3 and 4 focus on control measures.

Figure 15 Decision Tree



Verifying HACCP Step 7 – Verification of the Determination of CCPs

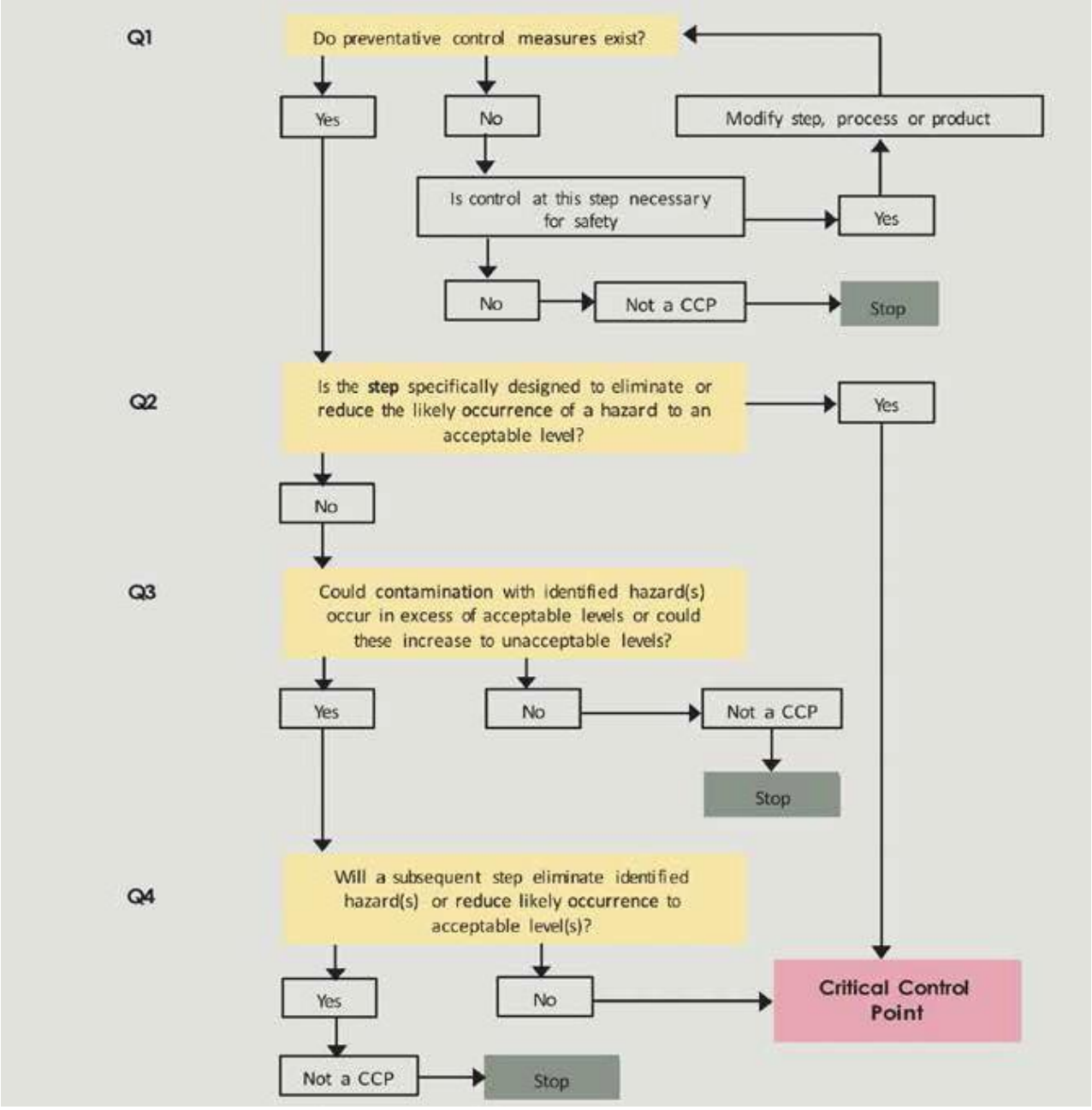
Relevant Inspection Stages: Preparation for Inspection

The verification of the determination of Critical Control Points is critical to the verification of a HACCP. Figure 16 reproduces The WHO-Codex Decision Tree, which is used for the purposes of this verification. The officer applies each significant hazard to every step within the product process flow to the decision tree.

One common error is the omission of Q3. Q3 performs a vital function i.e. the determination of whether the hazard is present at unacceptable levels or may increase to unacceptable levels.

In considering the increase in the hazard, the processing environment should be taken into account (e.g. personnel and equipment which represent a source of contamination).

Figure 16 Decision Tree for Verifying the Determination of CCPs

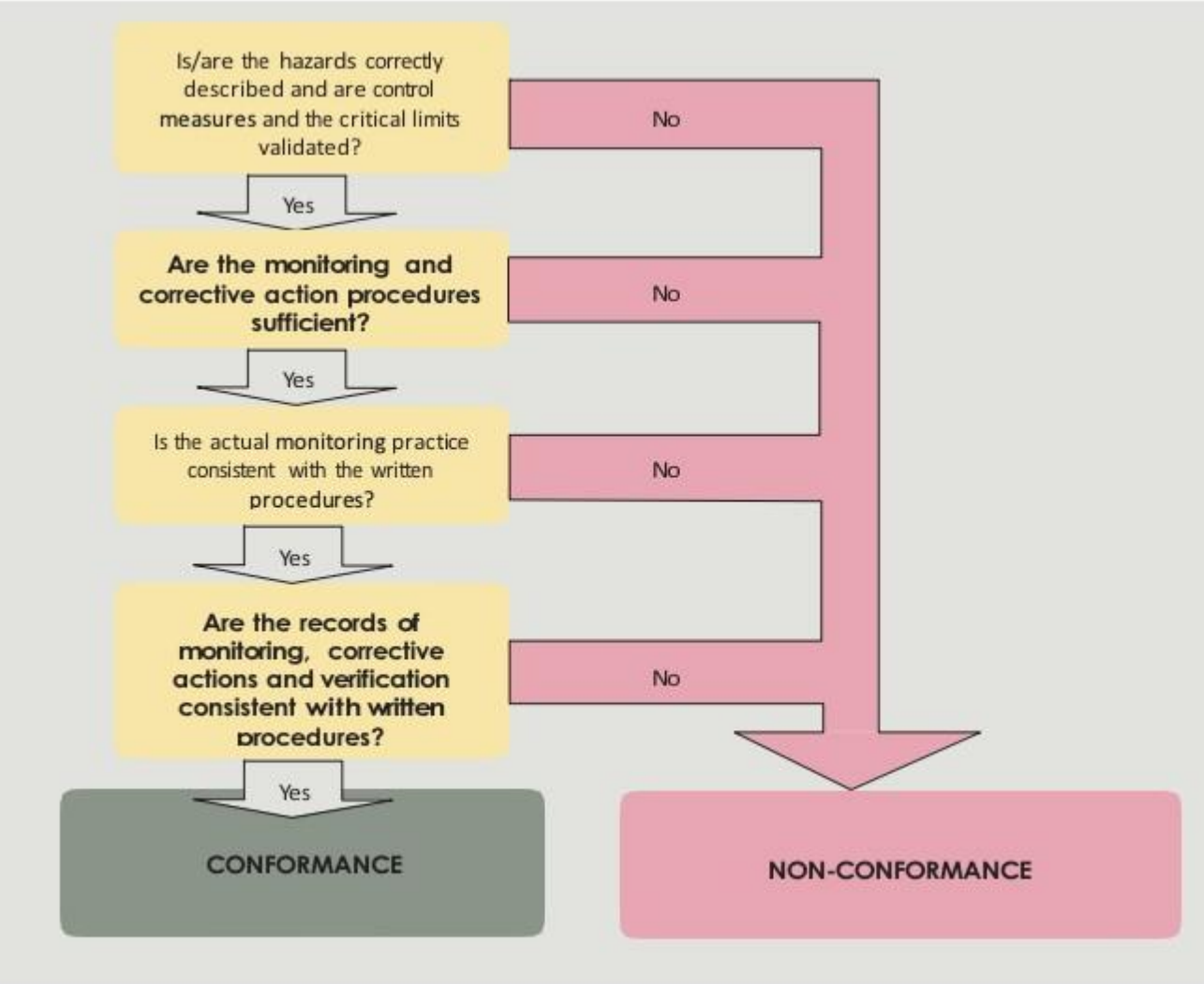


Verifying HACCP Steps 8 to 12 – Critical Limits, Monitoring Systems, Corrective Actions and Record Keeping

Relevant Inspection Stages: Preparation for Inspection and Main Inspection

HACCP Steps 8 to 10 and 12, relate to activities performed at CCPs. Verification may be performed as a straightforward process of compliance auditing, using the algorithm in Figure 17 below.

Figure 17 HACCP Steps 8 to 10 and 12



Process Step	Hazard Identification	Epidemiological Descriptor (P.I.I.M.S)	Causation and/or Source	Hazard Significance Assessment	Control Measure

*[1] 5 W 1 H

Structured & Epidemiological 5 W 1 H *[1] Approach to Step 6/Principle One:- Hazard Identification & Analysis Chart

= Inductive

= Deductive

1. What has been the epidemiological history of this product/process?_____

_____

_____

3. What (if any) are the contaminants/hazards?_____

_____

Process Step Number & Description (Where & When?)	Identification/ List Classify (What?)	*[2] Significance (Risk) (What?) Refer to Risk Quadrant etc LxS			Epidemiological Relevance Descriptor 3* (P.I.M.M.S) (Contributory Factor/ Manifestation of Hazard Qualitative Approach) (How?) *4	Causation/Source (Why?)	Control Measure (What we need to do to eliminate or reduce the hazard to an acceptable level?)

*[2] Risk Quadrant

*3 Mnemonic - P.I.M.M.S/P.I.M.S/P.I.G.S

P =Presence by inherent contamination
I= Introduction by direct contamination
I= Introduction by cross contamination
M= Multiplication
S = Survival

*4 P.I.M.M.S Algorithm