

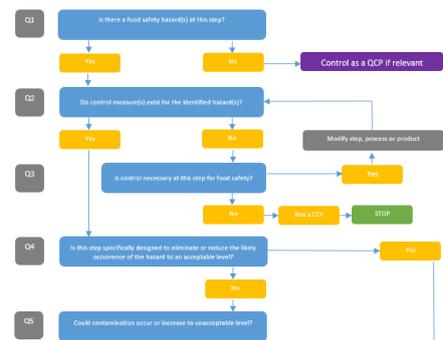
WHITEPAPER

Determining Control Measures in HACCP

CONTENTS

1. Introduction
2. What are control measures?
 - 2.1 Critical Control Point (CCP)
 - 2.2 Prerequisite Programme (PRP)
 - 2.3 Operational Prerequisite Programme (oPRP)
 - 2.4 Control Point (CP)
 - 2.5 Quality Control Point (QCP)
3. Determining Control Measures
 - 3.1 Requirements for determining control measures
 - 3.2 Risk assessments and “Significance”
 - 3.3 Determination models
4. Definitions
5. References

SUMMARY



This whitepaper is essential for anyone responsible for risk assessment and determination of control measures within a HACCP plan. The whitepaper will demystify much of the language and complex logic normally associated with risk assessment models and decision trees, which prevent many food companies from obtaining their objective of producing robust HACCP plans.

1. Introduction

Since its inception, HACCP has always been a risk assessment and management tool designed to help food companies identify specific hazards within their process, determine their significance and develop appropriate controls to ensure they do not reach the consumer. Over the decades numerous food safety standards, codes of practice, and regulatory directives have adopted the principles of HACCP and in the process put their own unique interpretation on how exactly these principles are effected.

The almost ubiquitous adoption of HACCP as the risk tool of choice by the food industry is a testament to its enduring scientific approach. It has facilitated the development of a safer food supply chain and provided food safety practitioners with a common work-flow, logic and language from which to work and communicate. It has also provided one of the essential ingredients required for objective auditing – a Standard. As is the case in many other industries, the food sector has found an important and valuable friend in risk assessment and more specifically HACCP.

However as with any good, lifelong friend we become aware more than others of their inherent character uniqueness and challenges. It does not prevent us benefiting from the relationship but it can often make things confusing. When we speak of HACCP it is clear that risk assessment and determination of control measures is an aspect which many users find difficult if

not mystifying on occasion.

To put it simply, the basic principle is to install within the process and operation some control measures which are appropriate for the specific hazards and the risk they pose to the final consumer. HACCP requires the user to identify these potential hazards. Next, the user determines the significance of these hazards by applying risk assessment techniques, the output of which is a measure of risk which then allows us to put in place appropriate control measures. Over the decades, various standards have attempted to define how this should be done and in the process have introduced their own unique terms, language, scope, methodology and workflows. Some of these have been good and helped the user meet requirements but much of the work has served only to confuse the user leading to HACCP plans which are unnecessarily complex and hinder the effective management of food safety.

This whitepaper will breakdown much of the confusion and inherent weaknesses present in many food safety standards surrounding the determination of control measures in HACCP. It will take the reader through the basic logic behind the methodology and build from a basic model up to a more detailed one covering all types of control measures after which a better insight and understanding of this area will be achieved.

2. What are Control Measures?

Before examining the methods for determining the appropriate control measure to apply for a particular hazard, it is essential to have a clear understanding of the various control measures typically referred to in food safety standards.

In the context of food safety, the International Standards Organisation (ISO) has defined a control measure as an action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. This definition is general and can be used to describe virtually any action, step, activity, job, task, process or procedure which has the intention of addressing a food safety hazard. As we look closer at the main food safety standards we can see that control measures become categorised according to their nature, direct relationship with the process and the level of risk to the consumer should the control measure fail. In recent years the following categories of control measures have emerged:

- Critical Control Point (CCP)
- Prerequisite Programme (PRP)
- Operational Prerequisite Programme (oPRP)
- Control Point (CP)
- Quality Control Point (QCP)

There are others; however, the above represent the main ones used widely in the food industry.

2.1 Critical Control Point (CCP)

The CCP is perhaps the most commonly known of all the control measures. The ISO defines it as a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

You will note that the definition is very similar to the general definition of a control measure; however, a CCP differs in the fact that it relates specifically to a step in the process e.g. cooking, cooling, freezing and not a general activity or action. The definition also states that a CCP is a step at which control can be applied. Therefore, if a CCP cannot by definition apply control it cannot be a CCP.

This might come into play where the control is subjective and cannot be measured accurately. In this case control is hard or impossible and would not lend well as a critical point of control. Another factor relating to CCP's is the risk posed by the hazard should the control not be exercised. For example, a salmonella in cooked meat would pose a significant risk to the consumer if cooking is not carried out to an adequate temperature and time specification. In this case control is critical and designed specifically to control the hazard.

2.2 Prerequisite Programme (PRP)

The ISO defines a PRP as the basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain and are suitable for the production, handling and provision of safe end products and safe food for human consumption.

There are a wide variety of PRPs depending on the particular product and process. They are often described in certain sectors of the industry as Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP). Examples of PRP's in a food manufacturing environment highlighted in the ISO 22000 standard would be:

- construction and lay-out of buildings and associated utilities
- lay-out of premises, including workspace and employee facilities
- supplies of air, water, energy and other utilities
- supporting services, including waste and sewage disposal
- the suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance

- management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), supplies (e.g. water, air, steam and ice), disposals (e.g. waste and sewage) and handling of products (e.g. storage and transportation)
- measures for the prevention of cross contamination
- cleaning and sanitizing
- pest control
- personnel hygiene

The key point in regard to PRP's is that they are usually general to the process and not focused on any particular step in the process. For example, cleaning and sanitizing are activities which can apply to all steps, rooms, items and building fabric.

They also have the character that their failure does not necessary lead to an immediate and imminent food safety risk. Generally, time and repeated failure is required to create a critical change in the safety of the product. Stated another way, they usually manage more general and lower risk hazards.

2.3 Operational Prerequisite Programme (oPRP)

The ISO defines an oPRP as a control measure identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards and/or the contamination or proliferation of food

safety hazards in the product(s) or in the processing environment.

As a concept of control it was introduced by the ISO in their food safety management standard ISO 22000. What is striking about this control measure and its definition is the almost universal confusion users have in differentiating it from CCP's and PRP's. The variation in the focus of the control measures appears to be based on a subtle difference in the description of hazards and risks. Users have found it hard to understand the nature of oPRP's and given that that standard provides no specific examples, it has remained the subject of some debate in the food safety community.

In an attempt to clarify what exactly an oPRP is, it has been described as a specific action relating to the process while not being critical for food safety; it is essential in reducing the likelihood of a specific hazard occurring. For example, a cooking step in a process may be critical to controlling the risk of a specific pathogen surviving e.g. E. coli. This is an intrinsic step in the process for producing a cooked product. Its removal from the process is not possible and therefore its correct control is critical. Therefore, the control applied at this step can be considered critical and therefore a CCP.

Alternatively, we can take the same process and look at metal detection. It too is a specific step in the process designed to reduce the likelihood of a hazard reaching the consumer and arguably could be a CCP also. However, the key difference

is that it is not an intrinsic step required for the production of safe cooked ham. It can be removed from the process and the company can practically still produce relatively safe products. Nonetheless, its presence may be deemed essential to reducing the likelihood of the hazard and therefore an oPRP. It is important to realise that this is simply one possible definition of an oPRP which provides some working understanding for users. It may not be the full definition or scope as intended by the ISO.

2.4 Control Point (CP)

A Control Point is used by some standards to describe an oPRP. The IFS Food Standard for auditing quality and food safety of food products Version 6, for example, defines a CP as being identical to an oPRP found in the ISO 22000.

2.5 Quality Control Point (QCP)

A Quality Control Point is a control measure essential in order to control quality, service and business risks.

It is used in various standards including the Woolworths Standard (WQA) for Manufactured Foods V8. In this standard, quality risks are provided almost equal importance as food safety.

3. Determining Control Measures

In order to determine which control measure is appropriate for the identified hazard, you need to employ a specific methodology encompassing risk assessment followed by a decision tree.

3.1 Requirements for Determining Control Measure

Various Standards set out requirements for determining control points. The following table summarizes some of these requirements as they relate to control measures.

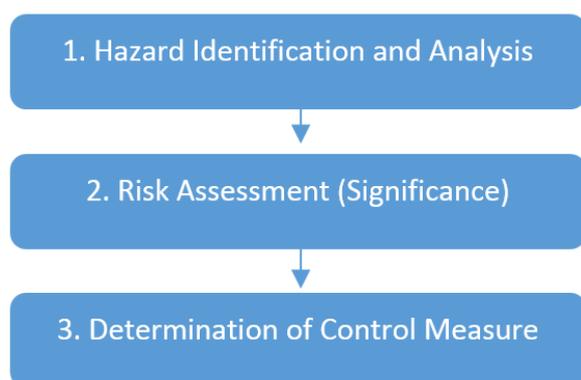
Standard	Requirements
ISO 22000	<p>7.4.4 Selection and assessment of control measures</p> <p>Based on the hazard assessment of 7.4.3, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels. In this selection, each of the control measures as described in 7.3.5.2 shall be reviewed with respect to its effectiveness against the identified food safety hazards. The control measures selected shall be categorized as to whether they need to be managed through operational PRP(s) or by the HACCP plan. The selection and categorization shall be carried out using a logical approach that includes assessments with regard to the following:</p> <ul style="list-style-type: none"> a) its effect on identified food safety hazards relative to the strictness applied; b) its feasibility for monitoring [e.g. ability to be monitored in a timely manner to enable immediate corrections]; c) its place within the system relative to other control measures; d) the likelihood of failure in the functioning of a control measure or significant processing variability; e) the severity of the consequence(s) in the case of failure in its functioning; f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s); g) synergistic effects [i.e. interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects]. <p>Control measures categorized as belonging to the HACCP plan shall be implemented in accordance with 7.6.</p> <p>Other control measures shall be implemented as operational PRPs according to 7.5. The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.</p>

Standard	Requirements
ISO 22000	<p data-bbox="408 275 1249 309">7.5 Establishing the operational prerequisite programmes (PRPs)</p> <p data-bbox="408 342 1353 409">The operational PRPs shall be documented and shall include the following information for each programme:</p> <ul style="list-style-type: none"> <li data-bbox="408 450 1302 483">a) food safety hazard(s) to be controlled by the programme [see 7.4.4]; <li data-bbox="408 488 823 521">b) control measure(s) [see 7.4.4]; <li data-bbox="408 526 1345 593">c) monitoring procedures that demonstrate that the operational PRPs are implemented; <li data-bbox="408 598 1393 665">d) corrections and corrective actions to be taken if monitoring shows that the operational PRPs are not in control [see 7.10.1 and 7.10.2, respectively]; <li data-bbox="408 669 839 703">e) responsibilities and authorities; <li data-bbox="408 707 735 741">f) record(s) of monitoring.
Woolworths Standard (WQA) Version 8	<p data-bbox="408 801 1433 902">Determine the Critical Control Points – for each significant hazard the Vendor shall determine which of the control measures developed is the critical point for control of the hazard, including significant quality hazards/regulatory issues.</p> <p data-bbox="408 943 1433 1182">Establish a system to monitor control of the CCP and QCP – procedures for monitoring the critical limits shall be developed, documented, implemented and reviewed. These shall include details of what is being measured or monitored, how this is to be carried out, the frequency at which measurements will be undertaken, where the monitoring activity is to be undertaken and who is to be responsible for monitoring. Monitoring activities shall be undertaken regularly so any deviations can be detected in-line and corrected immediately.</p>
Tesco Food Manufacturing Standard (TFMS)	<p data-bbox="408 1294 746 1328">Prerequisite Programmes</p> <p data-bbox="408 1361 1433 1496">All environmental and operational controls that are necessary to produce safe and legal food products must be in place. These cover good manufacturing practices throughout the site. The control measures and monitoring procedures for the prerequisite programme must be clearly identified and documented.</p> <p data-bbox="408 1536 624 1570">Hazard Analysis</p> <p data-bbox="408 1608 1433 1709">The HACCP team must conduct a hazard analysis to identify hazards which need to be prevented, eliminated or reduced to acceptable levels. The hazard analysis must include:</p> <ul style="list-style-type: none"> <li data-bbox="408 1749 815 1783">• Likely occurrence and severity <li data-bbox="408 1787 1002 1821">• Survival or multiplication of micro-organisms <li data-bbox="408 1825 1385 1859">• Presence or production of toxins, chemicals or foreign bodies and allergens <li data-bbox="408 1863 1082 1897">• Potential for adulteration/deliberate contamination

Standard	Requirements
Tesco Food Manufacturing Standard (TFMS)	<p data-bbox="411 300 639 327">Control Measures</p> <p data-bbox="411 371 1361 432">The HACCP team must assess whether an existing prerequisite adequately controls the hazard identified.</p> <p data-bbox="411 477 1398 607">The HACCP team must also consider what control measures (if any exist) for the remaining hazards can be applied to prevent, eliminate or reduce the risk to acceptable levels. If no control measures have been identified the product/process must be modified so a control measure can be applied.</p> <p data-bbox="411 651 703 678">Determination of CCPs</p> <p data-bbox="411 723 1361 784">The Codex decision tree or equivalent must be used to determine if control measures are CCPs (Critical Control Points).</p>
BRC Standard Food 6	<p data-bbox="411 857 1439 1093">For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. CCPs shall be those control points which are required in order to prevent or eliminate a food safety hazard or reduce it to an acceptable level. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be modified at that step, or at an earlier or later step, to provide a control measure.</p>
IFS Food Standard for auditing quality and food safety of food products Version 6	<p data-bbox="411 1200 647 1227">CP – Control point</p> <p data-bbox="411 1272 1398 1469">Identified by the hazard analysis as essential in order to control the likelihood of introducing or proliferation of food safety hazard in the product and/or the environment. A CP can be considered as an OPRP (Operational Prerequisite Program), as defined in ISO 22000. The basis of the company's food safety control system shall be a fully implemented, systematic and comprehensive HACCP system, based upon the Codex Alimentarius principles.</p> <p data-bbox="411 1514 1422 1610">It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The HACCP system shall be implemented at each production site.</p> <p data-bbox="411 1655 1439 1751">The determination of relevant critical control points (CCP's) shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.</p> <p data-bbox="411 1796 1398 1886">For all steps which are important for food safety, but which are not CCP's, the company shall implement and document control points (CP's). Appropriate control measures shall be implemented.</p>

In general the methods now universally employed in the global food industry are based on risk assessment followed by CCP determination. They are based on a principle that not all hazards are significant to food safety and therefore do not need to be controlled in a rigorous manner. Conversely, some hazards are significant and may be critical to food safety. These by definition require tighter control. This methodology can be summarized in the following steps:

Figure 1: Simple model for the determination of control measures



The above model is centred on HACCP. However, it is important to note that HACCP does not clearly define this approach which is a weakness of the system.

In the first stage, the specific hazards at specific steps are identified and characterized. This is followed by a risk assessment to determine which hazards if any are ‘significant’. Significant hazards are then applied to a decision tree to determine if they should be controlled as a CCP, PRP, oPRP, CP or QCP.

The benefit of this is ensuring that limited resources are deployed mainly to control high risk hazards.

3.2 Risk Assessment and ‘Significance’

The term Significant Hazard is used widely but often poorly understood. This is not helpful when we set about developing HACCP plans which are capable of controlling hazards in an appropriate manner. The term significance is used simply to describe those hazards which present a real risk of impacting on the consumer. It is used to separate those hazards which require tight control from those requiring lesser control. It may be said that significance is essentially an expression of Risk.

In food safety, risk (R) is a measure of the combined severity of impact (S) from a hazard and its probability of occurrence (P).

$$R = S \times P$$

In its simplest form, risk is expressed as being High, Medium or Low. When it comes to defining if a hazard is significant, risk is usually used. For example, you can say that any risk deemed to be high and medium are significant. While low risk hazards are deemed to be non-significant. This is the basic purpose of risk assessment in food safety and HACCP. The following is a simple model for risk assessment of a food safety and quality hazard:

Probability Rating

Rating	Food Safety Description	Quality Description
1	Unlikely - Would not expect to happen in 5 years	Practically impossible
2	Improbable - would not expect to happen in 2-3 years	Not expect to occur
3	Likely - Would be expected to occur once per year	Could occur or "I've heard of it happening" (published information)
4	High Probability - Could occur 2 or 3 times a year	Known to occur or "it has happened at our premises"
5	A Certainlv - Likely to occur at any time	Common occurrence

Severity Rating

No	Food Safety Description	Quality Description
1	Mild symptoms - prompt recovery	Not of commercial significance
2	Mild symptoms for a few days	Warning advice of non-conformance
3	Generally mild symptoms but some cases of hospitalisation	Rejection of a delivery by the customer
4	Severe symptoms, hospitalisation, some deaths	Food Recall
5	Death	Immediate and Final cessation of business

Risk Rating

Risk	From	To	Description
Low	1		Acceptable or tolerable risk – no specific action required
Medium			Undesirable risk - evaluation required, specific actions may be required
High		25	Intolerable risk - specific action required

Figure (above): Simple risk assessment model

3.3 Determination Models

We can now take the above and develop further our model for determining control measures. In the more advanced model below we can see clearly the role played by risk assessment in defining the significance of the hazard. Non-significant hazards are controlled by definition as PRP's and oPRP's while significant hazards are progressed to a CCP determination phase.

The model is based on 3 basic questions. The first is whether there is in fact an identified hazard at this step relating to food safety. If not, it is assumed to be a quality issue and controlled as such. If the answer to question 1 is "Yes" then a risk assessment is conducted on the hazard to determine if it is significant. If the hazard is deemed to be non-significant it is then controlled as a PRP or other control measure. Note the model below does not provide any guidance as to whether a non-significant hazard should be controlled as a PRP or operational PRP.

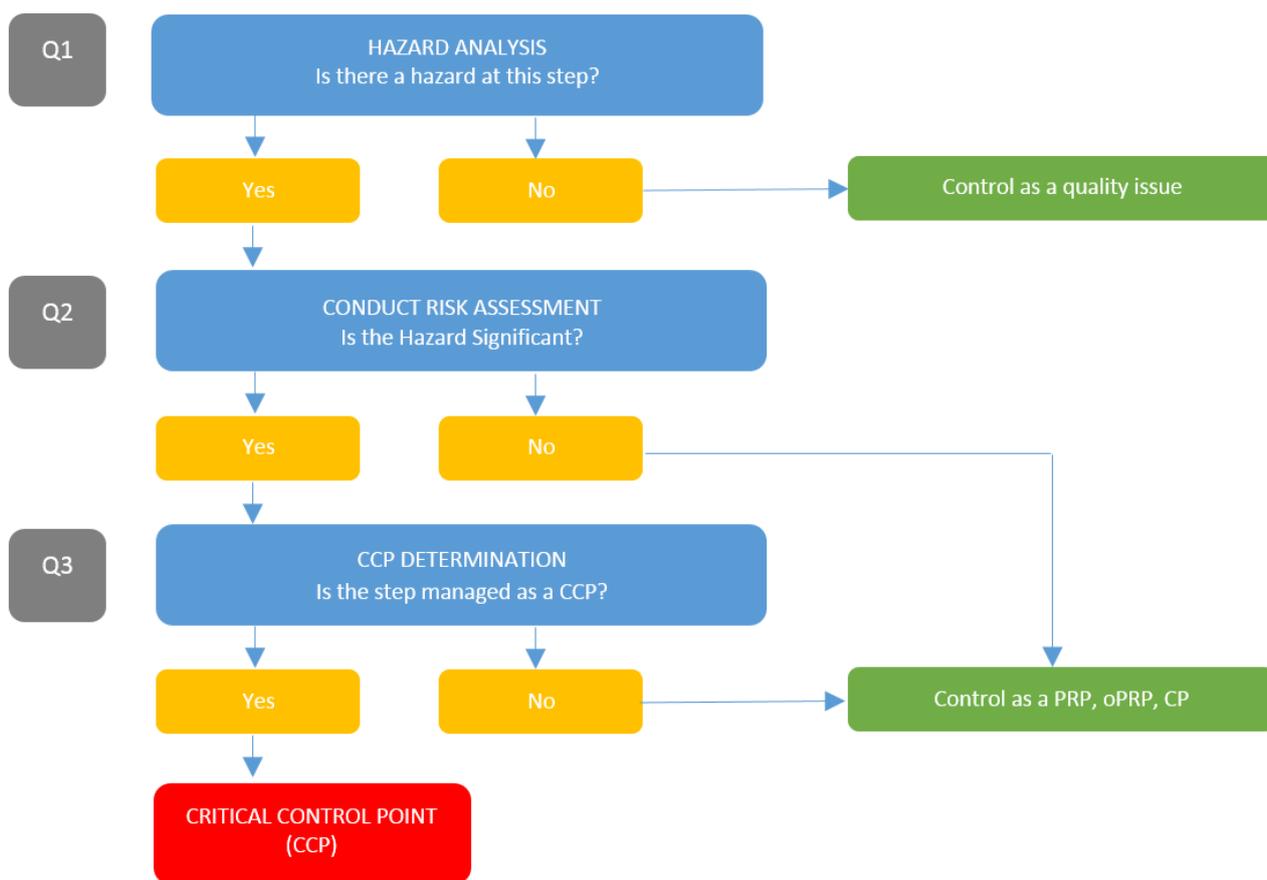


Figure (above): Model for determining control measures

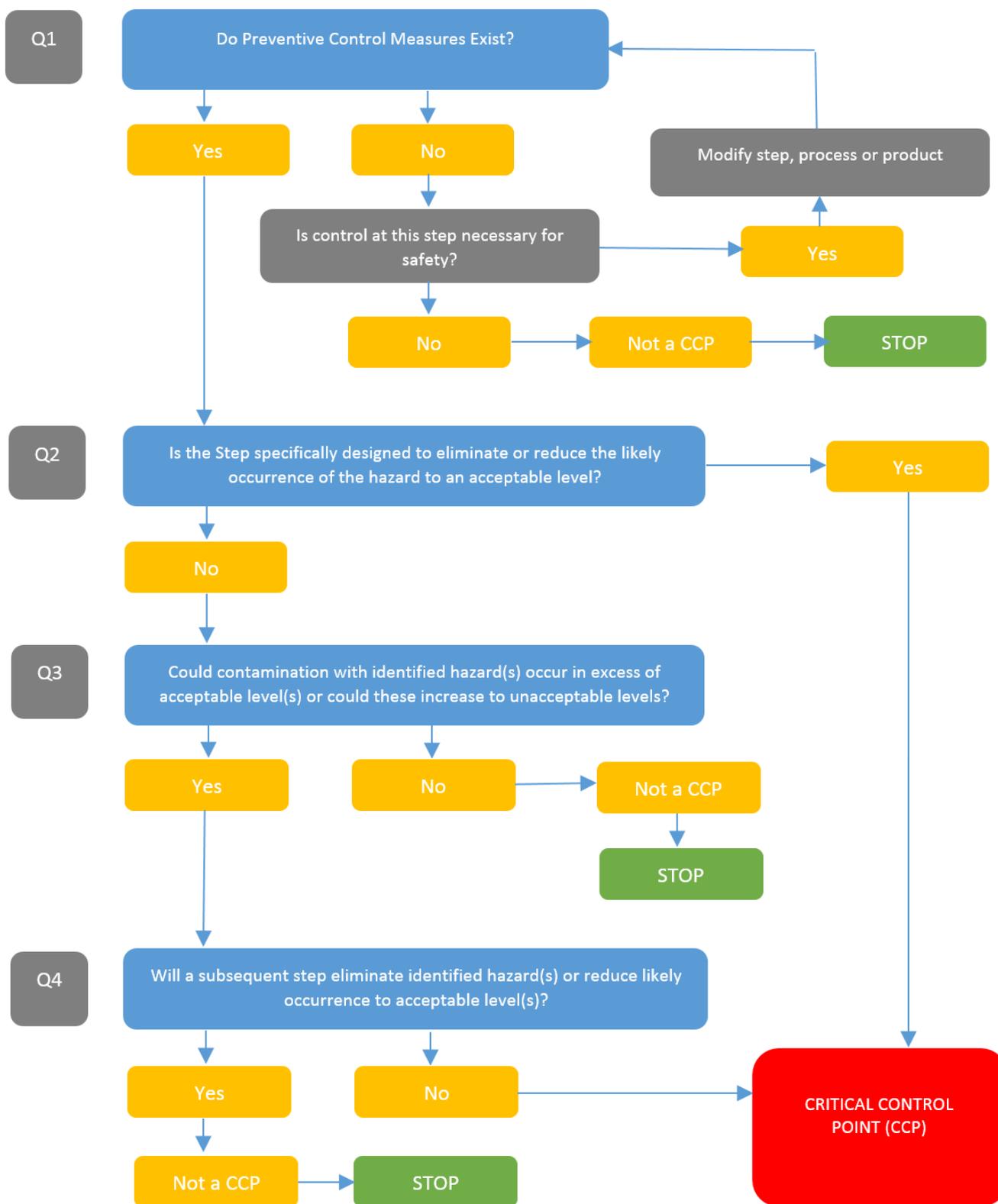
If the hazard may be deemed to be significant it does not automatically follow that it will be controlled as a CCP. This must be determined and here our model needs development. It must first go through a decision tree to determine if it meets the criteria for a CCP. This is because not every hazard identified as significant can be controlled in a manner defined as a CCP in many standards.

It may only be possible to control them through some other means and this may explain why oPRP have emerged in an effort to maintain the importance of the control failing its suitability as a CCP.

There are large numbers of decision trees employed and cited in various standards. Below we have set out the more detailed example of the decision tree found in the CODEX standard for HACCP.

You will notice that this decision tree focuses on determining whether the hazard should be controlled as a CCP or not. It does not attempt to assist the user in determining what type of control shall be employed where ‘Not a CCP’ is the outcome. This makes it limited for most modern food businesses seeking to develop a robust food safety plan.

Figure 4: CODEX Hazard Analysis and Critical Control Point (HACCP) system and Guidelines for its application, Annex to CAC/RCP 1-1969, Rev. 3 (1997) CCP Decision Tree



In order to fully address the requirements (both implicit and explicit) and the business needs of the company, a more robust decision tree is required to clearly and logically identify which control is appropriate for any significant hazards.

The following model is an example of a more detailed approach to determining the type of control measure which should be employed for a significant hazard. You will see that it covers both food safety hazards and quality issues. When used, it can provide a solid and logical approach to determine control measures and will clearly show an auditor how you arrived at your decisions.

The model pictured on the following page employs an eight question decision tree which is designed to take you through the logic step by step to determine if the hazard should be controlled as a CCP, oPRP, PRP or QCP. You will see it builds upon the Codex model but now brings into the decision process the other control measures covered in other food safety standards.

Q1. Is there a food safety hazard(s) at this step?

In this question we are again simply confirming the fact that a hazard has been identified or not. Where the answer is NO it is assumed it is a quality issue and is controlled as a QCP. If YES, then the user progresses to Q2.

Q2. Do control measure(s) exist for the identified hazard(s)?

In this question the user is asked if control measures have been identified. Where NO, Q3 is answered which may lead to revisions to the process or product. If YES, then the user will progress to Q4.

Q3. Is control necessary at this step for food safety?

If control is required then revision should be made to the process or product.

Q4. Is this step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level?

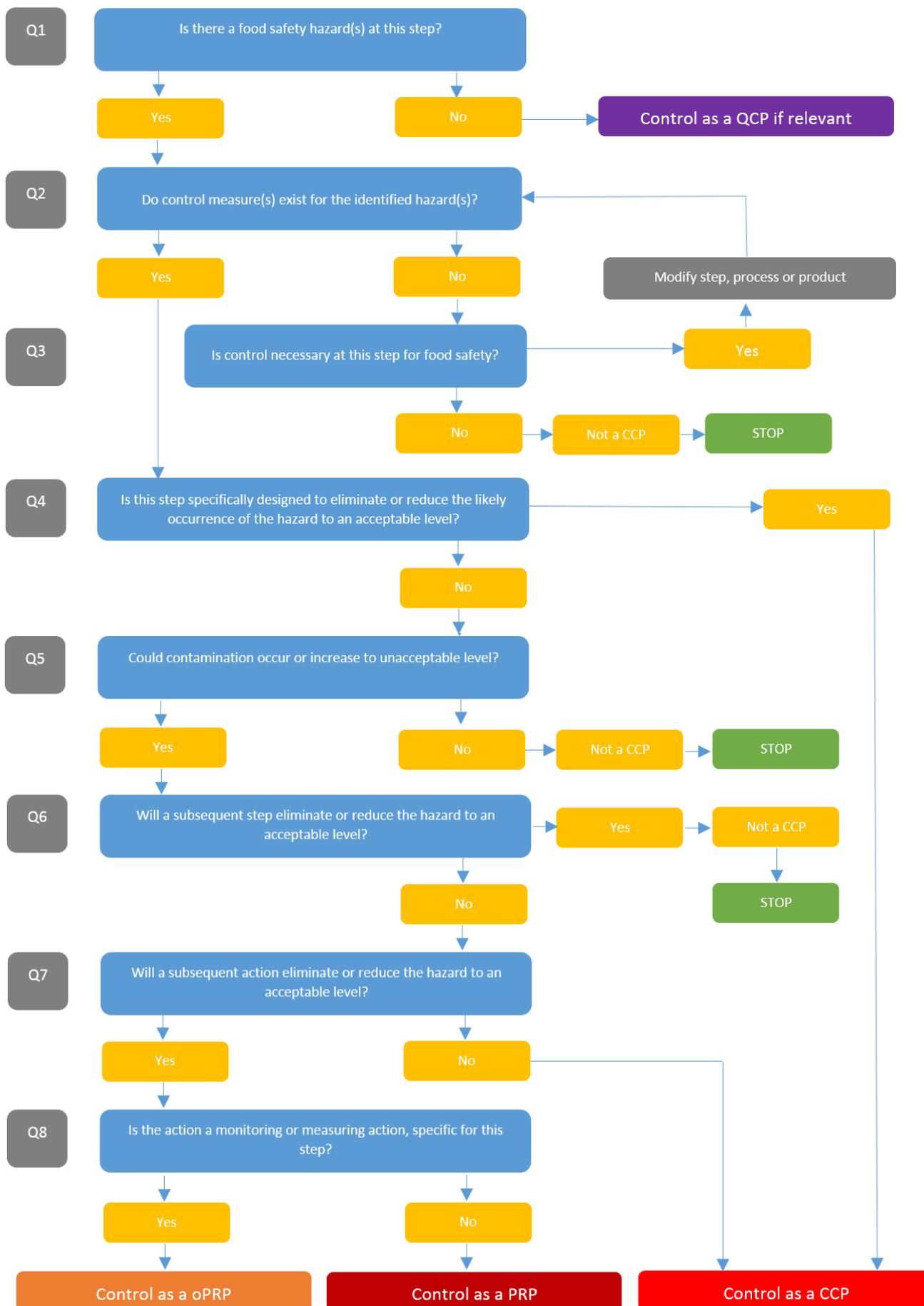
In this question the user is asked whether the step is specifically designed to eliminate or reduce the occurrence of the hazard. If YES, it will be determined as a CCP. If NO, Q5 is asked next in the sequence.

Q5. Could contamination occur or increase to an unacceptable level?

If NO, it is deemed not to be a CCP and the process STOPS. If YES, then the user progresses to Q6.

Q6. Will a subsequent step eliminate or reduce the hazard to an acceptable level?

If YES, then the determination is NOT A CCP and the process stops since some control later in the process will address the hazard. If NO, then the user progresses to Q7.



Q7. Will a subsequent action eliminate or reduce the hazard to an acceptable level?

In this question we now see the shift of the decision tree away from STEPS (which are relevant only for CCP's) to ACTIONS which are more relevant for PRP's. If NO, then this step is deemed to be the controlling step and therefore a CCP. If YES, then the user will progress to Q 8

Q8. Is the action a monitoring or measuring action, specific for this step?

The decision tree is attempting to determine if the action is general or more specific to the step. If YES, then it is controlled as an oPRP and No as a general PRP.

Figure (previous page): Detailed model for determination of Control Measures including CCP's, PRP's, oPRP's, CP's and QCP's

4 Definitions

Action – An action is any activity, task, job, or procedure which is designed to measure or control an aspect of the process or the production environment.

QCP - Quality Control Point – A process step at which control is required to prevent or eliminate a quality defect or reduce it to an acceptable level.

HACCP - A system which identifies, evaluates, and controls hazards which are significant for food safety.

Control Measure - Food safety action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Prerequisite Programme (PRP)

- basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain and are suitable for the production, handling and provision of safe end products and safe food for human consumption.

Operational Prerequisite

Programme (oPRP) - identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment.

Critical Control Point (CCP) - step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

Control Point (CP) - any step at which biological, chemical, or physical factors can be controlled.

Hazard - A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis - The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Step - A point, procedure, operation or stage in the food system from primary production to final consumption.

5 References

ISO 22000:2005 Food safety management systems - Requirements for any organization in the food chain

CODEX Hazard Analysis And Critical Control Point (HACCP) System and Guidelines for Its Application Annex to CAC/RCP 1-1969, Rev. 3 (1997)

BRC Standard for Food Issue 6

IFS Food Standard for auditing quality and food safety of food products Version 6

Woolworths Standard (WQA) for Manufactured Foods V8

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