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FOOD SAFETY SYSTEM CERTIFICATION 22000

GUIDANCE DOCUMENT: ISO 22000 INTERPRETATION

1. INTRODUCTION

In June 2018 the revised version of ISO 22000 has been published. This is the first revision since the original publication of the standard in 2005. All ISO 22000:2018 requirements are mandatory requirements for all scopes of FSSC 22000.

To support the users of FSSC 22000 this interpretation document has been developed to provide guidance for the most important changes in the new version and for the implementation of HACCP to ensure an effective food safety management system. This document does not replace the ISO 22000 requirements and is not pretending to be the “only truth”. The document aims to achieve a higher level of standardization and harmonization for all organizations that are currently certified for FSSC 22000 or want to be certified in future and for organizations involved in the certification process.

This interpretation document does not cover all ISO 22000:2018 requirements but focusses on the two significant changes:

- Alignment on ISO High Level Structure which brings new structure and new management system requirements in relation to risk-based thinking at organizational level.
- Elevation of OPRPs closer to CCPs into the ‘Hazard control plan’ in place of HACCP plan, with clarification of the requirement for the categorization and management of both two types of hazard control measures.

Another significant change is the control of externally provided processes, products and services, including externally developed elements of the food safety management, but they are not addressed here (see clauses 7.1.5 and 7.1.6 of ISO 22000:2018).

2. HIGH LEVEL STRUCTURE (HLS)

One of the most significant changes in ISO 22000 is the alignment with the High Level Structure (HLS). This structure has been developed by ISO and aims to have a common structure and content for all ISO management system standards. Management standards that have already been revised according to the HLS are ISO 9001 for quality, ISO 14001 for environment and ISO 45001 for occupational health & safety. The advantage of this approach is that it is easier to build, apply and maintain an Integrated Management System (IMS). This approach also allows integrated audits and certification.

For FSSC 22000 certified organizations that have no or limited knowledge of the HLS, the changes in ISO 22000 are substantial, but logical and beneficial. Organizations using FSSC 22000 need to understand the HLS changes in ISO 22000 and review if their Food Safety Management System meets the requirements.

This chapter explains some of the significant changes as a result from the HLS.

2.1 STRUCTURE OF THE STANDARD

The structure of the standard has been changed according to the HLS what means that all ISO management system standards have the same structure and headings of chapters. The change in structure between the ISO 22000 2005 and 2018 version is illustrated in figure 1.

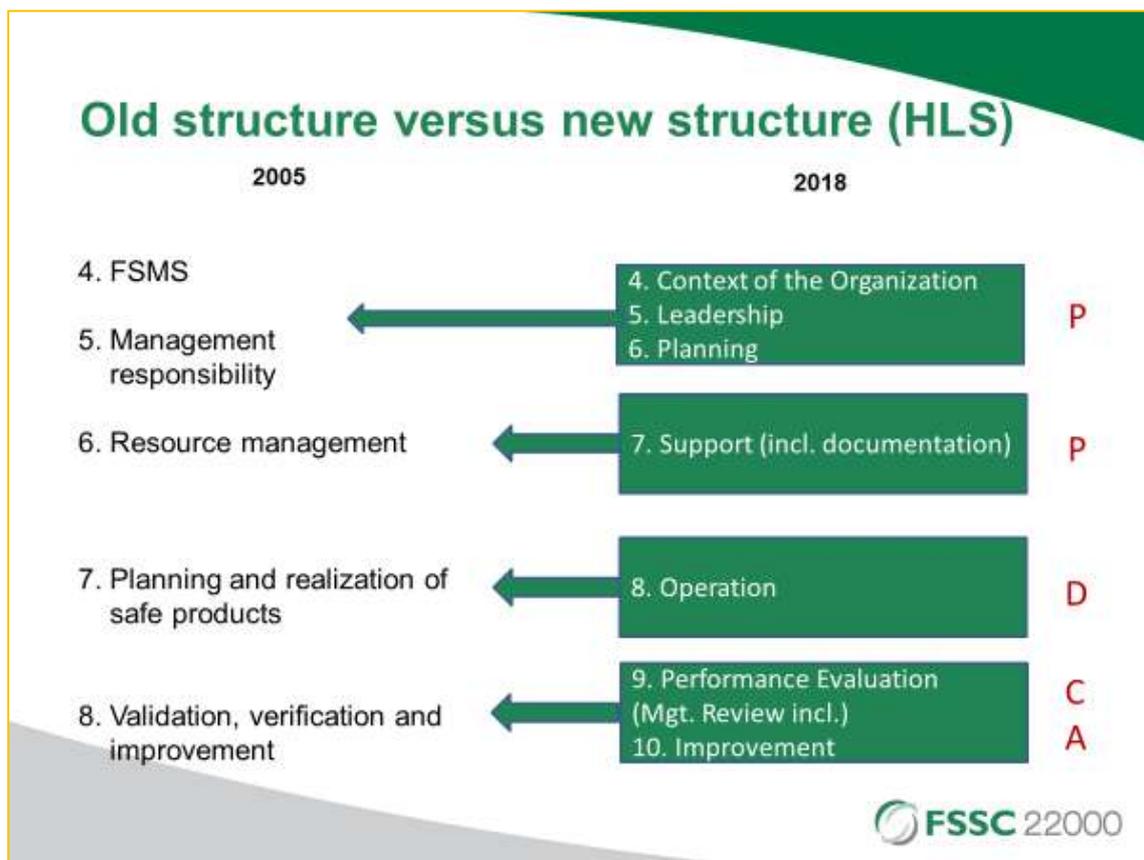


Figure 1: change of structure between ISO 22000 version 2005 and 2018

The sequence and structure of the standard follows the PDCA (plan-do-check-act) structure of continuous improvement.

2.2 PLAN DO CHECK ACT (PDCA)

ISO 22000:2018 is based on a process approach using the concept of the PDCA cycle. ISO 22000 describes this PDCA cycle at the organizational level and at the operational level.

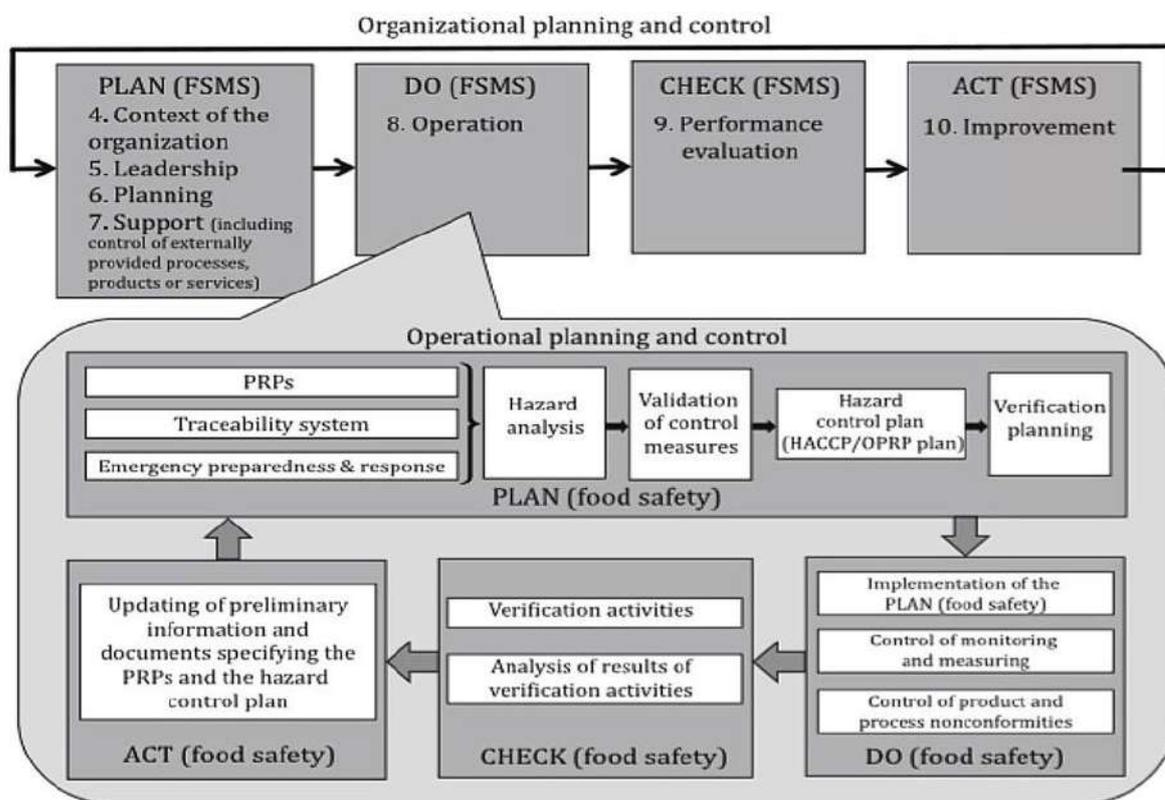


Figure 2: the two levels of PDCA in ISO 22000:2018

The connection between the PDCA approach on these two levels will be further explained in section 2.3 of this document.

The standard identifies corrective actions at two levels:

- 1) Corrections and corrective actions resulting from the monitoring of OPRPs and CCPs (chapter 8.9); and
- 2) corrective actions resulting from the verification of the effectiveness of the food safety management system (chapter 10.1).

2.3 ORGANIZATIONAL AND OPERATIONAL RISK-BASED APPROACH

The operational risk-based approach is defined in chapter 8. This is the hazard assessment to identify significant food safety hazards that shall be controlled by CCPs or OPRPs within the hazard control plan. This approach was already in place in ISO 22000:2005.

A significant change coming from the HLS is the requirement to identify food safety related risks and opportunities from the perspective of the organization. Figure 3 illustrates this organizational risk-based approach.

Such risk-based approach may lead to the identification and planning of actions that will complement the actions required by ISO 22000 in clause 8.2 and followings. In the context of FSSC 22000, these actions will include food defense and food fraud mitigation.

ORGANIZATIONAL RISK BASED APPROACH (HLS)

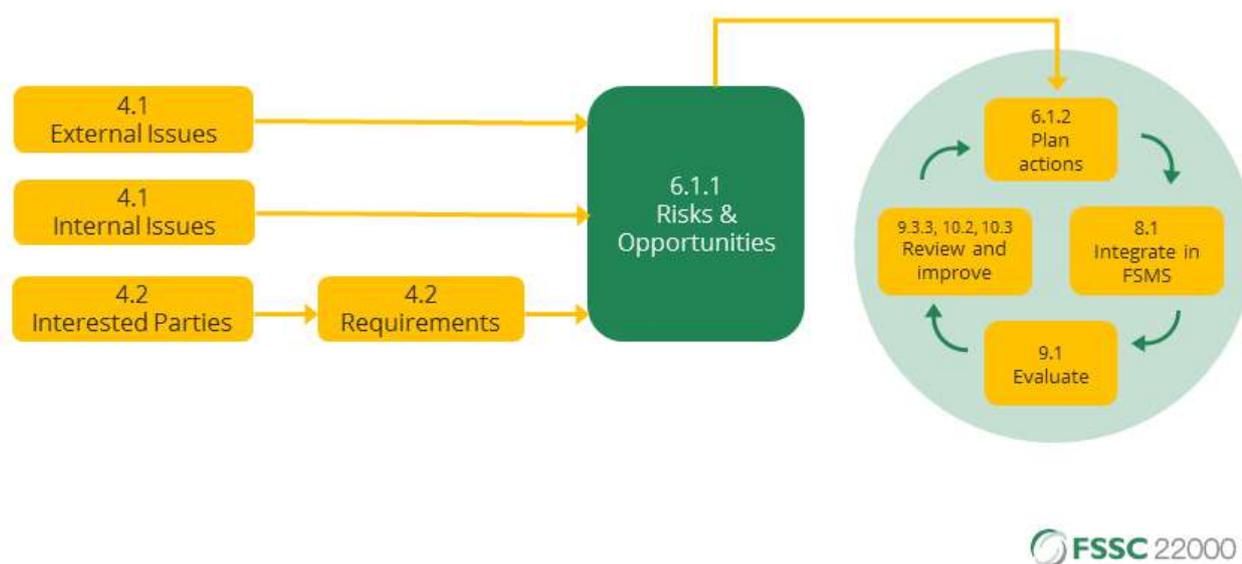


Figure 3: the organizational risk-based approach

To understand this organizational risk-based approach it is important to understand the requirements in and relation between the chapters 4, 6, 8, 9 and 10

- Chapter 4.1 requires identification of **internal and external issues** that might have an impact on food safety. Note 1 and 2 in chapter 4.1 of the standard provides examples of typical issues related to food safety.
- Chapter 4.2 requires identification of the relevant **interested parties** and their **expectations and requirements**.
- Chapter 6.1 requires identification of **risks and opportunities** (6.1.1) based on the issues and requirements of interested parties. It also requires identification of actions (6.1.2) for these risks and opportunities.
- Chapter 8.1 requires the actions to be **integrated in the operational processes** of the organization.
- Chapter 9.1 requires evaluating **effectiveness** of the implemented actions.
- Chapter 9.2 requires reviewing the effectiveness in the management review and to identify **additional actions** where required.
- Chapter 10.2 requires the organization to continually improve the suitability, adequacy and effectiveness of the food safety management system.
- Chapter 10.3 requires top management to ensure that the food safety management system is continually updated.

3. HAZARD CONTROL

3.1 GENERAL

The General Principles of Food Hygiene and its annex on the Hazard Analysis and Critical Control Points (HACCP) system of the Codex Alimentarius are the sound basis for hazard control in ISO 22000. ISO 22000 integrates these principles in a FSMS (Food Safety Management System) and facilitates the implementation of an IMS (Integrated Management System) as explained in chapter 2.

This chapter provides guidance to a number of ISO 22000:2018 requirements for which experience has shown that there are difficulties with and differences in the interpretation and implementation in practice.

Figure 4 shows how the HACCP principles, as established in the General Principles of Food Hygiene of the Codex Alimentarius, are defined in the ISO 22000:2018 chapters.

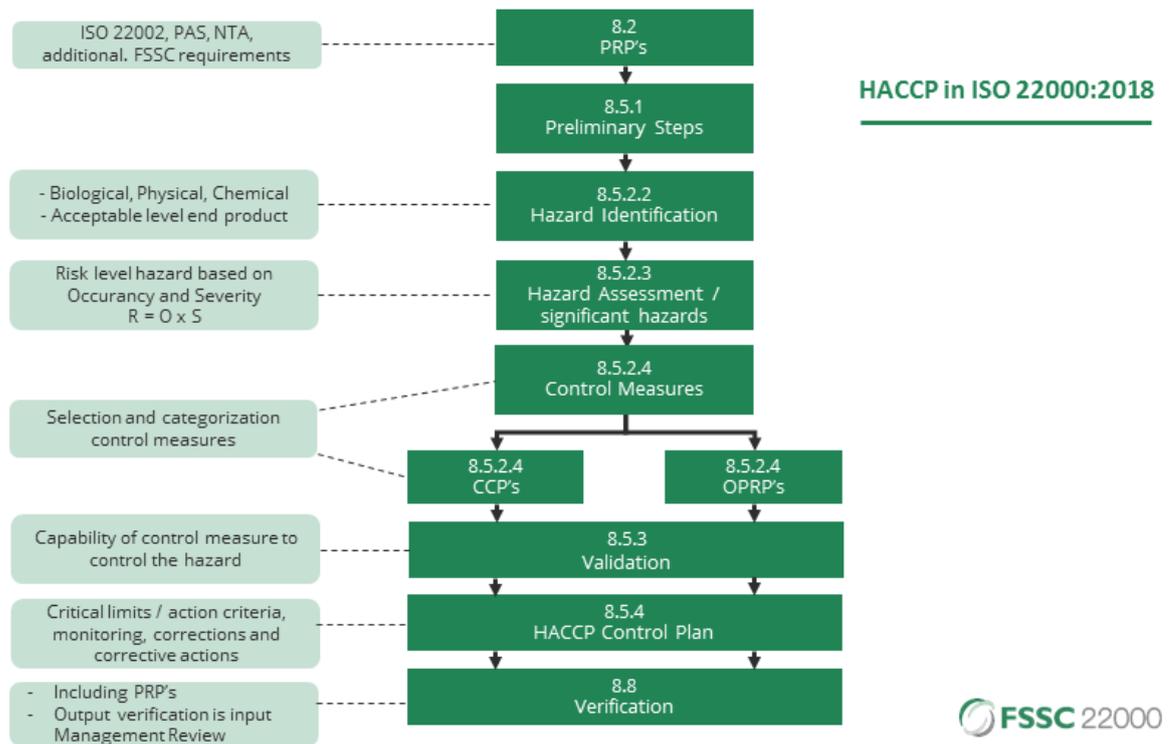


Figure 4: Hazard control in ISO 22000:2018

Note: Steps 8.5.2.2 till 8.5.2.4 are explained further in detail in this chapter and the Appendix.

3.2 THE SELECTION AND CATEGORIZATION OF CONTROL MEASURES: OPRPS AND CCPS

In 2005, the ISO 22000 standard was introduced as an auditable standard for food safety management systems. Being based on the principles of HACCP as established in the General Principles of Food Hygiene of the Codex Alimentarius, the ISO 22000 standard introduced the innovative concept of “operational prerequisite programs (OPRPs)” to add to the existing concepts of prerequisite programs (PRPs) and Critical Control Points (CCP).

Fundamental to the understanding of the categorization of CCPs and OPRPs, is that ISO 22000 makes a distinction between two levels in the assessment of severity and likelihood. The first level is focused on the assessment of hazards, the second level on the assessment of failure of control measures. In the 2018 version of ISO 22000, these two levels of assessment are made more explicit. At the first level, in clauses 8.5.2.2 and 8.5.2.3, hazards are identified, and their severity and likelihood are assessed to evaluate the need for control measures. At the second level, in clause 8.5.2.4, the severity and likelihood of failure of these control measures are assessed as part of the evaluation of the need and feasibility to establish critical limits, monitoring and corrections.

The application of the assessment at these two levels is illustrated in the case in the text-box below. The case on the pasteurization of milk illustrates the dawn of HACCP in the twentieth century.

A classical case: pasteurization of milk

In the first half of 20th century, Dutch society faced a relatively large number of foodborne infections caused by the consumption of raw milk. The milk was found to be frequently contaminated with pathogens, particularly Salmonella.

To end this situation, in the 1940s a law was adopted in which the pasteurization of milk was mandated. The pasteurization processes which then were introduced in dairy industry had to meet a minimum temperature of 72 °C, for at least 15 seconds. These limits were established through scientific research that showed that such a heat treatment was sufficient to reduce the number of pathogenic bacteria to an acceptable level. For fresh pasteurized milk for example, the acceptable level for Salmonella is that it is absent in 25 gram or ml.

However, in the years that followed, still every now and then, people still became ill due to Salmonella in pasteurized fresh milk. It turned out that pasteurization in dairy industry met with regular problems with the supply of heat. As a result, the temperature criteria were not met, causing so-called “under-pasteurization”. The insufficient pasteurized milk, which really should not be on the market, was still delivered, sold and consumed.

To deal with this, in the 1950s a law was passed that required that every piece of equipment for the pasteurization of fresh milk had to be provided with a so-called thermograph. The thermograph measured the temperature of the pasteurization and recorded it on a paper disk. The disks were to be retained and available for inspection by the competent authority.

Moreover, it was required that the thermograph was linked to an automated flow diversion valve. As soon as the pasteurization temperature dropped below 72 °C, the thermograph had to switch over the flow diversion valve. The flow diversion valve made sure that the insufficiently pasteurized milk was directly sent back to the storage tank where it came from.

Although the HACCP system was not yet established during the times described in the case, as shown the table 1 below, the key definitions of the HACCP system can already be identified.

		Key definition of the HACCP system according to Codex Alimentarius.
1940s: control of hazards	salmonella bacteria	1. Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
	pasteurization	2. Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
	scientific research	3. Validation: Obtaining evidence that a (combination of) control measure(s), if properly implemented, is capable of controlling the hazard to a specified outcome. (Guidelines for the validation of food safety control measures - cac/gl 69 - 2008)
	72 °C, 15 sec	4. Critical limit: A criterion which separates acceptability from unacceptability.
1950s: control of deviations	temp < 72 °C	5. Deviation: Failure to meet a critical limit.
	thermograph	6. Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.
	flow diversion valve	7. Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.
	inspection of records	8. Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Table 1: The case of pasteurization of milk presented as a two-stage approach and in relation to the definitions of the HACCP system.

As stated earlier, an important feature in the case is that there are two levels of control. At the first level, pathogens are controlled by the application of pasteurization. At the second level, the failure of the temperature of pasteurization is controlled by the application of - automated - corrective actions based on monitoring and critical limits.

In the HACCP system, the pasteurization will be identified as a CCP. CCPs are characterized by a high likelihood x severity of the hazard, a high likelihood x severity of failure and a good feasibility to detect and correct this failure. Control measures that are specifically designed to reduce hazards - like pasteurization - will in many cases have these characteristics.

Prerequisites on the other hand, are primarily aimed to prevent contamination and maintain a hygienic environment. To achieve this, prerequisites are applied as part of a program with a combination of measures that all contribute to food safety. This implies that in many practical cases, the likelihood x severity of failure of a single prerequisite only has minor impact on food safety. However, depending on the nature of a food and its process, failure of some prerequisites might have more than just minor impact on food safety.

As stated previously, one of the characteristics of a CCP is the good feasibility of measurements to detect and correct failure. However, in the practice of producing safe food, there are situations in which, despite of a high likelihood x severity of hazards and of failure, the feasibility of measurement to detect and correct failure is rather low. A typical example of low feasibility to

detect failure can be the measurement of control measures like the manual cleaning of equipment and the separation of raw materials and processes to control allergens. Basically, in cases like these, low feasibility of measurement to detect and correct failure means that control of the hazard cannot be guaranteed. A well accepted practice in these cases is that products are labelled as potentially unsafe with disclaimers like “may contain traces of peanuts”.

Despite high likelihood x severity of failure of control measures on food safety, when the feasibility of measurement to detect and correct of failure is low, a CCP cannot be established. In ISO 22000 this type of control measure is also identified as an OPRP. To express low feasibility of measurement, ISO 22000:2018 uses the expression “observations” for OPRPs, as counterpart of “measurement” for CCPs. Since “observation” is, to more or lesser extent subjective, the effectivity of the control measure cannot be guaranteed. Consequently, the organization shall consider (i) a redesign of the product, process or control measures, (ii) to take action to reduce de likelihood and severity of failure, (iii) to inform customer and/or consumers about the need to further control the hazards, or (iv) provide information about the potential presence of the hazard so customers and/or consumers can avoid to use or consume the product. In ISO 22000:2018 this situation is referred to in 7.4.2.b about external information (further explained in section 3.3 of this document). When this information is communicated to consumers through the label on the product, the likelihood and severity of failure to provide this information shall be assessed to decide on appropriate monitoring and/or correction and corrective action.

In clause 8.5.2.4, ISO 22000 includes both the assessment of likelihood x severity of failure and of the feasibility of detection and correction. ISO 22000:2018 is not explicit about how these assessments relate to the categorization of OPRPs and CCPs. Table 2 displays a possible interpretation for the outcomes of the assessment. Note that the categorization in clause 8.5.2.4 does not include PRPs: PRPs are added to table 2 to complete the overview. The impact of failure of PRPs is low, basically because they do not control significant hazards.

		Severity x likelihood of failure.		
		low	moderate	high
Feasibility of detection and correction of failure.	high	PRP	OPRP	CCP
	low	PRP	OPRP	OPRP

Table 2: PRPs, OPRPs and CCPs as a product of the likelihood x severity of failure and the feasibility for detection and correction of this failure.

The assessment of the likelihood x severity of failure in ISO 22000 is the basic to the understanding of OPRPs: a control measure, managed as an OPRP controls a significant hazard but failure of on OPRP does not necessarily lead to unsafe product. This is reflected in clause 8.5.2.4.1. In this clause control measures can be categorized as to be managed as OPRPs when a) the likelihood of failure is low and/or b) the severity of the consequence of failure is low.

The severity of failure of a control measure can be low, when:

- 1) the failure has little effect on the significant food safety hazards; and/or
- 2) there is a subsequent control measure that will reduce the hazard to an acceptable level (the location in relation to other control measures); and/or
- 3) the control measure is not specifically established and applied to reduce the hazards to an acceptable level, but rather to prevent hazards; and/or
- 4) the control measure is part of combination of control measure(s).

Since failure of an OPRP does not necessarily lead to unsafe product, it is not necessary to detect and correct each and every single case of failure. To express this, the criteria for the application of OPRPs are referred to as action criteria. Failure to meet an action criterion requires corrective actions towards the process. Correction towards the product is decided on case by case after assessment of causes and consequences of failure. For CCPs, where the likelihood x severity is high, the criteria for the application of the control measure are referred to as critical limits. Products affected by failure to remain within critical limits shall not be released but be handled in accordance with 8.9.4.3. This clause states that these products shall be reprocessed, redirected for other use or destroyed and/or disposed as waste.

Table 3 shows the differences between OPRPs and CCPs in ISO 22000:2018. Note that the two stages of assessment are reflected in the definition of OPRPs and CCP: the first part in the definitions refers to the control of hazards, the second part refers to the control of failure through detection (monitoring) and correction.

Operational Prerequisite Program - OPRP	Critical Control Point CCP
<p>3.31 - operational prerequisite program - OPRP control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level, and where action criterion and measurement or observation enable effective control of the process and/or product.</p>	<p>3.11 - critical control point CCP step in the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level, and defined critical limit(s) and measurement enables the application of corrections.</p>
<p>8.5.4.2 Determination of critical limits and action criteria Action criteria for OPRPs shall be measurable or observable. Conformance with action criteria shall contribute to the assurance that the acceptable level is not exceeded.</p>	<p>8.5.4.2 Determination of critical limits and action criteria Critical limits at CCPs shall be measurable. Conformance with critical limits shall ensure that the acceptable level is not exceeded.</p>
<p>8.5.4.3 Monitoring systems at CCPs and for OPRPs For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.</p>	<p>8.5.4.3 Monitoring systems at CCPs and for OPRPs At each CCP, the monitoring method and frequency shall be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product (8.9.4).</p>

<p>8.9.2.3 Where action criteria for an OPRP is not met the following shall be carried out:</p> <ul style="list-style-type: none"> a) determination of the cause(s) of failure; b) determination of the consequences of that failure with respect to food safety. c) identification of the affected products and handling in accordance with 8.9.4; 	<p>8.9.2.2 When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (8.9.4).</p>
<p>8.9.4.2 Evaluation for release Products affected by failure to meet action criterion for OPRPs shall only be released as safe when any of the following conditions apply:</p> <ul style="list-style-type: none"> a) evidence other than the monitoring system demonstrates that the control measures have been effective; b) evidence shows that the combined effect of the control measures for that particular product conforms with the performance intended (i.e. identified acceptable levels); c) the results of sampling, analysis and/or other verification activities demonstrate that the affected products conform with the identified acceptable levels for the food safety hazard(s) concerned. 	<p>8.9.4.2 Evaluation for release Products affected by failure to remain within critical limits at CCPs shall not be released but be handled in accordance with 8.9.4.3.</p>
<p>8.9.4.3 Disposition of nonconforming products. Products that are not acceptable for release shall be:</p> <ul style="list-style-type: none"> a) reprocessed or further processed within or outside the organization to ensure that the food safety hazard is reduced to acceptable levels; or b) redirected for other use as long as food safety in the food chain is not affected; or c) destroyed and/or disposed as waste. 	

Table 3: differences between OPRPs and CCPs in ISO 22000:2018

Table 4 shows a comparison between PRPs, OPRPs and CCPs and shows the relation between ISO 22000 and the ISO 22002-series.

Key definition of the Codex HACCP system.	Prerequisite programs PRPs. (suggested source: ISO 22002-series)	Operational Prerequisite Programmes - OPRPs.	Critical Control Points - CCPs.
Hazard analysis	Established and implemented prior to hazard analysis.	Identified through hazard analysis. (ISO 22000 - 8.5.2)	
Hazard	No specific hazards. Non-significant hazards.	Significant hazards. (ISO 22000 - 8.5.2.3) Specific hazard or group of hazards.	
Acceptable level	No requirements to establish acceptable levels for hazards.	Requirement to establish acceptable levels for hazards. (ISO 22000 - 8.5.2.2.3)	
Control measure	Not specific to a hazard. Prevention of contamination. Conditions and activities to create the hygienic environment.	Control measures to prevent or reduce significant hazard(s). (ISO 22000 - 8.5.2.4) Control measures to prevent: keep hazards below acceptable levels - keep safe product safe. Control to reduce: bring hazards below acceptable levels - make unsafe products safe.	
Validation	Not required	Yes, validation shall be carried out. (ISO 22000 - 8.5.3) Validation will determine the action criteria and/or critical limits.	
Monitoring	Not required	Measurement or observation. The monitoring method and frequency shall be proportionate to the likelihood of deviations and the severity of consequences. (ISO 22000 - 8.5.4.3)	Measurement. The monitoring method and frequency shall be capable of detecting all deviations. (ISO 22000 - 8.5.4.3)
Criteria	Not applicable.	3.2 action criterion. To produce safe food, OPRPs shall be operated within action criteria. Action criteria shall be measurable or observable.	3.12 critical limit. To produce safe food, CCPs shall be operated within action criteria. Critical limits shall be measurable.
Deviation	Deviation has minor impact on food safety. Affected product will usually still be safe.	Deviation may have impact on food safety.	Deviation has major impact on food safety.
Correction and Corrective action		Evaluation of the causes and consequences of failure. (ISO 22000 - 8.9.2.3)	Manage as potentially unsafe (ISO 22000 - 8.9.2.2)
Verification	Yes. Scheduled verification of implementation. (ISO 22000 - 8.8)	Yes. Scheduled verification of implementation and monitoring of control measures. (ISO 22000 - 8.8)	

Table 4: Comparison between CCPs, OPRPs and PRPs

3.3 SIGNIFICANT FOOD SAFETY HAZARDS & EXTERNAL COMMUNICATION (ISO 22000:2018 - 7.4.2.)

Earlier in this document it is stated that in case of high likelihood x severity of failure of control measure and a low feasibility of detection and correction, the control of this hazard cannot be guaranteed. Consequently, customers and/or consumers need to be informed about the likely presence of the hazard and/or how to control it (ISO 22000:2018 - 7.4.2.b). Failure to provide this information shall be assessed to decide on appropriate monitoring and correction procedures.

A typical example is the control of allergens. Allergens may be present in a consumer product through cross contamination or through addition as an ingredient. In practice, allergen information is put on the product label (ingredient list, or 'may contain statement') to inform consumers so they can control the hazard by not eating the product containing the allergen(s) they are allergic to.

Applying the correct product label with the correct allergen information has become an essential communication measure because of a significant food safety hazard (high likelihood x severity). In practice a large share of product recalls are executed because this communication measure has failed. So extra attention to this topic is necessary.

To assure the communication of correct allergen information on the product label, a combination of monitoring procedures is needed. Let's focus on 'applying the correct label on the consumer product at the packing line' as an example and take the assessment criteria in ISO 22000:2018 - 8.5.2.4 into account:

- The likelihood of failure is high.
- The severity of the consequences in case of failure is high (there are no subsequent monitoring procedures).
- The feasibility of critical limits and a monitoring procedure is high.
- The feasibility of timely correction is high.

Although 'labelling of the consumer product at the packing line' does not meet the definition of a CCP, it is likely that the required monitoring and corrections shall be performed similar to a CCP.

This assessment is also applicable for 'printing the correct allergen information on the label'. Depending on the situation - label printing in-line / pre-printed labels - a strict monitoring procedure on operating the label printer or releasing pre-printed labels is required.

This example shows the great importance to assess all communication procedures with regards to significant food safety hazards.

4. APPENDIX (INFORMATIVE)

The appendix to this document presents a decision tree (spread over two pages) that can be used to conduct a hazard analysis within the framework of ISO 22000. Potential users should be aware that this decision tree is a result of an interpretation and that other tools can be used.

ISO 22000:2018. Decision tree for the selection and categorization of OPRPs and CCPs.

8.5.2.2 Hazard identification - 8.5.2.3 Hazard assessment

