

Chapter 7: Principle 3: Establish Critical Limits

Notes:

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Objective:

In this module, you will learn:

- How to define critical limits.
- How to set critical limits for a CCP.
- How to find sources of critical limit information.
- How to determine the relationship between critical limits and operating limits.

Critical limits must be established for each CCP identified in the hazard analysis.

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Principle 3:

Establish critical limits.

Overhead 3

Definition:

Critical Limit: A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.

A critical limit represents the boundaries that are used to ensure that an operation produces safe products. Each CCP must have one or more critical limits for each food-safety hazard. When the process deviates from the critical limit, a corrective action must be taken to ensure food safety. Examples of critical limits are listed in Table 1.

Establishing Critical Limits

In many cases, the appropriate critical limit may not be readily apparent or available. Tests may need to be conducted or information gathered from sources such as scientific publications, regulatory guidelines, experts or experimental studies (Table 2).

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Table 1. Examples of Critical Limits

Hazard	CCP	Critical Limit
bacterial pathogens (biological)	pasteurizer	≥ 161 F for ≥ 15 seconds for elimination of pathogens from milk
bacterial pathogens (biological)	drying oven	Drying schedule — oven temperature: ≥ 200 F, drying time: ≥ 120 min., air flow rate: ≥ 2 cuft/min, product thickness: ≤ 0.5 inches (to achieve a_w ≤ to 0.85 to control pathogens in dried foods)
bacterial pathogens (biological)	acidification	Batch schedule — product weight: ≤ 100 lbs., soak time: ≥ 8 hrs., acetic acid concentration: ≥ 3.5 percent, volume ≤ 50 gal. (to achieve maximum pH of 4.6 to control <i>Clostridium botulinum</i> in pickled foods)

Explanatory Note:

These critical limits are for illustrative purposes only. They do not relate to any specific product but demonstrate how critical limits could apply at CCPs utilizing different control parameters for bacterial pathogens. In actual practice, critical limits must be scientifically based.

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Table 2. Sources of Information on Critical Limits

General Source	Examples
scientific publications	journal articles, food science texts, microbiology texts
regulatory guidelines	state and local guidelines, tolerances and action levels; USDA guidelines, tolerances and action levels; FDA guidelines, tolerances and action levels
FDA	FDA Fish and Fisheries Products Hazards and Controls Guidance Manual (referenced in Chapter 13)
experts	NACMCF (National Advisory Committee on Microbiological Criteria for Foods), thermal process authorities; consultants, food scientists/microbiologists, equipment manufacturers, sanitarians, university extension, trade associations
experimental studies	in-house experiments; contract labs

If the information needed to define the critical limit is not available, a conservative value should be selected. The rationale and reference material used to establish a critical limit should become part of the support documentation for the HACCP plan.

Often a variety of options exist for controlling a particular hazard. The control options usually necessitate the establishment of different critical

limits. The selection of the best control option and the best critical limit is often driven by practicality and experience. The following examples suggest control options and critical limits that could be applied at the fryer step to control bacterial pathogens in fried fish patties.

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Option No. 1
Monitoring for Pathogens
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — no pathogens detected

(Not typically the best option)

Setting a microbial limit as a critical limit for an in-process CCP is rarely practical. Microbiological limits are difficult to monitor, and testing to determine critical limit deviations may require several days. Therefore, microbiological limits cannot be monitored on a timely basis. Microbiological contamination is often sporadic, and samples may need to be large to be meaningful. In this example, sampling and microbiological tests of the fish patties are unlikely to be sensitive enough or practical.

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Option No. 2
Controlling Internal Temperature
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — minimum internal temperature of 150 F for one minute

Setting a microbial critical limit is not necessary in this example as long as an appropriate critical limit can be set that is based on the conditions needed to inactivate the microorganisms of concern. Pathogens of concern in fish patties are destroyed by cooking the patties to an internal temperature of 150 F for one minute. In this option, the product temperature at the end of frying is used as a critical limit. This option is typically more practical and sensitive than finished-product pathogen testing.

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Option No. 3

Controlling Factors that Affect Internal Temperature

Hazard — *presence of pathogens (microbiological)*

CCP — *fryer*

Critical limit — *minimum fryer oil temperature of 350 F*

Critical limit — *maximum patty thickness of 1/4 inch*

Critical limit — *minimum cook time in the oil of one minute*

In many cases, it is not practical to continually monitor the internal temperature of the food product to ensure conformance with a critical limit. As an alternative, critical limits may be set that establish conditions necessary to ensure that the cooking process achieves the necessary minimum product temperature. In this option, the oil temperature, the fish patty thickness and the time that the patty stays in the hot oil are all factors that affect the final patty temperature. Tests must be performed to ensure that controlling these factors within the critical limits will always result in an internal product temperature that will inactivate the microorganisms of concern. Typically, this option is easier to control and to monitor than the previous two. In addition, the cooker temperature and cooking time can be monitored continually, which gives greater confidence that every item has been adequately cooked.

The process should be capable of operating within the bounds set by the critical limit. The parameters for the fryer — minimum fryer-oil temperature, maximum patty thickness and minimum cook time — become the critical limits for the CCP. The critical limits should not be confused with the operating parameters of the equipment.

Establishing Operating Limits

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Definition:

Operating Limits: Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.

If monitoring shows a trend toward lack of control at a CCP, operators should take action to bring the CCP under control before the critical limit is exceeded. The point where operators take such an action is called the operating limit. Operating limits should not be confused with critical limits. Operating limits are established at a level that would be reached before the critical limit is violated.

Definition:

Process Adjustment: An action taken by the firm to bring the process back within operating limits.

The process should be adjusted when the operating limit is reached to avoid violating critical limits. These actions are called process adjustments. A processor may use these adjustments to avoid loss of control and the need to take corrective action. Spotting a trend toward loss of control early and acting on it can save product rework, or worse yet, product destruction. Corrective action is only required when the critical limit is exceeded.

Operating limits may be selected for various reasons:

- For quality reasons (e.g., higher cooking temperatures for flavor development or to control organisms that can cause spoilage).
- To avoid exceeding a critical limit (e.g., a cooking temperature higher than the critical limit could be used as an alarm point to warn the operator that the temperature is approaching the critical limit and needs adjusting).
- To account for normal variability (e.g., a fryer with a 5 F variability should be set at least 5 F above the critical limit to avoid violating it).

Figures 1 and 2 are graphical representations of several important points: 1) operating limits and process adjustments, 2) critical limits and corrective actions, and 3) implications of lot size. In this example of a generalized cooking process, an operating limit is established at 200 F and a critical limit at 190 F. Somewhere in the 10 F range between these two points, wise processors will make a process adjustment to bring the cook temperature back above 200 F. Because an adjustment is made before the temperature drops below the critical limit of 190 F, no HACCP record is required. However, if an adjustment is not taken until after the temperature drops below the critical limit, as shown in Figures 1 and 2, appropriate corrective actions must be taken and a corrective action report must be placed in the HACCP records file (corrective actions and records will be discussed in subsequent chapters).

When a corrective action is necessary, processors must be able to identify and segregate the affected lots. If lot sizes are big, large quantities of product may require segregation and corrective action despite the fact that only a small amount of product was produced when critical limits were exceeded. Coding production into smaller lots means far less product may be involved when violation of a critical limit occurs. Therefore, wise processors should change codes often during the production day and match monitoring frequency with code changes.

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Figure 1

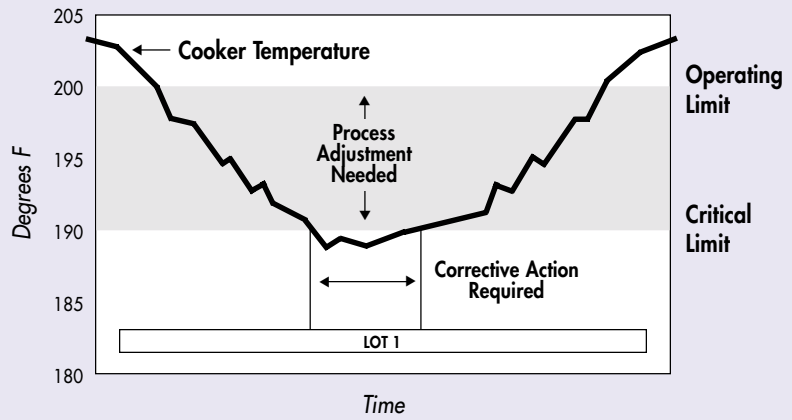
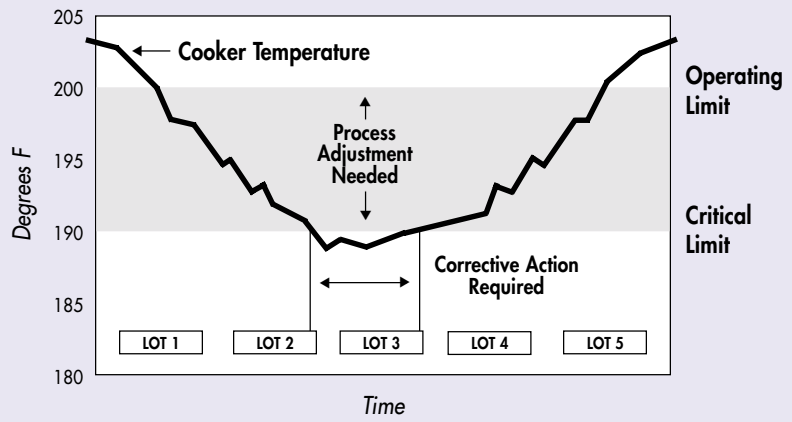


Figure 2



Critical Limits for ABC Shrimp Co.

The hazard-analysis worksheet for the IQF cooked-shrimp example identifies two CCPs: cooker and weigh-pack-label. The following table lists examples of critical limits for these CCPs.

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<i>Critical Control Point</i>	<i>Critical Limit</i>
CCP — Cooker	Cook at ≥ 212 F for three minutes (to achieve minimum internal temperature of 145 F for 15 sec.)
CCP — Weigh/Pack/Label	All product containing sulfiting agent must declare presence

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Critical Limits:									
1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
CCP	Hazard	Critical Limits	Monitoring <small>What How Frequency Who</small>				Corrective Action(s)	Verification	Records

The CCP, hazards and critical limits should be recorded in columns 1, 2 and 3 on the HACCP plan form.

Notes:

Explanatory Note:

For the purpose of this example, we have assumed that a study was performed to determine the worst case (e.g., largest shrimp, lowest initial temperature). The shrimp would be heated to an internal temperature of 145 F for 15 seconds by cooking for at least three minutes at 212 F or greater. In practice, processors may choose to vary process times depending on shrimp size. Therefore, shrimp size grading would likely become a CCP.

Explanatory Note:

Since residuals of sulfiting agents may trigger allergic-type reactions, labeling is required on product with detectable residues. Detection levels range above 10ppm.

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EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form
ABC Shrimp Co.
Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4)			(5) Monitoring		(7) Who	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	How	Frequency				
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 145 F for 15 seconds)									
Weight/Pack/Label	Allergic-type reaction for undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence									

Firm Name: <u>ABC Shrimp Co.</u>	Product Description: <u>Cooked and frozen, headless, peeled and deveined shrimp</u>
Firm Address: <u>Anywhere, USA</u>	Method of Storage and Distribution: <u>Frozen</u>
Signature: _____	Intended Use and Consumer: <u>Thaw and serve, general public</u>
Date: _____	

*Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.