

# Section 3-5: Principle 3: Determine Critical Limits

## Principle 3: Determine Critical Limits

# Section Overview

The third principle of HACCP is to determine the Critical Limits (CLs) in the process. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical Limits must be established for each control measure important to manage food safety at a Critical Control Point.

The following topics will be discussed in this section:

- Definitions and preliminary considerations
- Examples of parameters that may be critical limits
- Deviations
- Establishing critical limits
- Operating limits
- Choosing an effective critical limit
- Documenting critical limits

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### Principle 3: Determine Critical Limits

## Learning Objectives

At the conclusion of this section, the learner will be able to:

- define “Critical Limit” and describe the general process for determining critical limits in a HACCP plan,
- discuss examples of parameters that might be critical limits in a HACCP plan,
- define “Deviation” and discuss what a deviation could indicate in a HACCP system,
- discuss factors the HACCP team should consider when establishing critical limits,
- define “Operating Limit” and explain why operating limits might be used by a food facility,
- discuss considerations in establishing effective critical limits, and
- describe how to document critical limits in a HACCP plan.

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Principle 3: Determine Critical Limits

## Definitions and Preliminary Considerations

A Critical Limit is defined by the Codex Alimentarius Commission as “a criterion which separates acceptability from unacceptability.”

The U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has a more precise definition of a Critical Limit. The NACMCF definition is “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.”

CLs are identified only after the completion of the hazard analysis (HACCP Principle 1) and identification of the Critical Control Points (HACCP Principle 2).

Critical Limits are established only at Critical Control Points.



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### Principle 3: Determine Critical Limits

## Examples of Parameters that May Be Critical Limits

Critical limits must be scientifically based. For each CCP, there must be at least one criterion for food safety that is to be met. Critical limits may be based upon factors such as:

- Temperature
- pH
- Titratable acidity
- Humidity
- Moisture level
- Line Speed
- Time
- Flow rate
- Water activity
- Salt concentration
- Physical dimensions
- Weight
- Viscosity
- Available chlorine
- Preservative concentrations
- Sensory information such as aroma and visual appearance

In order to serve as effective critical limits at CCPs, these parameters must be:

- In place and operational
- Measurable and/or observable

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## Principle 3: Determine Critical Limits

# Deviations

In HACCP, a deviation refers to “a **failure to meet a critical limit.**” You also often see these events referred to as nonconformities.

Not meeting a critical limit could indicate:

- evidence that a direct health hazard **already exists** (e.g. bacterial contamination of a ready-to-eat food), or
- evidence that a direct health hazard **could develop** (e.g. under-processing of a low-acid food), or
- that a product was not produced under conditions **assuring safety** (e.g. metal detector calibrated incorrectly)

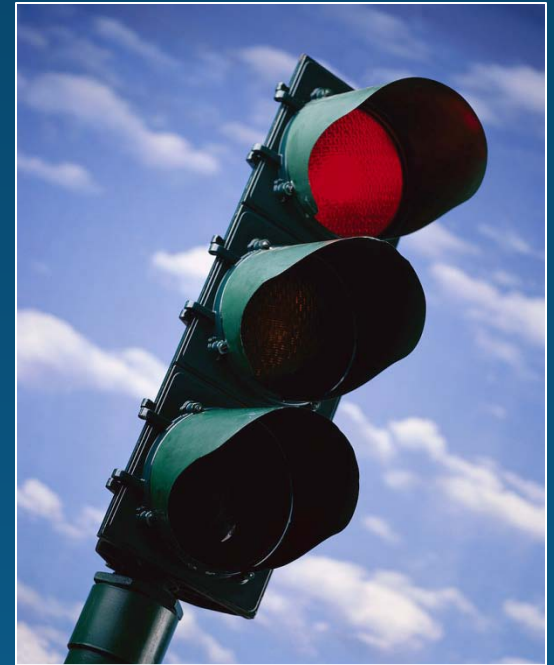


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Principle 3: Determine Critical Limits

## Establishing Critical Limits

Critical limits are defined based upon their ability to control (prevent, eliminate, or reduce to an acceptable level) the significant hazard(s) identified at a Critical Control Point.

The following list provides possible bases for selecting Critical Limits.

### Biological hazards

- Conditions necessary for inactivation of microorganisms, prevention of toxin formation, destruction of preformed toxins, prevention of growth of microorganisms.

### Chemical hazards

- Formulation and operating conditions necessary to control concentrations of chemical hazards below established safety limits. These safety limits for chemical hazards (such as regulatory Maximum Residue Levels) are often defined by toxicology studies in animal models or other methodologies.

### Physical hazards

- Criteria on foreign materials can be related to potential for causing injury (e.g. object size, hardness, sharpness).

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### Principle 3: Determine Critical Limits

## Establishing Critical Limits

The critical limits and criteria for food safety may be established by the HACCP team using information from sources such as:

- regulatory standards and guidelines,
- surveys of published research,
- experimental results (e.g. in-house experiments, contract laboratory studies), and
- experts (e.g. thermal process authorities, consultants, food scientists, microbiologists, equipment manufacturers, sanitarians, academics).

Regulatory standards are food safety criteria established by the responsible authority in a jurisdiction. The HACCP team must be aware of regulatory standards in the countries where they operate and, just as importantly, the countries where their company exports finished products. The following are some examples of regulatory standards established by federal food safety authorities in the United States.

- Mandatory time and temperature for milk pasteurization (161°F [72°C] for at least 15 seconds)
- 7-log reduction in *Salmonella* in fully cooked poultry products
- Zero tolerance for fecal contamination during meat animal or poultry slaughter
- 5-log reduction in the pertinent pathogen of concern for juice products

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Principle 3: Determine Critical Limits

## Operating Limits

An Operating Limit is defined as “a criterion that is more stringent than a critical limit and that is used by an operator to reduce the risk of deviation.”

Operating limits are parameters that **exceed** those necessary for safety and are established for reasons other than food safety.

For example, operating limits may be used to compensate for expected variation in operation of processing and monitoring equipment so that critical limits are not violated.



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### Principle 3: Determine Critical Limits

## Example of Critical and Operating Limits

The figure on the right, which is a representation of a temperature recording, provides an example of an operating limit. In this example, the Critical Limit is a minimum temperature of 160°F, whereas the Operating Limit is a minimum temperature of 165°F.

Failure to meet the operating limit does not result in a deviation in this example. It merely indicates to the operator that intervention should occur to bring the operation back into specification with the operating limit. Failure to meet the CL later in the recording indicates a time when corrective action (HACCP Principle 4) would be required.

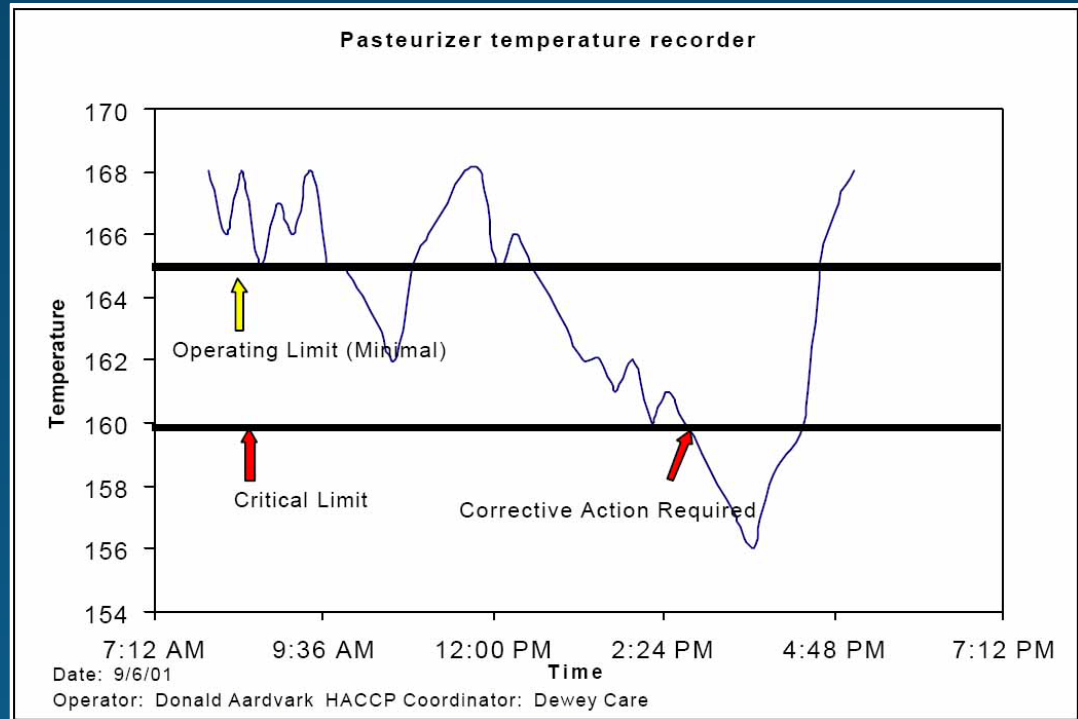


Illustration: US Juice HACCP Alliance

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Principle 3: Determine Critical Limits

## Choosing an Effective Critical Limit

Consider the following scenario for controlling a microbiological hazard in a juice beverage product:

- Hazard – presence of vegetative bacterial pathogens in apple juice (biological hazard)
- CCP – pasteurization step

In this situation, different methods can be used to determine if the hazard has been controlled at this CCP.

**Method 1** – Monitoring for presence of pathogens in finished product.

- Critical limit - no pathogens detected

If pathogen testing is used as a critical limit, appropriate testing procedures and sampling plans must be used. This is probably not an optimal choice of a critical limit because there is no guarantee that all products produced meet the specification.

**Method 2** – Controlling the pasteurization process to ensure that all juice has been treated in a manner that will destroy the hazard.

- Critical limit - minimum process temperature of 160°F for at least six seconds

This is a better choice for the critical limit, as pasteurization times and temperatures are readily measured and can be continuously monitored. Controlling hazards by process control is usually preferable to end-product testing

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### Principle 3: Determine Critical Limits

## Documenting Critical Limits

The critical limits determined by the HACCP team as well as the rationale for their selection must be **documented** and maintained as HACCP records. Remember that a critical limit is a maximum and/or minimum value, not an average value. Critical limits based on subjective data (e.g. visual inspection) must be supported by instructions or specifications and/or education and training.

Below is an example of the critical limits that might be established for a CCP in the cooking of a ground beef patty. Note that, in this case, temperature and time are not sufficient to define the process because the time required to reach an internal temperature which destroys bacterial pathogens depends upon the dimensions (i.e. thickness) of the beef patties. As this is a moist cooking process, oven humidity is also a consideration. This example illustrates the potential complexity associated with defining critical limits which will effectively control a hazard at a CCP.

Process Step	CCP	Critical Limits
5. Cooking	YES	Oven temperature: ___ F Time; rate of heating and cooling (belt speed in ft/min): ___ ft/min Patty thickness: ___ in. Patty composition: e.g. all beef Oven humidity: ___ % RH

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