Principle 3

Setting Critical Limits



Principle #3 - Critical Limits

Critical Limits

 Specification that indicate whether an operation is <u>in control</u> at a particular CCP for a specific hazard.

 Possible to have more than one Critical Limit at a particular CCP (e.g. for different types of hazards)



Critical Limit - definition

 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 hazard



Critical Limits - Examples

- <u>Time</u> (chilling of cooked products must begin within 90 minutes after end of cook cycle – USDA-FSIS App. B Compliance Guidelines)
- <u>Temperature</u> (minimum internal temperature of 155°F with cured, smoked turkey ham – USDA-FSIS App. A Compliance Guidelines, 3/99)



Critical Limits - Examples

- <u>Chlorine level</u> (150 to 200 ppm free Chlorine in bath for packaged RTE going into Clean Room)
- Presence of a Testing Declaration for *E. coli* O157:H7 indicating "*not detected*" in 100 g sample of a lot of incoming boneless beef using screening test meeting FSIS performance requirements
- <u>Minimum cook cycle for smoked salmon</u> 30 minutes at 145F



Critical Limits - Examples

- <u>Time & temperature</u>
 - Hold hot foods at or above 140°F till served
 [21CFR§110.80(b)(3) or 2001 Food Code 3-501.16]
 - < 1,000 "Degree-hours" when sausages fermented between 90 & 100°F (AMI GMPs)
- <u>FSIS "zero-tolerance" for fecal contamination on</u> <u>carcasses</u>
- Fruit wash/ Sanitize for Orange Juice Wash 200 PPM chlorine or Manufacturer's equivalent of like product.



Sources of Critical Limits

- Scientific publications
 - Journal articles
 - Food Microbiology or Food Science texts
- Predictive modeling programs
- Regulations or regulatory guidelines (USDA, FDA, State agencies)
 - FSIS Appendix A Compliance Guidelines for cooking (3/99)
 - FSIS Appendix B Compliance Guidelines for cooling (6/99)



Sources of Critical Limits

- Experts
 - NACMCF
 - Consultants (food scientists, microbiologists)
 - University extension personnel
 - Sanitarians
 - Equipment manufacturers
- Experimental studies
 - External labs
 - In-house experiments



Selection of Critical Limits

- Absolutely critical!
- Must
 - -be tied to food safety
 - -be scientifically supportable
 - -be attainable
 - -consider sensitivity of monitoring device



Action Limits

- More strict than Critical Limits &, thereby, reduce risk of a deviation
 - When Action Limit is exceeded, take action & record information.
 - Avoided a deviation!



Critical Limit vs. Action Limit

 <u>Critical Limit</u> for carcass hot water cabinet is 185°F at carcass surface, monitored once per "clock hour"

 <u>Action Limit</u> is 190°F at carcass surface, monitored on every 20th carcass with a temperature-indicator tape



Critical Limits Ex. #1

- Process: preparing hamburger sandwiches
- Hazard: biological, specifically microbial pathogens (e.g. *E. coli* O157:H7, *Salmonella*)
- CCP: cooking hamburger patties in a fryer
- Critical limits
 - Patty must not be frozen
 - Minimum fryer oil temperature of 350°F (176.7°C)
 - Maximum patty thickness of 1/4 inch (0.64 cm)
 - Minimum cook time in the oil of 1 minute



Critical Limits Ex. #2 Milk Pasteurization

- Process: producing ½ gallon jugs of homogenized
 2% milk
- Hazard: biological, Mycobacterium tuberculosis & Coxiella burnetti
- CCP: milk pasteurization
- Critical limits
 - 145°F for 30 min (LTLT) <u>OR</u>
 - 161°F for 15 seconds (HTST) OR
 - Other FDA-prescribed time/temperature combinations



Primeribbing

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If air chilling is a CCP what are the critical limits?