




CRITICAL LIMITS


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PRINCIPLE 3:
***ESTABLISH THE
CRITICAL LIMITS
WHICH MUST BE MET
AT EACH IDENTIFIED
CCP***



DEFINITIONS



NATIONAL ADVISORY COMM. FOR THE MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF)

- ***ONE (OR MORE) PRESCRIBED TOLERANCES THAT MUST BE MET TO ENSURE THAT THE CCP EFFECTIVELY CONTROLS THE BIOLOGICAL, CHEMICAL OR PHYSICAL HAZARD.***

FOOD & DRUG ADMIN. (FDA)

- ***A MAXIMUM 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 THE IDENTIFIED FOOD SAFETY HAZARD***



USDA/FOOD SAFETY & INSPECTION SERVICE (FSIS)

- ***CLs SHALL, AT A MINIMUM, BE DESIGNED TO ENSURE THAT APPLICABLE TARGETS OR PERFORMANCE STANDARDS ESTABLISHED BY FSIS, AND ANY OTHER REQUIREMENT SET FORTH.....***

CODEX ALIMENTARIUS

- ***A CRITERION WHICH SEPARATES ACCEPTABILITY FROM UNACCEPTABILITY***

ESTABLISHING CRITICAL LIMITS (CLs)

- **FAILURE TO MEET A CL RESULTS IN A DEVIATION**
- **A CL MEANS THAT—**
 - **BEYOND THAT LIMIT, A SAFETY HAZARD IS NOT CONTROLLED AND THE SAFETY OF THE FOOD PRODUCT IS IN QUESTION**




CLs MUST BE

- **REASONABLE & REALISTIC**
- **PRACTICAL**
- **ACHIEVABLE**
- **MEASURABLE OR MONITORABLE**
- **VERIFIABLE**



UNDERLYING PRINCIPLES

- **PREVENTATIVE OR CONTROL MEASURES ARE NEEDED TO ASSURE COMPLIANCE WITH A CL**
- **EVERY IDENTIFIED SIGNIFICANT HAZARD AT A CCP MUST BE CONTROLLED**



HACCP TEAM QUESTIONS

- **HOW ARE CLs IDENTIFIED?**
- **WHAT ARE APPROPRIATE AND REASONABLE PARAMETERS OR BOUNDARIES FOR FOOD SAFETY?**
- **HOW DOES ONE DETERMINE THE MAGNITUDE OF EACH PARAMETER?**
 - **WHAT ARE THE MEASURABLE CRITERIA?**



MONITORING & VERIFICATION ISSUES WITH SETTING CLs

- **MONITORING**

- **CONVENIENCE, REASONABLE, EASE OF MONITORING**
- **‘MONITORABLE’**

- **VERIFICATION**

- **DEALING WITH A CRITERION THAT IMPACTS A DIRECT OR POTENTIAL HEALTH HAZARD**
- **“VERIFIABLE”**


PRECISION & ACCURACY ISSUES REGARDING CLs

- **ACCURATELY DEPICTS OUT OF CONTROL CONDITION?**
 - **ERR ON SIDE OF SAFETY**
- **BASED UPON SCIENTIFICALLY SOUND PRINCIPLES?**
 - **RELIABLE INFORMATION SOURCES**
 - **STATISTICAL VARIABILITY ISSUES**



COMPONENTS OF CCPs (AND CLs)

- **SINGLE VS. MULTIPLE COMPONENTS**
- **PRIMARY VS. SECONDARY COMPONENTS**



***EXAMPLES OF
MULTIPLE AND/OR
SECONDARY
COMPONENTS***



RETORT PROCESSING OF CANNED VEGETABLES

- **PRIMARY: TEMP/TIME**
- **SECONDARY: FILL WEIGHT,
COMPOSITION, OTHER
FACTORS**



HEAT PASTEURIZATION

- **PRIMARY: TEMP/TIME**
- **SECONDARY: FAIL SAFE OPERATING PARAMETERS**
 - FLOW RATE, PRESSURE DIFFERENTIAL, ETC.



COOKING A MEAT PATTY

- **PRIMARY: TEMP/TIME**
- **SECONDARY: THICKNESS,
GRILL OPERATING
PARAMETERS**

METAL DETECTION IN FOODS

- **PRIMARY: OPERATION OF INSTRUMENT**
 - SENSITIVITY?
 - WHAT ARE YOU REALLY MEASURING OR MONITORING?
- **SECONDARY: LINE SPEED, OTHER PARAMETERS**

SANITIZER RINSE ON FRESH PRODUCE

- **PRIMARY: EFFECTIVE CONCENTRATION/CONTACT TIME**
- **SECONDARY: LINE SPEED, PHYSICAL PARAMETERS OF PRODUCE SURFACE**

CHOOSING THE CL – WHAT TO PUT IN HACCP PLAN

- **OFTEN ONLY PRIMARY CL IS INCLUDED IN HACCP PLAN**
- **SECONDARY CLs MAY BE COVERED BY PRE-REQUISITE PROGRAMS**
- **EXAMPLE**
 - **HTST PASTEURIZER**
 - **MEASURABLE PARAMETER IS TEMPERATURE**
 - **TIME A CONSTANT**
 - **SEALED TIMING PUMP OR FLOW DEVICE**



CRITICAL LIMITS ARE VERY PRODUCT SPECIFIC

- **SAME PROCESS LINES MAY HAVE SEVERAL DIFFERENT PRODUCTS AND DIFFERENT CLs**
- **EXAMPLE**
 - **PASTEURIZATION**
 - **FLUID MILK**
 - **EGG NOG**
 - **ICE CREAM**
 - **JUICE**



EXAMPLES OF CRITICAL LIMITS

- **TIME**
- **TEMPERATURE**
- **VISUAL OBSERVATIONS**
 - **OBJECTIVE VS. SUBJECTIVE**
- **PRODUCT CHARACTERISTICS**
 - **COMPOSITIONAL FACTORS**
 - **pH AND TITRATABLE ACIDITY**
 - **SALT CONCENTRATION**
 - **PHYSICOCHEMICAL FACTORS**
 - **VISCOSITY**
 - **WATER ACTIVITY (A_w)**



EXAMPLES OF CRITICAL LIMITS

- **PROCESSING/HANDLING AID MEASUREMENT**
 - **SANITIZER STRENGTH**
 - **DETERGENT STRENGTH**
- **HAZARD DETERMINATION**
 - **CHEMICAL ANALYSES**
 - **PHYSICAL ANALYSES**
 - **MICROBIOLOGICAL ANALYSES**
- **SUPPLIER REQUIREMENTS**
 - **CERTIFICATE OF ANALYSIS (COA)**
 - **LETTER OF GUARANTEE (LOG)**

SOME SPECIFIC EXAMPLES OF CLs

- **COOK TO AN INTERNAL TEMPERATURE OF 165 F (73.9 C)**
- **DO NOT BREAK CARCASS UNTIL INTERNAL ROUND TEMPERATURE IS BELOW 45 F (7.2C)**
- **ABSENCE OF FECAL CONTAMINATION ON CARCASSES (FSIS REQUIREMENT)**
- **MUST CONTAIN AT LEAST 4% SALT**
- **HOLD AT ABOVE 140 F (60 C) UNTIL SERVED**



INFORMATION SOURCES FOR CLs

- **SCIENTIFIC LITERATURE**
- **TRADE ASSOCIATIONS**
- **REGULATORY COMPLIANCE
STANDARDS/GUIDELINES**
- **IN-HOUSE EXPERIMENTATION**
- **EXPERT OPINION**
 - **CONSULTANTS**



SETTING THE “TARGET” POINT

- **OPERATING LIMITS (OLs) VS. CRITICAL LIMITS (CLs)**



OPERATING LIMITS (OLs)

- ***CRITERIA THAT ARE ESTABLISHED IN MANUFACTURING PROCEDURES WHICH ARE MORE STRINGENT THAN CLs***
- ***ALLOW FOR ON-LINE ADJUSTMENT WITHOUT DEVIATION***

OPERATING LIMITS (OLs)

- **PASTEURIZATION**
 - **REGULATORY REQUIREMENT (161 F) = CL**
 - **PLANT REQUIREMENT (170 F) = OL**
- **RAW PRODUCT TEMPERATURE**
 - **REGULATORY (41 F) = CL**
 - **PLANT REQUIREMENT (38 F) = OL**