

# **REGULATORY REQUIREMENTS AND HACCP**

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# HACCP & FOOD REGULATION

- THEME OF THE 1990s & 2000s
- MANDATORY HACCP PROGRAMS
- CHANGING THE FACE OF REGULATION
  - TRADITIONAL -- INSPECTION
  - HACCP -- AUDITING

# FOOD AND DRUG ADMIN.

- EMBRACING HACCP

# FDA HACCP PROGRAMS

- SEAFOOD
  - FINAL RULE (21CFR123)
- FRUIT AND VEGETABLE JUICES
  - FINAL RULE (21CFR120)
- FLUID DAIRY PRODUCTS
  - NATIONAL CONFERENCE ON INTERSTATE MILK SYSTEMS
    - VOLUNTARY HACCP PROGRAM
- OTHER FOODS
  - PILOT PROGRAMS
  - SPROUTS
    - PROPOSED RULE

[WWW.FDA.GOV](http://WWW.FDA.GOV)

PROCEDURES FOR THE SAFE AND  
SANITARY PROCESSING AND  
IMPORTING OF FISH AND FISHERY  
PRODUCTS [21CFR123]

# FDA SEAFOOD HACCP

- APPLIES TO
  - U. S. PROCESSORS
  - FOREIGN PROCESSORS (EXPORTING TO U. S.)
  - IMPORTERS

# GENERAL REQUIREMENTS

- MUST HAVE FOUNDATION AND PREREQUISITE PROGRAMS
  - WRITTEN DOCUMENTATION
- MUST HAVE AN ACCEPTABLE HACCP PLAN
- ABSENCE OF HACCP PLAN = FOOD ADULTERATION
  - *PREPARED, PACKED, OR HELD UNDER INSANITARY CONDITIONS*

# PREREQUISITE PROGRAMS

- GENERAL
  - COMPLIANCE WITH *FOOD, DRUG & COSMETIC ACT*
  - CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)[21CFR 110]
- SPECIFIC

# SPECIFIC PREREQUISITE PROGRAMS

- SHOULD HAVE AND IMPLEMENT WRITTEN SANITATION STANDARD OPERATING PROCEDURES (SSOPs)
  - SPECIFIC TO EACH LOCATION
- SHALL MONITOR SANITARY CONDITIONS AND PRACTICES
- SHALL MAINTAIN SANITATION CONTROL RECORDS (SCRs)
- SHALL CORRECT INSANITARY CONDITIONS IN A TIMELY MANNER

# FDA'S EIGHT KEY SANITATION CONDITIONS

1. WATER SAFETY
2. FOOD CONTACT SURFACES
  - CONDITION/CLEANLINESS
3. PREVENTION OF CROSS CONTAMINATION
4. MAINTENANCE OF HAND-WASHING & TOILET
5. PROTECTION FROM CONTAMINATION
6. PROPER LABELING, STORAGE, & USE OF TOXIC MATERIALS
7. CONTROL OF EMPLOYEE HEALTH
8. EXCLUSION OF PESTS

# HACCP TRAINING

- “TRAINED INDIVIDUALS” FOR KEY HACCP FUNCTIONS
- “STANDARDIZED” CURRICULUM RECOGNIZED BY FDA

**HAZARD ANALYSIS AND  
CRITICAL CONTROL POINT  
(HAACP) ; PROCEDURES FOR  
THE SAFE AND SANITARY  
PROCESSING AND IMPORTING  
OF JUICE; FINAL RULE  
(21CFR120)**

# GENERAL REQUIREMENTS

- MUST HAVE FOUNDATION AND PREREQUISITE PROGRAMS
  - WRITTEN DOCUMENTATION
- MUST HAVE AN ACCEPTABLE HACCP PLAN
- ABSENCE OF HACCP PLAN = FOOD ADULTERATION
  - *PREPARED, PACKED, OR HELD UNDER INSANITARY CONDITIONS*

# WHO MUST COMPLY?

- DOMESTIC
  - ANY JUICE SOLD AS SUCH OR USED AS AN INGREDIENT IN BEVERAGES IN INTERSTATE COMMERCE
- IMPORTERS
  - SHALL OBTAIN
    - DOCUMENTATION OF EQUIVALENT REGULATORY PROGRAM
    - WRITTEN PROCEDURES FOR ENSURING EQUIVALENT PROCESSING/HANDLING
      - MAY INCLUDE
        - » HACCP PLAN AND PREREQUISITE PROGRAMS

# INTERSTATE COMMERCE??

- APPLIES TO
  - “INTERSTATE JUICE”
    - SHIPPED INTERSTATE
    - ONE OR MORE COMPONENTS SHIPPED INTERSTATE
  - “INTRASTATE JUICE”
    - JUICE MADE ENTIRELY IN STATE AND SOLD IN STATE
- JUSTIFICATION CITED
  - *PUBLIC HEALTH SERVICE ACT*
    - PREVENT INTRODUCTION, TRANSMISSION, OR SPREAD OF INFECTIOUS DISEASE FROM ONE STATE TO ANOTHER
  - PREVIOUS COURT RULINGS

# JUICE DEFINED

- *AQUEOUS LIQUID EXPRESSED OR EXTRACTED FROM ONE OR MORE FRUITS OR VEGETABLES, OR*
- *PUREES OF THE EDIBLE PORTIONS OF ONE OR MORE FRUITS OR VEGETABLES, OR*
- *ANY CONCENTRATE OF SUCH LIQUID OR PUREE*

# EXEMPTED

- RAW AGRICULTURAL INGREDIENTS
  - SHOULD APPLY FDA GOOD AGRICULTURAL PRACTICES (GAPs) GUIDANCE

# PREREQUISITE PROGRAMS

- GENERAL
  - COMPLIANCE WITH *FOOD, DRUG & COSMETIC ACT*
  - CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)[21CFR 110]
- SPECIFIC

# FDA JUICE HACCP (21CFR120.6)

- SHALL HAVE AND IMPLEMENT WRITTEN *SANITATION STANDARD OPERATING PROCEDURES (SSOPs)*
  - SPECIFIC TO EACH LOCATION
- SHALL MONITOR SANITARY CONDITIONS AND PRACTICES
- SHALL MAINTAIN *SANITATION CONTROL RECORDS (SCRs)*
- SHALL CORRECT INSANITARY CONDITIONS IN A TIMELY MANNER

# FDA HACCP -- RELATIONSHIP OF SSOPs & HACCP PLAN

- MAY BE INCLUDED IN HACCP PLAN
- *HOWEVER, TO THE EXTENT THAT THEY ARE IMPLEMENTED IN ACCORDANCE WITH 21CFR120.6, THEY NEED NOT BE INCLUDED*

# WRITTEN HAZARD ANALYSIS

- SHALL IDENTIFY FOOD HAZARDS
  - PROVIDE GENERAL LIST
- SHALL EVALUATE WHETHER REASONABLY LIKELY TO OCCUR
- SHALL IDENTIFY CONTROL PROCEDURES
- SHALL REVIEW OF CRITICAL PROCESSES
- SHALL IDENTIFY CRITICAL CONTROL POINTS
- SHALL INCLUDE HAZARDS WITHIN AND OUTSIDE FACILITY
  - INCLUDING BEFORE, DURING & AFTER HARVEST
- SHALL BE SUBJECT TO RECORD KEEPING REQUIREMENTS

# HAZARD ANALYSIS -- PROCESSORS SHOULD EVALUATE

- PRODUCT INGREDIENTS,
- PROCESSING PROCEDURES
- PACKAGING
- STORAGE
- INTENDED USE
- FACILITIES & EQUIPMENT
- PLANT SANITATION

# HAZARD ANALYSIS NOT NEEDED

- IF FOOD HAZARDS CONTROLLED BY LOW ACID CANNED FOOD REGULATIONS

# THE HACCP PLAN

- SPECIFIC TO
  - EACH LOCATION WHERE JUICE IS PROCESSED
  - EACH TYPE OF JUICE

# THE HACCP PLAN

- SHALL CONTAIN
  - ALL IDENTIFIED FOOD HAZARDS
  - THE CRITICAL CONTROL POINTS
  - THE CRITICAL LIMITS FOR EACH CCP
  - MONITORING PROCEDURES FOR EACH CCP
  - CORRECTIVE ACTION PLANS
  - VERIFICATION AND VALIDATION PROCEDURES
- MAY CONTAIN
  - SANITATION CONTROL PROCEDURES (DISCUSSED ABOVE)

# CORRECTIVE ACTIONS

- WHENEVER A DEVIATION FROM A CRITICAL LIMIT, A PROCESSOR SHALL TAKE CORRECTIVE ACTIONS
- MAY DEVELOP WRITTEN CORRECTIVE ACTION PLANS (BECOMES PART OF HACCP PLAN)
  - NO VIOLATIVE PRODUCT ENTERS COMMERCE
  - CAUSE OF DEVIATION CORRECTED

# VERIFICATION

- VERIFICATION
  - SHALL VERIFY THAT THE HACCP SYSTEM IS BEING IMPLEMENTED
- VALIDATION
  - SHALL VALIDATE THAT THE HACCP SYSTEM IS ADEQUATE TO CONTROL IDENTIFIED FOOD HAZARDS
  - VALIDATION OF HACCP PLAN
  - VALIDATION OF THE HAZARD ANALYSIS
    - WHEN NO HACCP PLAN BECAUSE NO IDENTIFIED HAZARDS
    - REASSESS ADEQUACY OF HAZARD ANALYSIS WHEN PROCESS CHANGES

# RECORDS

- REQUIRED
  - SSOP RECORDS
  - HAZARD ANALYSIS
  - HACCP PLAN
  - ONGOING APPLICATION/IMPLEMENTATION
    - MONITORING CCPs
    - CORRECTIVE ACTIONS
    - VERIFICATION/VALIDATION

# PATHOGEN REDUCTION

- PROCESS CONTROLS (21CFR120.24)
- PROCESS VERIFICATION (21CFR120.25)

# PROCESS CONTROLS

- *PROCESSORS SHALL INCLUDE PROCESS CONTROL MEASURES THAT WILL CONSISTENTLY PRODUCE, AT A MINIMUM, A 5 LOG REDUCTION IN “PERTINENT PATHOGEN”*
  - AT LEAST AS LONG AS THE SHELF LIFE WHEN STORED UNDER NORMAL & MODERATE ABUSE CONDITIONS
- *SINGLE FACILITY OPERATING UNDER cGMPs*

# PROCESS CONTROLS

- EXEMPTIONS
  - PROCESSORS SUBJECT TO LOW ACID CANNED FOOD REGULATIONS
  - PROCESSORS USING A SINGLE THERMAL TREATMENT FOR SHELF STABILITY OR CONCENTRATION
    - DOCUMENT IN HAZARD ANALYSIS

# WHAT TYPE OF PROCESS OR TREATMENTS??

- TREATMENTS APPLIED DIRECTLY TO JUICE
  - EXCEPT
    - CITRUS MAY USE FRUIT TREATMENTS
      - 5 LOG REDUCTION BEGINS AFTER CULLING AND CLEANING
      - WITHIN SINGLE FACILITY

# PROCESS VERIFICATION

- PROCESSORS *THAT RELY ON TREATMENTS THAT DO NOT COME INTO DIRECT CONTACT WITH ALL PARTS OF THE JUICE SHALL*
  - ANALYZE THE FINISHED PRODUCT FOR BIOTYPE I *E.COLI* (GENERIC *E. COLI*)
  - SPECIFIC METHODS/PROTOCOLS DEFINED

# PROCESS VERIFICATION

- IF POSITIVE SAMPLE (DEFINED BY PROCEDURES)?
  - SHALL REVIEW MONITORING RECORDS FOR 5 LOG CONTROL MEASURES
    - MAKE CORRECTIONS/ADJUSTMENTS
    - IF 5 LOG STANDARD NOT ACHIEVED, MUST TAKE CORRECTIVE ACTIONS AS DEFINED IN HACCP PLAN
- IF 2 OUT OF 7 SAMPLES POSITIVE
  - 5 LOG STANDARD DEEMED INADEQUATE

# NCIMS VOLUNTARY HACCP PROGRAM

# NCIMS PROGRAM

- FEDERAL/STATE COOPERATIVE PROGRAM
  - ROLE OF NCIMS BIENNIAL CONFERENCE
- SCOPE OF PROGRAM
  - FARMS
  - PROCESSING PLANTS
  - RECEIVING AND TRANSFER STATIONS
  - LABORATORIES
- INSPECTION UNDER THE PASTEURIZED MILK ORDINANCE (PMO)

# NCIMS: STATE AND LOCAL AGENCIES

- DESIGNATED ENFORCEMENT AGENCY
  - STATE/LOCAL AGENCY
  - ROUTINE INSPECTION (PMO)
- STATE SURVEY OFFICER
  - SURVEY RATING
    - FARMS, PLANTS, REGULATORY AGENCY
    - BASED UPON 100 POINT SYSTEM

# NCIMS: ROLE OF FDA

- LIAISON BETWEEN STATES
- PUBLISH QUARTERLY IMS RATINGS
- CONDUCT “CHECK RATINGS” TO VALIDATE THE AUTHENTICITY OF STATE RATINGS
  - DELISTING PROCEDURES
- PROVIDE INTERPRETATIONS TO THE PMO

# NCIMS HACCP PROGRAM

- ALLOWS MANUFACTURERS TO IMPLEMENT A HACCP SYSTEM AS AN ALTERNATIVE TO THE TRADITIONAL INSPECTION SYSTEM
- MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS PERMITTED UNDER THE NCIMS HACCP PROGRAM SHALL MEET THE APPLICABLE PROVISIONS OF THE PMO, INCLUDING APPENDIX K.

# CRITERIA FOR PARTICIPATION

- VOLUNTARY
- THE REGULATORY AGENCY AND FACILITY MUST AGREE TO PARTICIPATE
- BOTH PARTIES MUST PROVIDE WRITTEN COMMITMENT TO EACH OTHER THAT THE NECESSARY RESOURCES TO SUPPORT PARTICIPATION IN THE NCIMS VOLUNTARY HACCP PROGRAM WILL BE MADE AVAILABLE

# CRITICAL LISTING ELEMENTS (CLE's)

- FLOW DIAGRAM AND HAZARD ANALYSIS CONDUCTED & WRITTEN FOR EACH KIND OF GROUP OF MILK OR MILK PRODUCT PROCESSED.
- WRITTEN HACCP PLAN PREPARED FOR EACH KIND OR GROUP OF MILK OR MILK PRODUCT PROCESSED .
- CL(S) ARE ADEQUATE TO CONTROL THE HAZARD IDENTIFIED.
- CORRECTIVE ACTION TAKEN FOR PRODUCTS PRODUCED DURING A DEVIATION FROM CRITICAL LIMITS DEFINED IN THE HACCP PLAN.
- CALIBRATION OF CCP PROCESS MONITORING INSTRUMENTS PERFORMED AS REQUIRED AND AT THE FREQUENCY DEFINED IN THE HACCP PLAN.
- INFORMATION ON HACCP RECORDS NOT FALSIFIED.
- INCOMING MILK SUPPLY FROM NCIMS LISTED SOURCE(S) WITH SANITATION SCORES OF 90 OR BETTER OR ACCEPTABLE HACCP LISTING.
- DRUG RESIDUE CONTROL PROGRAM IMPLEMENTED.
- A SERIES OF OBSERVATIONS THAT LEAD TO A FINDING OF A POTENTIAL HACCP SYSTEM FAILURE THAT IS LIKELY TO RESULT IN A COMPROMISE TO FOOD SAFETY

# TRADITIONAL PMO INSPECTION VS. HACCP AUDITING PROGRAM

# LISTING/PASS-FAIL CRITERIA

- TRADITIONAL
  - PASSING = SCORE 90 OR BETTER ON A RATING
- HACCP AUDITING
  - PASSING = NO VIOLATION OF ANY CRITICAL LISTING ELEMENTS (CLE's) ON A RATING

# FDA RESPONSIBILITY

- TRADITIONAL
  - CHECK RATING PROCEDURES
  - RATING OF 80 OR HIGHER TO REMAIN ON LIST
- HACCP AUDITING
  - NO CLE's TO REMAIN ON LIST

# PASTEURIZATION

- TRADITIONAL
  - COMPLY WITH PMO ITEM 16p
  - REGULATORY DOES OFFICIAL EQUIPMENT CHECKS
- HACCP SYSTEM
  - COMPLY WITH PMO ITEM 16p
  - PASTEURIZATION MUST BE CCP
  - REGULATORY MAY AUTHORIZE INDUSTRY EQUIPMENT CHECKS

# TRAINING

- STATE/FEDERAL PERSONNEL
- INDUSTRY
- *DAIRY HACCP CORE CURRICULUM*
  - IN PMO

# RECORDS REQUIRED

- HACCP PROGRAM TABLE OF CONTENTS,
- PREREQUISITE PROGRAM,
- FLOW DIAGRAM(S),
- HAZARD ANALYSIS,
- HACCP PLAN,
- CORRECTIVE ACTIONS,
- CENTRAL DEVIATION LOG,
- ANNUAL VERIFICATION AND VALIDATION EXERCISES,
- VERIFICATION OF CCP MONITORING RECORDS,
- HACCP RECORDS SUMMARY TABLE,
- OTHER RECORDS DOCUMENTING IMPLEMENTATION OF THE HACCP PROGRAM.

# FDA FOOD CODE—RETAIL HACCP?

- MODEL CODE FOR ADOPTION INTO STATE/LOCAL REGULATIONS
- FOOD SERVICE/RETAIL FOODS SECTOR
- “HACCP-BASED” DOCUMENT

# USDA/FOOD SAFETY & INSPECTION SERVICE (FSIS)

## ■ MANDATORY HACCP PROGRAM

- MEAT & POULTRY INDUSTRY
- TERMED THE “MEGA REG’

## ■ PROPOSED?

- EGG PRODUCTS

PATHOGEN REDUCTION: HAZARD  
ANALYSIS AND CRITICAL CONTROL  
POINT (HACCP) SYSTEMS  
[9CFR304 ET. AL.]

# PATHOGEN REDUCTION [9CFR304.....]

- PROCESS CONTROL
  - MICROBIAL TESTING
    - GENERIC *E.COLI*
  - VERIFICATION PERFORMANCE CRITERIA (GUIDELINES)
- PATHOGEN REDUCTION PERFORMANCE STANDARDS
  - *SALMONELLA*

**HAZARD ANALYSIS AND CRITICAL  
CONTROL POINT (HACCP) SYSTEMS  
[9CFR417]**

# FSIS --MEATS & POULTRY HACCP

- HACCP PLAN REQUIREMENTS
  - HAZARDS LIST
  - CCPs
  - CLs
  - MONITORING
  - CORRECTIVE ACTIONS
  - RECORDKEEPING
  - VERIFICATION
- FOUNDATION/PREREQUISITE PROGRAMS
  - WRITTEN SANITATION STANDARD OPERATING PROCEDURES (SSOPs)

# PATHOGEN REDUCTION [9CFR304.....]

- PROCESS CONTROL
  - MICROBIAL TESTING
    - GENERIC *E.COLI*
  - VERIFICATION PERFORMANCE CRITERIA (GUIDELINES)
- PATHOGEN REDUCTION PERFORMANCE STANDARDS
  - *SALMONELLA*
  - *GENERIC E. COLI*

# OTHER ASPECTS

- ANTI-MICROBIAL TREATMENTS
- TIME/TEMPERATURE CONTROLS

# REGULATORY PHILOSOPHY REGARDING CCPs

# CRITICAL CONTROL POINTS (CCPs) - FDA

- FDA REGULATORY PHILOSOPHY
  - RULE OF THUMB –EACH HAZARD IDENTIFIED AS SIGNIFICANT IN THE HAZARD ANALYSIS MUST BE CONTROLLED (AT A CCP?)
    - ????
  - NO HAZARDS IDENTIFIED
    - DO YOU NEED A HACCP PLAN?
    - DO YOU NEED CCPs?

# CRITICAL CONTROL POINTS (CCPs) – USDA/FSIS

- FSIS REGULATORY PHILOSOPHY
  - RULE OF THUMB –EACH HAZARD IDENTIFIED AS SIGNIFICANT IN THE HAZARD ANALYSIS MUST BE CONTROLLED (AT A CCP)
  - NO HAZARDS IDENTIFIED
    - DO YOU NEED A HACCP PLAN?
    - DO YOU NEED CCPs?
    - PREAMBLE OF REGULATION – *FSIS NOT AWARE OF ANY MEAT OR POULTRY PRODUCT THAT CAN BE DEEMED CATEGORICALLY TO POSE NO LIKELY FOOD SAFETY HAZARD*

**VOLUNTARY HACCP AUDIT  
SERVICES BY FEDERAL AGENCIES**

# USDA/AMS QUALITY AUDITING PROGRAMS

- HACCP COMPONENT INCLUDED

# USDA/AGR. MARKETING SERVICE (AMS)

- FRESH FRUITS & VEGETABLES
  - PARTNERS IN QUALITY (PIQ)
- PROCESSED FRUITS & VEGETABLE PRODUCTS
  - QUALITY THROUGH VERIFICATION (QTV)
- DAIRY PRODUCTS
  - PARTNERS IN DAIRY QUALITY (PDQ)

# NATIONAL MARINE & FISHERIES SERVICE (NMFS)

- HACCP AUDITING PROGRAMS
- FISHERIES ONLY.

# GLOBAL REGULATORY HACCP

- CODEX ALIMENTARIUS
- EUROPEAN UNION [[WWW.EU.GOV](http://WWW.EU.GOV)]
- CANADIAN FOOD INSPECTION AGENCY
- AUSTRALIA/NEW ZEALAND