

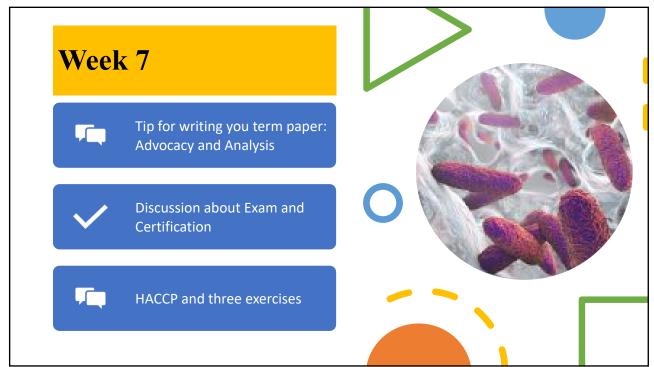
Hazard Analysis and Critical Control Point (HACCP)
Principles, and Application in Meat and Juice Industries

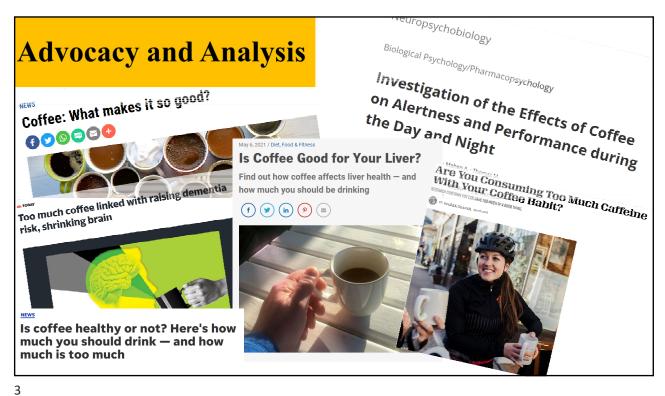
# AGSC 5540: Food Policies and Regulations 9-30-2021

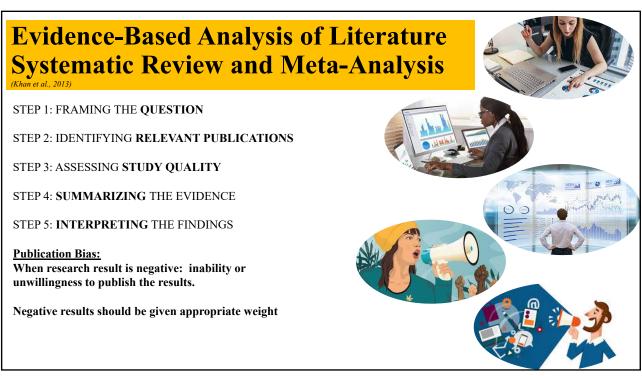
Tennessee State University, Nashville, TN

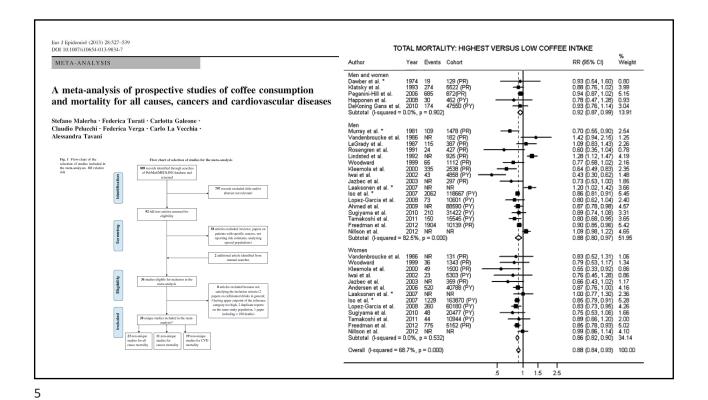
A. Fouladkhah: Faculty Director, Public Health Microbiology Laboratory

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Review article Psychological stress and wound healing in humans: A systematic review and meta-analysis Jessica Walburn<sup>a,\*</sup>, Kavita Vedhara<sup>b</sup>, Matthew Hankins<sup>a</sup>, Lorna Rixon<sup>a</sup>, John Weinman<sup>a</sup> <sup>a</sup>Institute of Psychiatry, Department of Psychology, King's College London, London, UK <sup>b</sup>Institute of Work, Health, and Organizations, University of Nottingham, Nottingham, UK Received 18 October 2008; received in revised form 3 March 2009; accepted 7 April 2009 abstract) by searching of e AMED, BNI, CINAHL, Cool MEDLINE®, MEDLINE In-J. Walburn et al. / Journal of Psychosomatic Research 67 (2009) 253-271 Correlation and 95% CI Study name Statistics for each study wound type Upper limit Z-Value p-Value Total Cole-King et al. 2001 George et al. 1980 -2.75 -1.77 0.01 53 0.08 38 clinical wound -0.81 -0.19 -0.56 0.03 clinical wound -0.29 Holden-Lund 1988 Bosch et al. 2007 clinical wound -0.54 -0.77 -0.17 -2.75 0.01 -0.45 183 -0punch biopsy -0.33 -0.20 0.00 Ebrecht et al. 2004 punch biopsy -0.59 -0.80 -0.24 -3.11 0.00 24 punch biopsy -2.28 -3.95 0.02 26 0.00 11 Marucha et al. 1998 -0.60 -0.78 -0.34 punch biopsy -0.24 -0.44 -0.03 -0.33 -0.63 0.06 -2.21 -1.68 0.03 21 0.09 27 tape stripping paradigm Garg et al. 2001 tape stripping paradigm Muizzuddin et al. 2003 Robles 2007 -0.64 -0.77 -0.45 -0.29 -0.47 -0.08 -5.47 -2.70 tape stripping paradigm 0.00 55 0.01 tape stripping paradigm -0.42 -0.51 -0.32 -7.58 0.00 -0.50 -1.00 0.00 0.50 1.00

# Exam and PC QI Workshop

- Exam next week 10/7/2021
- In-person, closed book, in the class
- Starts at 4:40 to 6:00 pm

If you cannot join the exam for a justifiable reason, please let me know before the exam so we could arrange for an alternative time.

- · Questions come from the packet (except for extra credit questions)
- 1 table, one multiple choice, 28 short answers and one extra credit point essay
- · After a short break we will start the PC QI certification
- The curriculum is co-developed and recognized by the food and drug administration and attendance in all sessions are required to be able to obtain the certificate.
- · A few members from the food industry will also join the session via Zoom.





LATIONAL ENVIRONMENTAL

HEALTH ASSOCIATION

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#### **Food Safety Auditor Credentials**

#### Stand Out in the World of Food Safety

The Food Safety Modernization Act (FSMA) has revolutionized the food safety landscape adding to the arsenal of required knowledge needed by those involved in any aspect of the food supply chain. Competent, Qualified Individuals are needed to carry out the functions described in the regulations. Equally, competent Qualified Individuals are needed for auditing the effectiveness of food safety programs internally, for supplier, and as an external third party observer.

The NEHA Certified in Food Safety Supplier Audits (CFSSA) credential has been developed to help build the global capacity of qualified, vetted professionals that will be needed to meet the requirements of FSMA. Upon successfully passing the exam, the CFSSA credential holder will be prepared to complete 1st and 2nd party audits. They will be accomplished in understanding and planning food safety audits, conducting an audit, verifying food safety and prerequisite programs, and conducting post-audit activities. It is also a career path to becoming a third party auditor.

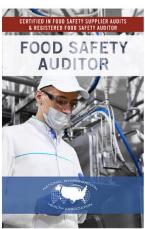
The NEHA Registered Food Safety Auditor (RF5A) credential enables individuals to complete third party audits. The RF5A is for more experienced food safety professionals who are one of the last lines of defense in the complex global food supply chain. If you're responsible for conducting risk-based facility audits (foreign or domestic) against internationally recognized food safety standards designed to mitigate risk, promote food safety, and enhance consumer confidence in the food supply, then the RF5A credential is the right choice for you.

Food Safety Magazine published two articles, <u>NEHA Credential Creates a Professional Pathway for Food Safety Auditors</u> and <u>New Food Safety Auditing Credentials</u>, that outlined the work that went into creating this Influential credential. The CFSSA credential with food sector specific auditing experience can lead to the Registered Food Safety Auditor (RFSA) credential for those who wish to become third party auditors.

#### Certified in Food Safety Supplier Audits (CFSSA)

If you're responsible for conducting risk-based facility audits (foreign or domestic) against internationally recognized food safety standards designed to mitigate risk, promote food safety, and enhance consumer confidence in the food supply, then the CFSS credential is the right choice for you.

APPLY NOW



iew Interactive Brochure

HACCP: Hazard Analysis and Critical Control Points

# Systematic approach and a Food Safety Management system to:

- · Hazard identification
- · Assessment of risk
- · Control hazard and risk
- Very common in food industry (meat packing and RTE meat products) to assure foods safety, and prevent, eliminate, and/or reduce hazards



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# What is HACCP?

- HACCP originated in the 1960's, by:
  - National Aeronautics and Space Administration (NASA)
  - The Pillsbury Company
  - The U.S. Army Laboratories
- <u>Purpose</u>: Safe food for upcoming **space expeditions** to eliminate "critical failure areas"
- <u>Origin</u>: NASA's engineering management requirements, <u>Critical</u> <u>Control Points</u>, would be used as a guideline for this food safety initiative



- HACCP had been a success in space expeditions' food preparation
- Shortly after implementation, Pillsbury outbreak/recall (1970)
  - Farina with pieces of glass (farina, carbohydrate rich food for infant/adults very rich in iron)
- A microbiologist at Pillsbury (Howard Baumann), who worked with NASA initiative:
  - Advocated adoption of HACCP in food industry because of the outbreak



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# What is HACCP?

- 1971 Panel Discussion in National Conference on Food Protection, Denver, CO:
- [Food Protection, International Association for Food Protection]
- Conference Sponsored by:
  - Food and Drug Administration (FDA)
  - American Public Health Association (APHA)
- Examined concept of:
  - Critical Control Points (CCP)
  - Good Manufacturing Practices (GMP)
- After the conference:
  - FDA requested Pillsbury to establish/manage training program for canned foods

[b/c botulism concern by Clostridium botulinum]

[Botulism is now very rare and mostly occur as infant botulism associated honey]



- The initial HACCP course (developed by Pillsbury):
- **Title:** Food Safety through the Hazard Analysis and Critical Control Point System
- First introduced: September 1972
- HACCP was not a regulatory requirement when stablished
- Since 1985 was **recommendation** for poultry and meat industry [prevalence of pathogens, adopted by USDA FSIS] [Meat industry is the largest segment in food industry]



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# What is HACCP?

- Jack-in-the-box outbreak: 1992-1993
- The outbreak strain of E. coli O157:H7
- Isolated from **11 lots of hamburger patties** produced on November 29 and 30, 1992,
- Jack-in-the-Box issued a recall of all ground beef produced on that day
- 73 Jack-in-the-Box restaurants involved in outbreak



#### · Washington:

- · 144 people were hospitalized
- 30 developed HUS\* (about 25-30%)
- 3 died (about 10%)

#### · Idaho:

- · 4 people were hospitalized
- 1 developed HUS

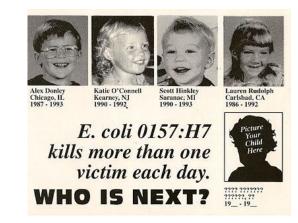
#### · California

- 14 people were hospitalized
- 7 developed HUS
- 1 child died

#### Nevada

- 9 people were hospitalized
- 3 developed HUS

More patients in IL, NJ, MI



\*Hemolytic Uremic Syndrome (HUS)

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# What is HACCP?

- After the jack-in-the-box outbreak and similar outbreaks in juices (*E. coli* O157:H7) and ready-to-eat products (*Listeria monocytogenes*)
- HACCP became **regulatory requirement** for :
- Meat industry, poultry industry, shelled egg and cat fish (USDA FSIS)
- Juices and seafood and intact egg (FDA, DHHS)



United States Department of Agriculture

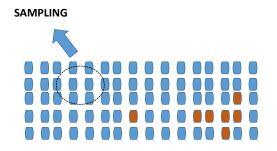
United States Department of Agriculture

and Inspection

April 1997

Guidebook For The Preparation Of HACCP Plans

# Understanding HACCP: HACCP and End Point Sampling



- Contamination in a food batch is **not homogeneous**
- Relying solely on sampling provides false sense of security
- HACCP is a systematic food safety management system to **prevent**, **eliminate**, **or reduce risk** of foodborne hazards

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# **Understanding HACCP**

- Food Safety Management System
- Purpose is "prevention"...



Table 1. <b>H</b>	ACCP Principles
Principle 1	Conduct a hazard analysis.
Principle 2	Determine the critical control points.
Principle 3	Establish critical limits.
Principle 4	Establish monitoring procedures.
Principle 5	Establish corrective actions.
Principle 6	Establish verification procedures.
Principle 7	Establish record-keeping and documentation procedures.

# HACCP Prerequisite Programs GMP: Good Manufacturing Practices

Very specific requirements

Specific forms

Specific documentations

#### **Production and Process Controls:**

- · Raw materials
- · Manufacturing operations

#### **Topics to Consider for GMP:**

#### Internal characteristics of food (intrinsic factors)

- available nutrients [bioprotection in yogurt and wine]
  available water activity [<0.82, danger zone, 2 hours]</li>
- pH (acidity or alkalinity) [>4.2 botulism concern]
- physical structure [moisture permeability]

#### External characteristics of processing (extrinsic factors)

- temperature
- atmosphere (presence or absence of O2)
- packaging



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# HACCP Prerequisite Programs GMP: Good Manufacturing Practices

#### **Building and Facilities**

- Grounds and area outside [microbiologically cleanable]
- Cafeteria or lunch area [4 zones recommended]
- Entrances [Positive air flow, air curtain, footbath]
- Hand washing stations

# Program Prerequisites(PP) Good Manufacturing Practice(GMP) Sanitation Standard Operating Procedure(SSOP)

#### **Equipment and Utensils**

- Design and construction of equipment [microbiologically cleanable]
- Instruments for control of temperature or pH must be accurate [calibration]

# HACCP Prerequisite Programs GMP: Good Manufacturing Practices

#### Personnel Education [>20% worker could carry S. aureus] [GMP violations, QC personal]

- · Periodic training for all employees
- Diseases control [Salmonella and Shigella positive]
- Open lesions or infected wounds
- · Personal cleanliness in production
- · Clean outer garments
- · Wash hands
- Remove jewelry
- · Storage of personal belongings
- · No chewing gum or smoking
- Hair nets and beard nets



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# GMP's in Manufacturing [Chapter 3 of FSMA certification] Lighting devices Countermature against Air-conditioning duct Sock duct so that cold air is not fell Appropriate local Appro

# HACCP Prerequisite Programs SSOP: Sanitation Standard Operating Procedure

Specific documents, developed by the facility/company

Must address: pre-operational sanitation and operational sanitation (mid-shift) and

Plant needs to update SSOPs to reflect changes in equipment and facilities

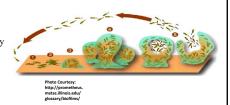
**SSOP:** [Portfolia of products are available for planktonic cells and biofilms]

- Cleaning
- Dissemble and more cleaning
- Sanitizing
- Assembly and final rinse (or use of no-rinse sanitizer such as 200 ppm Sodium Hypochlorite)



- Operational Sanitation: Equipment cleaning during production
- Post-operational sanitation: Detailed descriptions of equipment disassembly and re-assembly





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# A Sample of SSOP and Sanitation Logs

#### SAMPLE - SANITATION STANDARD OPERATING PROCEDURE (SSOP)

XYZ Meat Packers, Inc. is a red meat processing establishment. This plant receives beef and pork for further processing. This plant cuts and grinds product and also packages it

#### MANAGEMENT STRUCTURE

Plant Manager –

Team Captains -

The Team Captains are responsible for implementing and daily monitoring of Sanitation SOP and recording the findings and any corrective actions. The Team Captains are responsible for training and assigning specific duties to other employees and monitoring their performance within the Sanitation SOP. All records, data, checklists, and other information pertaining to the Sanitation SOP will be maintained on file and made available to inspection personnel.

- I. Preoperational Sanitation Equipment and Facility Cleaning Objective

  A. All equipment will be disassembled, cleaned, and sanitized before starting production.
  - - Establishment sanitary procedure for cleaning and sanitizing equipment.

      a. All equipment will have product debris removed.

      b. Equipment will be rinsed with water to remove remaining debris.
      - An approved cleaner will be applied to equipment and properly
      - Equipment will be sanitized with approved sanitizer and rinsed with

Food Contact Surfaces (Sodium Hypochlorite in organic operation, Vortex) Non-food Contact Surfaces (Quaternary Ammonium Compounds)

# **Understanding HACCP**

- Food Safety Management System
- Purpose is "prevention"... unlike end point sampling
- End product: HACCP plan



Principle 1 Conduct a hazard analysis.  Principle 2 Determine the critical control points.  Principle 3 Establish critical limits.  Principle 4 Establish monitoring procedures.  Principle 5 Establish corrective actions.  Principle 6 Establish verification procedures.  Principle 7 Establish record-keeping and documentation	Table 1. <b>H</b> /	ACCP Principles
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procedures.  Principle 7 Establish record-keeping and documentation	Principle 5	
and documentation	Principle 6	
Tomacon Company	Principle 7	

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## Exercise 1

- What HACCP stands for and what is it?
- What was the initial origin and purpose for HACCP? What Agencies developed the HACCP?
- What outbreak episode that resulted in introduction of HACCP in the food industry as a **recommended** food safety management system?
- What was the main outbreak episode that resulted in introduction of HACCP in the food industry as a **required regulatory** food safety management system?
- What are the products that are currently under the jurisdiction of mandatory HACCP? What regulatory agencies are overseeing the HACCP compliance?
- What is the difference between HACCP and End point sampling? What is the main limitation of end point sampling?
- What are the Prerequisite programs of HACCP?
- What are the seven principles of HACCP?

# Preparing a HACCP Plan

#### Two Prerequisite Programs for HACCP plan development:

- GMP: Good Manufacturing Practices
- SSOP: Sanitation Standard Operating Procedures

#### The **Five Preliminary Steps** to develop a HACPP plan:

- 1. Bring together your HACCP resources/assemble the HACCP team
- 2. Describe the food and its method of distribution [Defines regulatory path]
- 3. Identify the intended use and consumers of the food [RTE, RTH, frozen]
- 4. Develop a process flow diagram
- 5. Verify the diagram in the operation it is meant to represent



# Preparing a HACCP Plan

- Application of Seven Principles of HACCP:
- 1. Conduct a hazard analysis.
- 2. Identify critical control points.
- 3. Establish critical limits for each critical control point.
- 4. Establish monitoring procedures.
- 5 Establish corrective actions.
- 6. Establish recordkeeping procedures.
- 7. Establish verification procedures.



# STEP 1 - BRING TOGETHER YOUR HACCP RESOURCES-ASSEMBLE THE HACCP TEAM

#### **Small Company:**

- One or two employees, one of whom has had HACCP training. [HACCP International Alliance or equivalane] [FSMA only PC QI]
- · Outside expertise:
- · Local Extension Office,
- · Trade or professional association, or a
- · Contractor of your choice.
- Purpose: Cross-functional expertise to adequately analyze all biological physical and chemical hazards.

#### Larger plant: [Standard outfit colors]

- · Production managers
- · Quality control manager
- · Sanitation Manager
- Engineering/maintenance



# **STEP 1** - BRING TOGETHER YOUR HACCP RESOURCES-ASSEMBLE THE HACCP TEAM

- HACCP Team Would need to have knowledge of:
- The technology and equipment used in your processing lines
- The practical aspects of food operations and food policies
- Flow of the process in your plant
- **Food microbiology** (could be supplemented by outside experts)
- HACCP principles and techniques (could be supplemented by outside experts)



# STEP 2 - DESCRIBE THE PRODUCT AND ITS METHOD OF DISTRIBUTION INCLUDING THE INTENDED USE AND CONSUMERS OF THE FOOD (defines the regulatory pathway)

- 1. Common name? For example, a cooked sausage could be called franks/hot dogs/wieners.
- 2. How is it to be used? Categories might include: Ready-to-eat, ready-to-serve, raw, frozen
- 3. The type of package? For example, is it modified atmosphere packaging?
- 4. Length of shelf life? In the cooked sausage example, the length of shelf life might be 30 to 50 days for modified atmospheric packaging. [Accelerated shelf-life testing]
- 5. Where will it be sold? For example, will it be sold to wholesale, retail or institutions?
- **6. Labeling instructions?** "Keep Refrigerated" would be a common labeling instruction for meat and poultry products.
- 7. How is the product(s) distributed? For instance, should the product be kept refrigerated at or below 40 °F?
- **8. Who is the consumer** and how will the product be used by the consumer? *YOPI? 30% of population*



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## STEP 2 - DESCRIBE THE PRODUCT AND ITS METHOD OF DISTRIBUTIONINCLUDING THE INTENDED USE AND CONSUMERS OF THE FOOD

	PROCESS DESCRIPTION
PRO	DDUCT:
THI	E FOLLOWING QUESTIONS NEED TO BE ANSWERED WHEN DEVELOPING THE DDUCT DESCRIPTION:
1.	COMMON NAME?
2.	HOW IS IT TO BE USED?
3.	TYPE OF PACKAGE?
4.	LENGTH OF SHELF LIFE,
	AT WHAT TEMPERATURE?
5.	WHERE WILL IT BE SOLD? CONSUMER? INTENDED USE?
	E-TE-DED USE.
6.	LABELING INSTRUCTIONS?
7.	IS SPECIAL DISTRIBUTION CONTROL NEEDED?

# STEP 3 - DEVELOP A COMPLETE LIST OF INGREDIENTS AND RAW MATERIALS

- Written list of ingredients
- Written list of raw materials for each process/product.
- Basic FSIS forms suggest diving ingredients to:
- Main Ingredients: e.g. Meat (meat such as boneless beef or chicken parts with skin)
- Other Ingredients: e.g. Such as spices and preservatives
- Basic from are recommended by FSIS, companies may elect to use more elaborate form
- Example: Commercial Beef Stew



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# STEP 3 - DEVELOP A COMPLETE LIST OF INGREDIENTS AND RAW MATERIALS

LIST PRODUCT(S) AND INGREDIENTS

PROCESS CATEGORY: THERMALLY PROCESSED-COMMERCIALLY STERILE

PRODUCT EXAMPLE: BEEF STEW

MEAT\*

FROZEN COOKED DICED BEEF

INGREDIENTS\*

FROZEN SLICED CARROTS FROZEN DICED POTATOES FROZEN SLICED CELERY

REFRIGERATED ONION JUICE CONC. REFRIGERATED GARLIC PUREE

VEGETABLE OIL STARCH HVP PLANT GUM DEHY. BEEF STOCK

DEHY. BEEF STOCK SALT SPICE MIX WORCESTERSHIRE SAUCE

\* The dice size of the ingredients should be listed in a specific plan if it is a critical formulation factor. Amounts of each ingredient may also be included.

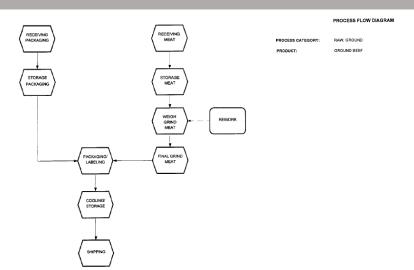
#### STEP 4 - DEVELOP A PROCESS FLOW DIAGRAM

- Process flow diagram identifies:
  - All the steps used to prepare the product from receiving through final shipment that are directly under the control of the establishment.
- The diagram should not be so complex that it is difficult to follow and understand.
- The diagram must be complete from the beginning of your process to the end.
- The flow diagram may also include steps that occur before or after the processing occurs in the establishment.
- The diagram would need to be verified: i.e. walking through the plant to make sure that the steps listed on the diagram describe what really occurs in producing the product.
- Example: Ground beef Flow diagram



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# STEP 4 - DEVELOP A PROCESS FLOW DIAGRAM



# STEP 5 - MEET THE REGULATORY REQUIREMENTS FOR SANITATION STANDARD OPERATING PROCEDURES

- Perhaps, good sanitation is the most important way to ensure a safe product is produced.
- Pre-HACCP requirement (prerequisite programs) that must be carried out in all establishments.
- Other prerequisite programs for HACCP can be developed which are extremely useful (such as GMP's)
- SSOPs must be microbiologically validated for planktonic cells and biofilms:
  - · Suppliers of the sanitizers
  - · Challenge studies in the literature
- Example: Validation of Sodium Hypochlorite in Planktonic and Sessile environment

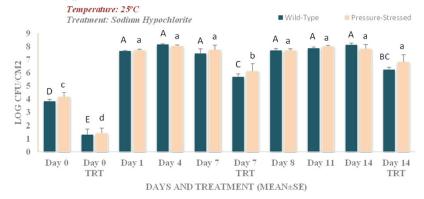


Food Contact Surfaces (Sodium Hypochlorite in organic operation, Vortex) Non-food Contact Surfaces (Quaternary Ammonium Compounds)

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# STEP 5 - MEET THE REGULATORY REQUIREMENTS FOR SANITATION STANDARD OPERATING PROCEDURES

#### Biofilm Formation and Decontamination of Wild-Type and Pressure-Stressed *Cronobacter Sakazakii*



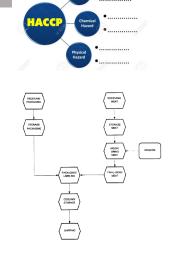
#### 1. Conduct a hazard analysis.

- 2. Identify critical control points.
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- 7. Establish verification procedures.

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# Development of a HACCP Plan Conduct a hazard analysis

- Hazard Identification.
- "Prepare a list of steps in the process where significant hazards occur and describe the preventive measures."
- HACCP definition of Hazard:
- "Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."
- HACCP definition of Preventive Measure: (in FSMA called Control Measure)
- "Physical, chemical, or other means that can be used to control an identified food safety hazard."



# Conduct a hazard analysis

# Biological Hazards

- · Biological Hazards in Foods:
  - Bacterial
  - Viral
  - Parasitic
  - · Prions
- (1) Could directly infection human: Parasites
- (2) Zoonotic: Transmitted from live animals
- (3) Foodborne: cause infection, intoxication, and toxicoinfection after ingestion
- During production, processing, packaging, transportation, preparation, storage and service, any food may be exposed to bacterial contamination.
- · Major pathogens of concern in meat processing:

Salmonella, Clostridium perfringens, Listeria monocytogenes, Staphylococcus aureus, Campylobacter jejuni, Yersinia enterocolitica, Bacillus cereus, Clostridium botulinum, and Escherichia coli O157:H7.

#### Biological Hazards Associated with a product would need to be identified:

- Literature
- · Existing documents and company history

Meat and Poultry Hazards and Controls Guide

Food Safety and Inspection Service
United States Department of Agriculture
March 2018



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# Development of a HACCP Plan Conduct a hazard analysis

#### Chemical Hazards

- 1. <u>Naturally occurring</u> poisons, chemicals, or deleterious substances:
- Are natural constituents of foods
- Are not the result of environmental, agricultural industrial, or other contamination.
- **Examples:** aflatoxins, mycotoxins, and shellfish toxins. [Secondary metabolites of molds]



## Conduct a hazard analysis

#### Chemical Hazards

- 2. Added chemicals or deleterious substances:
- Are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing, or distribution.

#### **Examples:**

- (1) **Agricultural additives**: pesticides, fungicides, insecticides, fertilizers, drug residues, and antibiotics
- (2) Direct food additives: preservatives, flavorings
- (3) **Indirect food additives**: lactic acid after rinsing carcass
- (4) Others (accidentals): lubricants, cleaners, paints, and coatings



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## Development of a HACCP Plan

# Conduct a hazard analysis

#### **Chemical Hazards**

Five Classes of Chemical Hazards in Meat Industry HACCP plan:

FSIS recommendation is placing special emphasis on:

- (1) **Drugs and pesticides** routinely used in raising the animals which are the source of your meat and poultry ingredients (e.g. **sub-therapeutic antibiotics**)
- (2) Feeds and supplements fed to the animals.
- (3) Environmental contaminants, (naturally occurring or added contaminants).
- (4) Pesticides and other chemicals used in plant that may end up as residues in the animal.
- (5) The source of the water for the animals [heavy metals]
- Chemical Hazards Would need to be identified based on:
  - · Review of processing condition and company historical data
  - · Review of literature
  - Review of regulatory guidelines

Meat and Poultry Hazards and Controls Guide

Food Safety and Inspection Service
United States Department of Agriculture
March 2018



# Conduct a hazard analysis

#### Physical Hazards

- A physical hazard is any physical material not normally found in a food which causes illness or injury to the individual using the product.
- · Such as: glass, metal, and plastic.
- Foreign objects which cannot or do not cause illness or injury are not hazards, even though they may not be aesthetically pleasing to your customers.

#### Sources of physical hazards:

- (1) Contaminated raw materials: Pieces of metal or stone
- (2) Poorly designed or poorly maintained facilities and equipment. An
  example would be <u>paint chips falling</u> from overhead structures onto exposed
  product or <u>pieces of metal</u> from worn or improperly maintained equipment
  entering product. [Metal detector and keeping track of objects]
- (3) Improper procedures or improper employee training and practices. For example, <u>broken glass jars</u>, by improper loading on the line by employees or improper or inadequate condition examination, glass pieces from broken or chipped jars could be included when filling product containers.



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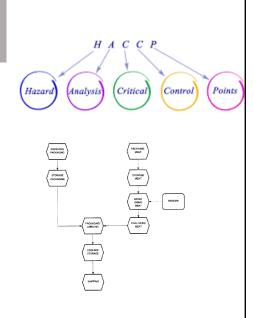
# Development of a HACCP Plan Conduct a hazard analysis

#### **5 Steps in Conducting the Hazard Analysis:**

(1) Assure that the prerequisite program (GMP's and SSOP's) are in place.

(2) Hazard Identification: For each processing step identified in the process flow diagram, determine if a biological, chemical or physical hazard(s) could exist at that step.

- Tips for Hazard Identification: Ask questions (also software and paperbased decision trees and exist)
  - Could contaminants reach the product during this processing step?
  - Could any pathogens multiply during this process step to the point where they became a hazard?
  - Could this step create a situation where an ingredient, work in process, or finished product became contaminated with pathogens?
  - Could this step introduce a chemical hazard into the product?
  - Could this step introduce a physical hazard into the product?
  - Are the hazards addressed in the SSOP's?



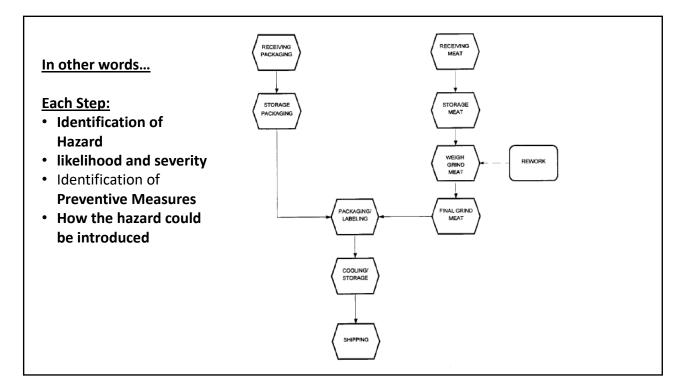
## Development of a HACCP Plan Conduct a hazard analysis

- (3) Fully describe the hazards identified for each step and describe in detail.
- (4) Evaluate the likelihood and severity of occurrence of the hazard:
- Likelihood of occurrence: Frequency of disease (*Campylobacters*, Botulism)
- Severity of occurrence: How serious it could be (Norovirus, HUS)
- (5) Identification of Control Measures for each hazards:

i.é. existing measures to control the hazard



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	PROCESS CAT	EGORY : RAW, GROUNI		s
	Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
	RECEIVING - MEAT	B (Microbial Growth) - Insufficient temperature control will result in unacceptable microbial growth. Apers, J.C. 1879 B (Mishandling) - The integrity of the immediate container is compromised such that microbial contamination could occur. P (Foreign Material) - Visible foreign material that could compromise product safety. Meat and Poultry Products Hazards and Control Guide.	Maintain product temperature at a level sufficient to preclude bacterial ground.  Visual inspection of containers to ensure that immediate container is not compromised.  Visual inspection of a sufficient representative sample to ensure no foreign material is present.	B-Transport refrigeration unit is not functioning properly (out of freen).  B-The shipping container (the cardboard combo bin) was crushed by a forklift and the immediate container (the film wrapped around the individual travy) was form and punctured introducing harmful microbes into the product.  P-Pieces of glass found in product from a broken light bulb, metal clips, knives, plastic, etc.
Chapter 8 of FSMA, we will conduct Hazard Analyses, would suggest choosing a product	RECEIVING - NON-MEAT	C (Deleterious Chemicals) - Chemicals/non-meat ingredients/packaging materials, are acceptable for intended use. Should be food grade material approved for intended use.  Bean, N.H. and P.M. Griffin 1990.  P (Foreign Material) - Visible foreign material that could compromise product safety; rodent droppings, insects, etc.	Verify that the letter of guarantee is on file and appropriate for product use. Visual inspection of a sufficient representative sample to ensure no foreign material is present.	C-The new tray pack "diapers" ordered came in and the letter of guarantee is present with the shipment, however the letter states that of the diapers are acceptable for industrial use and not food grade.  P-Black material that resembles rodent droppings are found on the surface of the styrofoam trays.
	STORAGE - MEAT	B (Microbial Growth) - Insufficient temperature control could result in unacceptable microbial growth. Insternal product temperature and environmental temperature must be monitored. Ayers, J.C. 1979, Bryan, F.L., 1988, Palumbo, S.A., et.al. 1994	Monitor the internal product temperature and environmental temperature (ex. cooler or freezer) to ensure that the meat does not exceed a level sufficient to preclude bacterial growth for more than 1 hour, and the temperature of the cooler or	B-Cooler generator breaks down and the ambient room temperature in the cooler increase above 50° For 10 hours increasing product temperature above compliance permitting excessive bacterial growth.

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# Development of a HACCP Plan

- 1. Conduct a hazard analysis.
- 2. Identify critical control points.3. Establish critical limits for each critical control point.
- 4. Establish monitoring procedures.
- 5 Establish corrective actions.
- 6. Establish recordkeeping procedures.
- 7. Establish verification procedures.

#### Exercise 2

- According to "Guidebook for Preparation of HACCP plan" issued by FSIS, what are the five Preliminary steps before development of HACCP plan?
- What are the eight sections of the recommended form for describing a product and its method of distribution/consumption by consumers?

According to "Guidebook for Preparation of HACCP plan" issued by FSIS, a flow diagram of the operation would need to be developed before development of the HACCP plan. What a flow diagram identifies and what are the general recommendation for its development?

What are the four types of biological hazards in a HACCP plan for meat industry?

• According to "Guidebook for Preparation of HACCP plan," what are the main pathogens of concern in meat processing?

What are the two main categories of Chemical hazards? Please name one example for each category?

What are the five steps of conducting hazard analyses?

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#### Development of a HACCP Plan

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# Development of a HACCP Plan Identify critical control points

• Critical Control Point (CCP) is definition "A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels."

**Purpose of determining CCP:** Prevented, eliminated, or reduced the risk to acceptable level

#### So far we have done:

- · Identification of biological, chemical, and physical hazards
- · Preventive measures for each hazard

#### Now, Determining Critical Control Points: [# of CCP a great question?]

- · CCP decision tree
- · Any other decision tree
- · Or a logical process

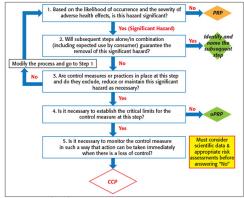
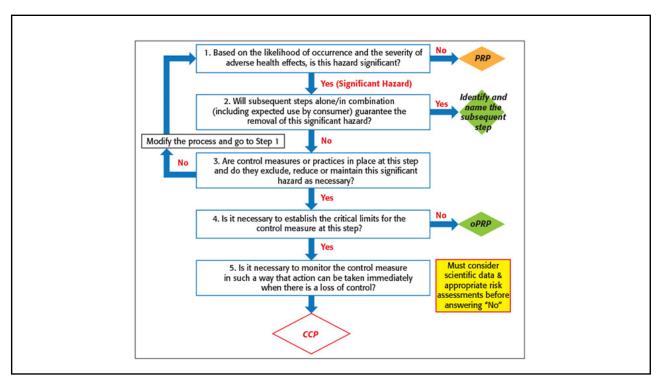


Figure 1: Coca-Cola/Michigan State Decision Tree

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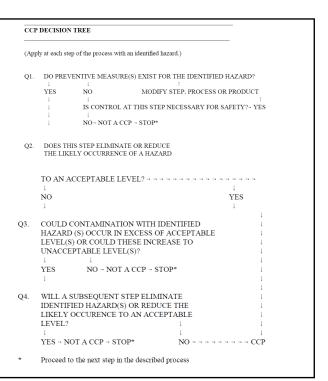


<u>Question #1</u> - Do **preventive measures exist** for the identified hazard?

<u>Question #2</u> - Does this step eliminate or reduce the likely occurrence of the hazard(s) to an acceptable level? (is it a kill step?)

<u>Question #3</u> - Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?

**Question #4** - Will a **subsequent step eliminate** identified hazard(s) or reduce the likely occurrence to an acceptable level?

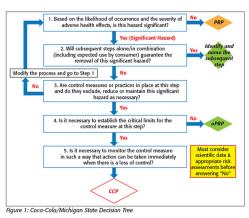


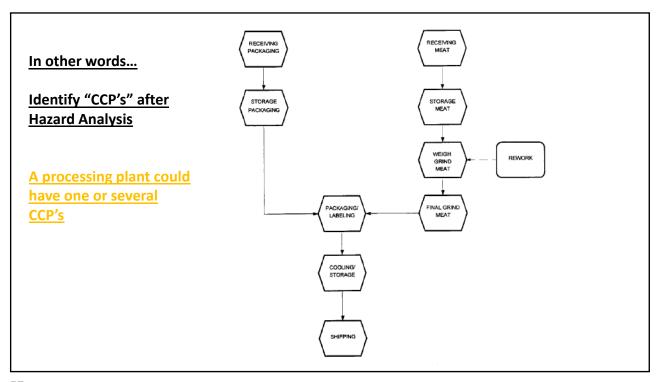
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# Development of a HACCP Plan Identify critical control points

#### **Typical Critical Control Points: [rule of thumb]**

- Chilling when appropriate.
- Cooking that must occur for a specific time and temperature in order to destroy microbiological pathogens.
- **Product formulation** controls, such as addition of culture or adjustment of pH or water activity.
- Certain processing procedures, such as filling and sealing cans.
- Certain slaughter procedures, such as evisceration or antimicrobial interventions.





	RAW GROUND  CCP DETERMINATION  A CRITICAL CONTROL POINT IS DEFINED AS A POINT, STEP OR PROCEDURE AT WHICH CONTROL CAN BE APPLIED AND A FOOD SAFETY HAZARD AN BE PREVENTED, ELIMINATED, OR REDUCED TO ACCEPTABLE LEVELS)							
PROCESS STEP	HAZARD(S)	QL DOPREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? "Ifformote a CCP-Ident fs how and where this huxard well be controlled." "If yes—move to next quanti ons.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURANCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL?  *If no-move to the next question.  *If yes-CCP	Q3. COULD CONTANINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If non-mot a CCP *If year-move to the non question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARDS) OR REDUCE THE LIKELY OCCURANCE TO AN ACCEPTABLE LEVEL? *Ifso-CCP	ACCP		
	B - Microbial Growth.	YES	YES			CCPIB		
Receiving-Mest	C - N/A (Not Appli cable)							
	P - Foreign Material	YES	YES			CCP 1P		
Receiving-Non-Meat	B - N/A low risk							
	C - Deleterious Chemicals.	YES	YES			CCPIC		
	P-Foreign Material.	YES	YES			CCP 2P		
Storage-Meat	B - Microbial Growth.	YES	YES			CCP 2B		
	C - N/A							
	P - N/A low risk							
Storage-non-mean	B - Microbial Growth.							
	C - N/A							
	P - Forei gn Material Material/Adul teruti on.	YES	YES			CCP3P		
Assemble/pre- weigh/re-work/final	B - Microbial growth	YES	YES			ССРЗВ		
grind	C-N/A							
	P. Foorier Material	VES	NO	VES	VES	CCP4P		

- 1. Conduct a hazard analysis.
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## Development of a HACCP Plan

# Establish critical limits for each critical control point

#### • Main Critical Limits are:

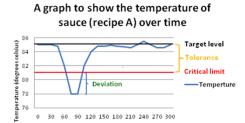
- Time/temperature
- · Relative Humidity
- · Water activity
- pH
- · Salt concentration
- · Chlorine level

#### How to set the Critical Limits:

- Determine if there is a regulatory critical limit set for ensuring food
- If there are no regulatory critical limits, establishment of critical limits based on literature and other plans

#### • Example:

- Cooking RTE poultry products to internal temperature of 165°F
- The pH of 4.2 for canned products (control of botulism)



30 60 90 120 150 180 210 240 270 300

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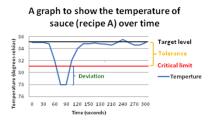
## Development of a HACCP Plan

## **Establish monitoring procedures**

• Example of monitoring: Measuring the pH of ever 20 cans to assure it stays at 4.2 or below

#### FSIS 5 steps for successful development of monitoring:

- 1. For each CCP, identify the best monitoring procedure.
- 2. Determine the **frequency of monitoring** for each CCP.
- 3. If **random monitoring** needed, Determining a random monitoring plan
- 4. Determine **what testing procedures** need to be done for each monitoring function. For example, will you need to do a chlorine check or a temperature measurement?
- 5. Identify and train the employee(s) responsible for monitoring.



				HACCP PLAN			
PROCESS C.			W, GROUND OUND BEEF				
PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	ССР	CRITICAL LIMITS	MONITORING PROCE DURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERS RESPONSIBLE
RECEIVING - MEAT	B - Microbial Growth.  B - Container Integrity  P - Foreign Material.	1 B 1 B	Temperature within plant specifications.*  Immediate container is intact.  No visible hazar dous non-food material.	Internal temperature monitored when a shipment is received by the receiving personnet. Visual inspection of immediate container at the time a shipment is received and before processing by the receiving personnel.	If product temperature is out of compliance, immediate container is compromised or foreign material is noted in/on the meat product, identify and control affected product for disposition; take corrective action to prevent reoccurrence. Notify plant de signe.	Record all results and corrective action(s) in a plant specific log/record. Signs record and records time and date of observation.	Twice Weekly visual observation of produce and receiving proceed done by an individual did not produce the records and who has successfully complete course of instruction. HACCP, or the
			* Carcasses or red meat must be received at 40° F or below.  *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above will control quality and limit the growth rates of even psycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.	Record all findings in HACCP receiving log. Include by #, date, condition, time of inspection and sign the record.	Receiving personnel documents actions taken in HACCP receiving log. Signs record and records time of observation.	Corrective Action	re sponsible establishm official.  Andit to verify sampli techniques and accuracy of records; verify accuracy of temperat devices; determine in Critical Limit corresponds to the plant records; to see if Critical Limit corresponds on the plant records; to see if Critical Limit corresponds and equate for huzard; assure corrective acting are adequate; docume findings.  Weekly calibration of thermometers.

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# Development of a HACCP Plan

- 1. Conduct a hazard analysis.
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- **5** Establish corrective actions.
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# **Establish corrective actions**

- Corrective Action is needed when there is **departure** from critical limits
- Example: When pH of a batch is 4.4, higher than critical limit of 4.2: Corrective Action Needed

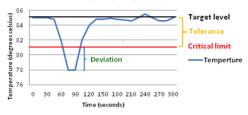
#### **Corrective actions should include:**

- Handling the non-complying product (discarding or rework)
- · Correcting the cause of non-compliance
- Assure that CCP is under control
- · Maintaining a record

#### **Example of corrective action:**

- · Stopping the production
- Measuring the pH of main batch before canning
- Reworking products with high pH
- · Documenting the incident and training the formulation staff

# A graph to show the temperature of sauce (recipe A) over time



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				HACCP PLAN			
PROCESS CA PRODUCT E			W, GROUND OUND BEEF				
PROCESS STEP	CHEMICAL PHYSICAL HAZARD DESCRIPTION	ССР	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - MEAT	B - Microbial Growth.	1 B	Temperature within plant specifications.*	Internal temperature monitored when a shipment is received by the receiving personnel.	If product temperature is out of compliance, immediate container is compromised or foreign material is noted in/on	Record all results and corrective action(s) in a plant specific log/record.	Twice Weeldy visual observation of product and receiving procedures, done by an individual who
	B -Container Integrity	1 B	Immediate container is intact.	Visual inspection of immediate container at the time a shipment is received and before	the meat product, identify and control affected product for disposition; take corrective	Signs record and records time and date of observation.	did not produce the records and who has successfully completed a
	P - Foreign Material.	1 P	No visible hazardous non-food material	processing by the receiving personnel. Record all findings in HACCP	action to prevent reoccur rence. Notify plant designee.  Receiving personnel documents	Corrective Action	course of instruction on HACCP, or the responsible establishment official.
			* Carcasses or red meat must be received at 40° F or below.	receiving log. Include lot#, date, condition, time of inspection and sign the record.	actions taken in HACCP receiving log. Signs record and records time of observation.	Log	Audit to verify sampling techniques and accuracy
			*Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above will				of records; verify accuracy of temperature devices; determine in the Critical Limit corresponds to the plant records; check to see if Critical Limit is adequate for hazar d; assure corrective actions
			control quality and limit the growth rates of even paycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.				are adequate; document findings. Weekly calibration of ther mometers.

- 1. Conduct a hazard analysis.
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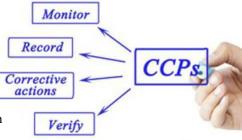
# Development of a HACCP Plan

## **Establish recordkeeping procedures**

Maintaining proper **HACCP records** is an important part of the HACCP system.

#### **Benefits of Record Keeping:**

- Records allow you to trace the history of an ingredient, inprocess operations, or a finished product, should problems arise.
- Records help you **identify trends** in a particular operation that could result in a deviation if not corrected.
- If you were ever faced with a product recall, HACCP records could help you identify and narrow the scope of such a recall (batch numbers, rework)
- Well-maintained records are good evidence in protection against legal actions and audits.

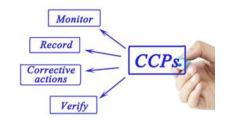


# **Establish recordkeeping procedures**

#### FSIS 5 Steps for Successful Record Keeping:

Must be in **permanent ink** and available for **auditors** 

- 1. Review existing documentation to determine what other record keeping methods are needed
- 2. **Develop forms for documentation** necessary to document corrective action deviations (*calibration log for pH meter*, *GMP violation form* etc.)
- 3. **Develop forms verification** to document your HACCP system verification
- 4. Identify the employees responsible for record keeping
- 5. Incorporate the forms in appropriate HACCP Plan



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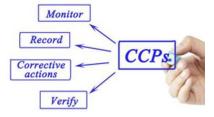
				HACCP PLAN			
PROCESS C PRODUCT E			W, GROUND OUND BEEF	MONITORING PROCEDURESFREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PRE VENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - ME AT	B - Microbial Growth.  B - Container Integrity P - Foreign Material.	1B 1B 1P	Temperature within plant specifications.*  Immediate container is intact.  No visible huzar dous non-food material.  **Carcasses or end asf  **Carcasses or end asf  **Carcasses or end asf  **Carcasses or end asf  **Note: Insufficient scientific data exist regarding the growth of pathogens data exist regarding the chilling. However the chilling parameters provided above will control quality and hint the growth rates soften provided above will control quality and hint the growth rates soften provided above will control quality and hint the growth as soften provided above will control quality and hint the growth as soften provided above will be controlled as a soften provided as a soften	Internal temperature monitored when a shipment is received by the receiving personnet. Visual inspection of immediate container at the time a shipment is received and before processing by the receiving personnet. Record all findings in HACCP receiving log. Include by the date, condition, time of inspection and sign the record.	If product temperature is out of compliance, immediate container is compromised or foreign the compromised or foreign the compromised or foreign the composition of the composition of the corrective and composition; take corrective as done to present reoccurrence. Notify plant designer.  Receiving personnel documents actions taken in HACCP receiving log. Signs record and records time of observation.	Record all results and corrective action(s) in a plant specific log/record. Signs record and records interested and date of observation.	Twice Weelly visual observation of product and receiving procedures, done by an individual who did not roduce the contained who has assessfully completed a course of instruction on HACCP, or the responsible establishment official.  Audit to verify sampling techniques and accuracy of yearly accuracy of temperature devices, determine in the Critical Limit corresponds to the plant records; check to see iTC risical Limit is adequate for hazard; assure corrective actions are adequate; document findings.  Weekly calibration of thermometers.

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# Development of a HACCP Plan Establish verification procedures

- Verification in HACCP
- "Establish procedures to verify that the HACCP system is working correctly."
- Common Verification of HACCP system are:
- Analytically test or audit your monitoring procedures (metal detector)
- Calibrate your temperature/test equipment (calibration log)
- Sample your product, including microbiological sampling;
- Review your monitoring records
- Inspect and audit your establishment's operations Sample for environmental and other concerns (third party agencies).



				HACCP PLAN			
PROCESS C. PRODUCT E			W, GROUND OUND BEEF				
PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	ССР	CRITICAL LIMITS	MONITORING PROCE DURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PEI RESPONSIBLE
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			psycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophillic enteric bacterial pathogens.				Weekly calibration ther mometers.

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#### Exercise 3

- What is CCP and what is the purpose of determining CCP's in a HACCP plan?
- What are some typical CCP's in an operation?
- Please name common Critical Limits in a HACCP plan and provide one example of Critical limit for a HACCP certified operation.
- When do we need to use corrective action in a HACCP certified operation?
- What is Verification in HACCP and what are some common examples of verification in a HACCP plan?

