

Principle 1
Hazard Analysis

Is HACCP Important?

Maple Leaf Foods plant linked to Listeria outbreak

- There have been 21 confirmed cases of listeriosis across the country. Three people have died in Ontario and one in British Columbia.

Deadly outbreak officially tied to Maple Leaf meats

Death Toll Rises in Maple Leaf Foods Outbreak

Meatpacker, Topps, closes after big E.coli recall

Maple Leaf Foods settlements range from \$750 to \$125,000

- ▶ Toronto-based processor Maple Leaf Foods announced details about its Canada-wide settlement with plaintiffs in class-action lawsuits filed in the wake of last year's listeriosis outbreak and recall.

Maple Leaf initially confirmed the \$27 million settlement in December.

Plaintiffs with "serious and long-lasting physical injuries" could qualify for up to \$125,000, the company said, while those with symptoms lasting between 24 and 48 hours could receive \$750. The estates of those who died of listeriosis will be paid \$120,000 each, plus "substantial amounts" to immediate family members.

The courts must still approve the settlement.

Current list of affected products, including individual product codes and best-before dates

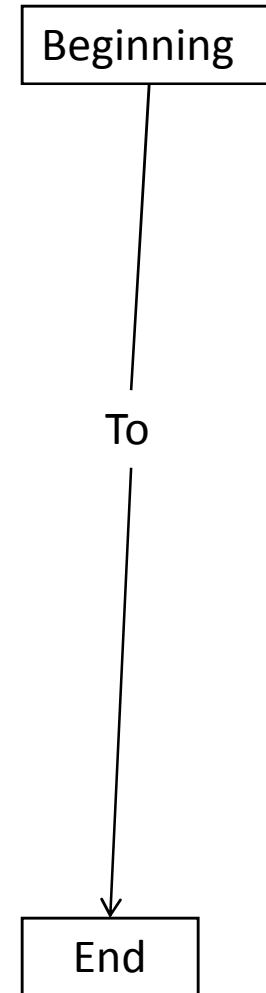
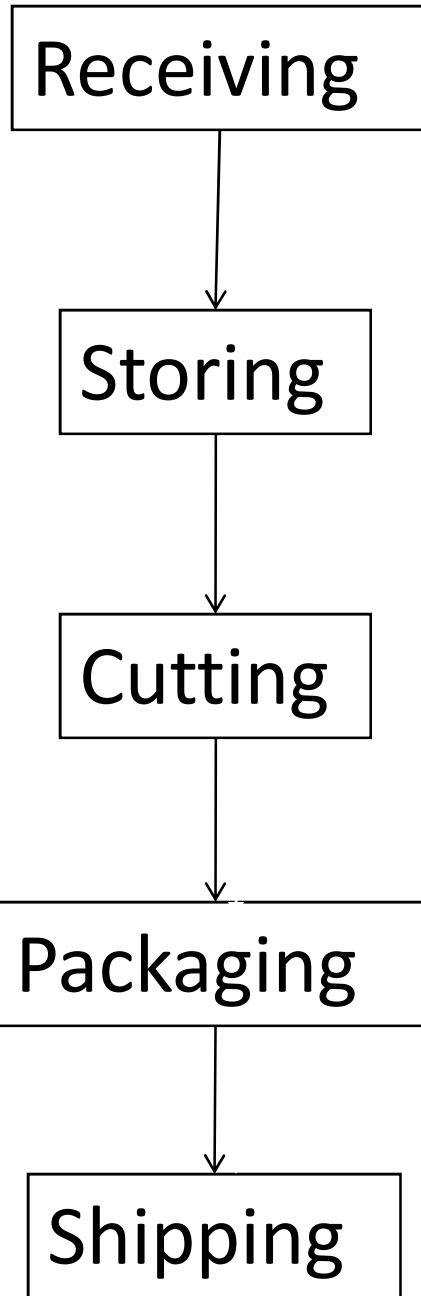
- ▶ :
- ▶ 26365, Sliced Cooked Turkey Breast, 470 grams, Sept. 30;
- ▶ 02106, Schneiders Bavarian Smokies, 1 kilogram, Oct. 28;
- ▶ 02126, Schneiders Cheddar Smokies, 1 kilogram, Oct. 28;
- ▶ 21333, Sure Slice Roast Beef, 1 kilogram, Sept. 30;
- ▶ 21388, Sure Slice Combo Pack, 1 kilogram, Sept. 30;
- ▶ 60243, Deli Gourmet Roast Beef slices, 1 kilogram, Sept. 30;
- ▶ 02356, Seasoned Cooked Roast Beef, 500 grams, Oct. 7;
- ▶ 42706, Roast Beef, Seasoned and Cooked, 500 grams, Oct. 7;
- ▶ 21334, Sure Slice Turkey Breast Roast, 1 kilogram, Oct. 14;
- ▶ 21444, Sure Slice Corned Beef, 1 kilogram, Oct. 14;
- ▶ 44938, Montreal Style Corned Beef, 500 grams, Oct. 14;
- ▶ 21440, Sure Slice Black Forest Style Ham, 1 kilogram, Oct. 21;
- ▶ 21447, Sure Slice Salami, 1 kilogram, Oct. 21;
- ▶ 21331, Sure Slice Smoked Ham, 1 kilogram, Oct. 21;
- ▶ 48019, Schneiders Deli Shaved Corned Beef, 200 grams, Oct. 21;
- ▶ 48020, Schneiders Deli Shaved Smoked Meat, 200 grams, Oct. 21;
- ▶ 48016, Schneiders Deli Shaved Smoked Ham , 200 grams, Oct. 21;
- ▶ 48018, Schneiders Deli Shaved Smoked Turkey Breast, 150 grams, Oct. 21;
- ▶ 48017, Schneiders Deli Shaved Fully Cooked Smoked Honey Ham, 200 grams, Oct. 21;
- ▶ 21360, Burns Bites Pepperoni, 500 grams, Jan. 21, 2009;
- ▶ 99158, Turkey Breast Roast, 1 kilogram, Sept. 30;
- ▶ 71330, Roast Beef Cooked, Seasoned, 2.5 kilograms, Sept. 30;
- ▶ 71331 Corned Beef, Smoked Meat, 2.5 kilograms, Sept. 30.

Where you should be now.

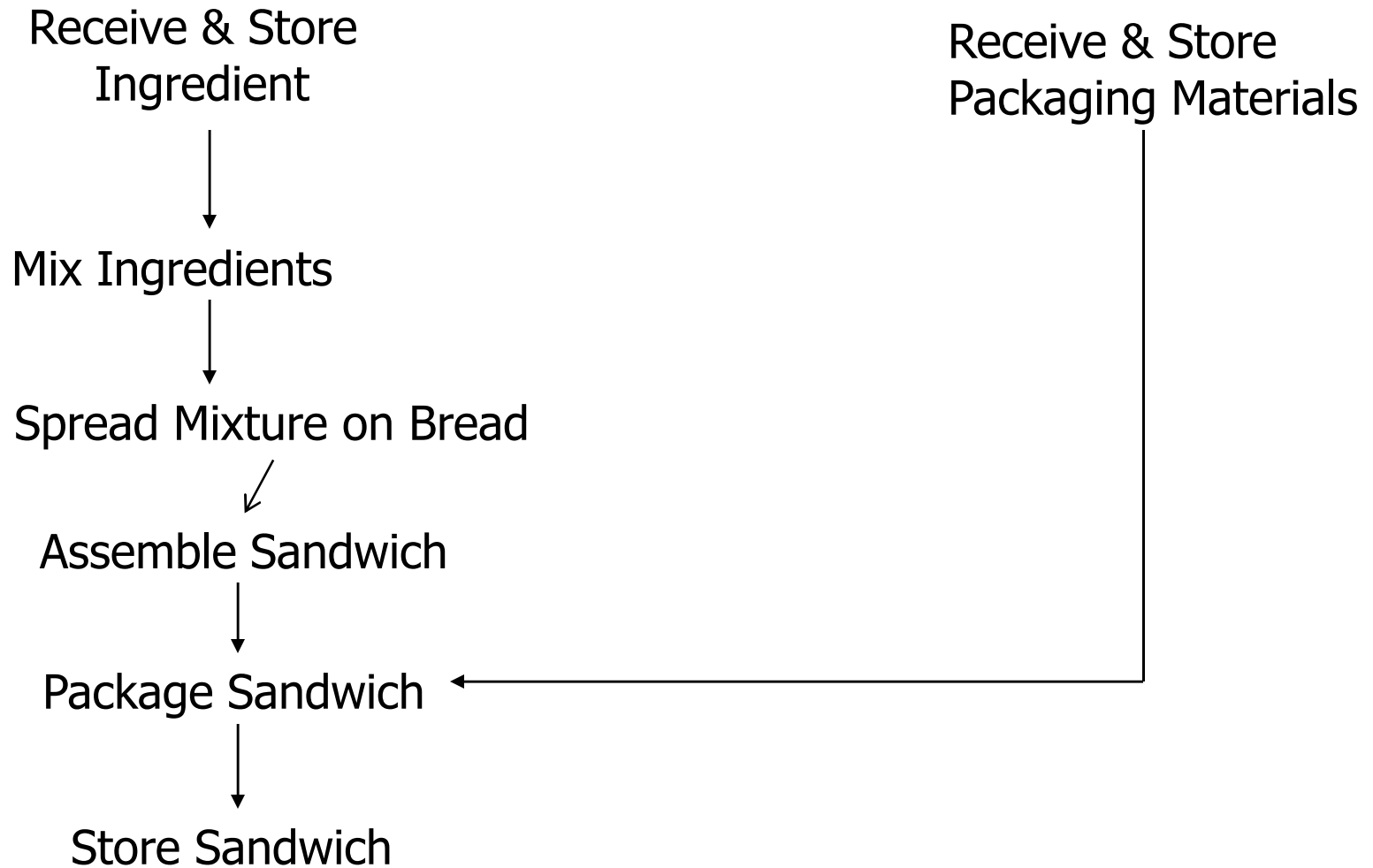
- Working on
 - Pre-requisite programs
 - Product description
 - Flow chart

Principle #1 – Hazard ID & Analysis

- Make ordered list of process steps (flow chart)



HACCP Flow Diagram PB & J Sandwich



Principle #1 - Hazard ID & Analysis

- ▶ For each step, identify all actual or potential hazards that are:
 - Biological
 - Chemical
 - Physical in nature, and
- ▶ That could be:
 - Introduced,
 - Increased OR
 - Controlled at that step

Hazard Analysis

- USDA
 - Meat & Poultry
 - Requires a HA be conducted and a written analysis be available to inspectors
- FDA
 - Seafood
 - HA only conducted not recorded
 - Juice
 - HA and a written analysis

HAZARD ANALYSIS DOCUMENTATION

- APPROPRIATE HAZARD ANALYSIS FORM
 - WORKABLE FORMAT
- JUSTIFICATION OF DECISION FOR EACH HAZARD
 - WHY SIGNIFICANT OR NOT SIGNIFICANT
 - SEVERITY ASSESSMENT
- WHERE CONTROLLED AT
 - PREVENTATIVE MEASURES & CONTROL MEASURES IN PLACE

Hazard Analysis Table

Step	Potential Hazard	Severity of Hazard & Justification	Frequency of Hazard & Justification	Control Measure	Carry to a CCP Decision Table?
Receive & Store Ingredient	B: C: P:				
Mix Ingredients	B: C: P				
Spread Mixture on Bread	B: C: P				
Assemble Sandwich	B: C: P				
Package Sandwich	B: C: P				
Store Sandwich	B: C: P:				
Receive & Store Packaging Materials	B: C: P				

Hazard ID & Analysis

- Consider
 - raw ingredient
 - perishable ingredients
 - potential for allergens
- Process step hazards
 - Hazards unique to the plant
 - Rework addition

Hazard ID & Analysis

- Packaging
- Product hazards
 - Species susceptibility
 - Because of the intended consumers of product
- Consider potential for abuse
 - Especially with returned product if reworked

Hazard Analysis

Hazard evaluation:

assess the **severity** associated with each potential hazard

& estimate the **frequency** at which the hazard may occur.

Hazard Analysis

- Severity
 - Would the hazard result in a life-threatening situation?
 - Would the hazard result in hospitalization (or worse)?
 - In the case of microbiological hazards, would the illness be mild & resolve itself within 2 days?

Hazard Analysis

- Frequency
 - Are conditions resulting in the hazard likely to occur?
 - If so, how frequently are they likely to occur?

More Questions to Ask

- How Severe or Critical
 - long-term situation which could compromise quality of life and/or cause serious loss of \$\$\$ to victim?
 - Includes cancer caused by continued exposure to some chemicals
- Is a future step in our operation/process likely to eliminate the hazard(s) or significantly reduce the risk?

(CODEX) Grid

Severity	Likelihood of Occurrence			
	Remote	Low	Medium	High
High	H-R	H-L	H-M	H-H
Medium	M-R	M-L	M-M	M-H
Low	L-R	L-L	L-M	L-H

Factors Influencing likelihood of Occurrence

- Effectiveness of prerequisite programs
- Frequency of association of the hazard with the food or ingredient
- Method of preparation in the establishment
- Expected storage conditions
- Preparation step before consumption

Significant Hazards

- Those Biological, Physical, or Chemical Hazards that are judged to
 - Occur frequently AND
 - Pose a serious threat to human health (e.g. death, long term complications that negatively impact quality of life)
- Should be carried to the CCP decision table

If not controlled, significant hazards can impact food safety!

HACCP is designed to control this type of hazard

Control Measures

- For each potential significant hazard that might be
 - introduced,
 - increased, or
 - controlled at a particular step,
- describe **control** measures

**Remember that HACCP is a risk
minimization program!**

100% risk-free is a myth

Appendix D of 1997 NACMCF Guidelines

Hazard Analysis Stage	Commercial, frozen cooked beef patties	Commercial, frozen, pre-cooked boned chicken for further processing
Stage 1, Hazard ID: determine potential hazards associated with product	Enteric pathogens (<i>E. coli</i> O157:H7, <i>Salmonella</i>)	<i>Staphylococcus aureus</i> in finished product
Stage 2, Hazard Evaluation: assess severity if potential hazard is not properly controlled	Epidemiological data indicate that these pathogens cause severe health effects (including death) in children & elderly. Undercooked beef patties have been linked to disease from these pathogens	Certain strains of <i>S. aureus</i> produce an enterotoxin that can cause a moderate foodborne illness

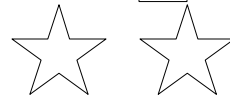
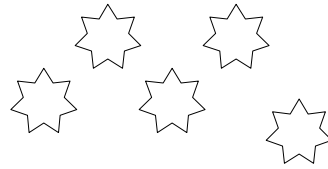
Appendix D of 1997 NACMCF Guidelines

Hazard Analysis Stage	Commercial, frozen cooked beef patties	Commercial, frozen, pre-cooked boned chicken for further processing
Stage 3, Hazard Evaluation: determine frequency of potential hazard if not properly controlled	<i>E. coli</i> is of very low frequency & <i>Salmonella</i> is of moderate frequency in raw beef	Human handling during deboning may add <i>S. aureus</i> . Unless pathogen multiplies to about 1,000,000/g, enterotoxin capable of causing illness will not occur. Temperatures during boning & freezing prevent growth, meaning that frequency is low
Based on this info, should this potential hazard be addressed in the HACCP Plan?	HACCP team decides that enteric pathogens are significant hazards for this product. Hazards must be addressed in Plan	HACCP team decides that potential for enterotoxin formation is very low. But, it's still desirable to keep <i>S. aureus</i> levels low – this can be accomplished through GMPs, rapid freezing, & handling instructions. Potential hazard does not need to be addressed in Plan

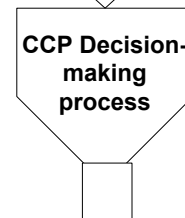
Step	Potential Hazard	Severity of Hazard & Justification	Frequency of Hazard & Justification	Control Measure	Carry to CCP Decision Table?
Receive & Store Ingredients	B: Salmonella	B: High; Can be fatal to certain segments of population CDC 1980	B: Low: Peanut butter is less than 1% moisture and is not favorable to support bacteria growth UGA Publication Number: FDNS-E-30	B: SOP for visual appraisal of peanut butter packaging. Letter of guarantee from supplier C: SOP for visual	B: Yes
	C: Mold on bread producing aflatoxins	C: Low; takes large quantities over extended periods	C: Low: Historical data shows no incidence of mold on bread at time of purchase. P: Historical data shows that there has never been	appraisal of bread for mold. Bread is discarded when mold is present. P: SOP for visual appraisal of harmful objects	C: No
	P: None identified		harmful physical object in ingredients.		

Control Measures

- Completed Hazard Analysis
 - Identify measures to control specific hazards
 - Can reduce or eliminate the risk
 - Not all hazards can be prevented, but
 - Virtually all can be controlled to some degree



Significant hazards are those hazards that occur frequently and pose a potentially severe risk to human health



Center for Science in Public Interest (CSPI)

- 1991 to 2005
 - 5,316 outbreaks of illness linked to specific foods
- 157,830 individual illnesses
- An outbreak involves two or more ill people.
- The food categories most commonly linked to outbreaks were:
 - **Seafood:**
 - 1,053 outbreaks involving 10,415 cases of illness
 - **Produce:**
 - 713 outbreaks involving 34,049 cases of illness
 - **Poultry:**
 - 580 outbreaks involving 17,661 cases of illness
 - **Beef:**
 - 506 outbreaks involving 13,873 cases of illness
 - **Eggs:**
 - 352 outbreaks involving 11,224 cases of illness

HAZARD EVALUATION GUIDELINES

- LIKELIHOOD OF OCCURRENCE?
- WHERE CAN MISHANDLING OCCUR?
- WHAT ARE THE VEHICLES OF TRANSMISSION?
- WHAT ARE CONTRIBUTING FACTORS?
- WHAT IS PAST EXPERIENCE?
 - COMPANY FILES
 - EPIDEMIOLOGICAL REPORTS
- ARE CONTROL MEASURES IN PLACE?
 - WHAT ARE THEY?
- EFFECTIVENESS OF PREREQUISITE PROGRAMS AND SYSTEM?

FACTORS TO INCLUDE

- PRODUCT CHARACTERISTICS
 - SOURCES OF INGREDIENTS
 - FORMULATION CONSIDERATIONS
 - TARGET CUSTOMER
- PROCESSING CONSIDERATIONS
 - EQUIPMENT
 - METHODS
- TIME FACTORS
 - STORAGE
 - PROCESS TIMES
- POTENTIAL FOR ABUSE
- KNOWLEDGE, TRAINING, AND EXPERIENCE

DATA COLLECTION IN HAZARD EVALUATION

- EVALUATE HAZARDS SOURCES
 - ADAPT TO YOUR SYSTEM
- OTHER
 - CONSUMER COMPLAINT DATA
 - INSPECTION RESULTS

EVALUATE HAZARD SOURCES

- RAW FOODS
 - GENERAL
 - RAW AG. PRACTICES
- INFECTED PERSONNEL
- CROSS-CONTAMINATION POTENTIAL

EVALUATE HAZARD SOURCES

- IMPROPER CLEANING & SANITIZING
- POST HEAT TREATMENT INGREDIENT ADDITION
- PACKAGING CONSIDERATIONS
 - PROTECTION
 - SEAM DEFECTS

EVALUATE HAZARD SOURCES

- RESTRICTED FOOD ADDITIVES
 - ALLERGENS
 - VITAMINS
- POISONOUS CHEMICAL INVENTORY/STORAGE
- STORAGE RISKS
 - LEAKAGE, BROKEN CONTAINERS

EVALUATE HAZARD SOURCES

- PROCESSING CONSIDERATIONS
 - HEATING
 - TIME/TEMPERATURE
 - RE-HEATING
 - HOT HOLDING
 - COOLING RATES
 - STORAGE
 - COLD CHAIN
 - SHELF-LIFE
 - FERMENTATION
 - SLOW OR INADEQUATE CONTROL
 - COMPOSITIONAL CHANGES
 - CHANGE IN A_w , SALTS, ETC.

JUSTIFICATION VS. CONTROL

- CONTROL MEASURE SHOULD NOT BE LISTED IN JUSTIFICATION COLUMN ON HAZARD ANALYSIS FORM!!!!

HAZARD JUSTIFICATION – SOURCES OF INFORMATION

- EPIDEMIOLOGY DATA
 - VARIOUS WEBSITES
- SCIENTIFIC EVALUATION
 - CHARACTERISTICS OF HAZARD
 - WILL IT PROLIFERATE IN MY PRODUCT?

HAZARD ANALYSIS VS. CRITICAL CONTROL POINT DETERMINATION

- TRULY A SEPARATE PROCESS!!!
 - PRINCIPLE 1 vs. PRINCIPLE 2
- OFTEN COMBINED
 - RONNIE DON'T PLAY THAT
 - HEY FDA -- ARE YOU LISTENING?