

PRINCIPLE 1: CONDUCT A HAZARD ANALYSIS

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HAZARD ANALYSIS (NACMCF)

***THE PURPOSE OF HAZARD ANALYSIS IS
TO DEVELOP A LIST OF HAZARDS
WHICH ARE OF SUCH SIGNIFICANCE
THAT THEY ARE REASONABLY LIKELY
TO CAUSE INJURY OR ILLNESS IF NOT
EFFECTIVELY CONTROL***

HAZARD ANALYSIS

- ***PRINCIPLE 1: CONDUCT A HAZARD ANALYSIS.***
 - ***PREPARE A LIST OF STEPS IN THE PROCESS WHERE SIGNIFICANT HAZARDS OCCUR AND DESCRIBE THE PREVENTATIVE MEASURES***

HAZARD ANALYSIS

- ***A SIGNIFICANT HAZARD MUST BE CONTROLLED IF IT IS:***
 - ***REASONABLY LIKELY TO OCCUR,***
 - ***LIKELY TO RESULT IN AN UNACCEPTABLE RISK TO CONSUMERS IF NOT CONTROLLED***



***WRONG HAZARD = WRONG
HACCP PLAN***

OBJECTIVES OF HAZARD ANALYSIS

- **HAZARD IDENTIFICATION**
 - IDENTIFY ACTUAL & POTENTIAL HAZARDS
- **HAZARD EVALUATION**
 - CHARACTERIZE HAZARD SEVERITY
 - LOW, MEDIUM, OR HIGH
 - CATEGORIZE RISKS

HAZARD IDENTIFICATION GUIDELINES (NACMCF) -- (OLD SCHOOL HACCP)

- **HAZARD A**
- **HAZARD B**
- **HAZARD C**
- **HAZARD D**
- **HAZARD E**
- **HAZARD F**

RISK CHARACTERIZATION GUIDELINES (NACMCF)

- **CATEGORY 0**
- **CATEGORY I**
- **CATEGORY II**
- **CATEGORY III**
- **CATEGORY IV**
- **CATEGORY V**
- **CATEGORY VI**

GRID FOR RANKING OF HAZARD RISK (CODEX)

<u>SEVERITY</u>				
HIGH	<i>H-R</i>	<i>H-L</i>	<i>H-M</i>	<i>H-H</i>
MEDIUM	<i>M-R</i>	<i>M-L</i>	<i>M-M</i>	<i>M-H</i>
LOW	<i>L-R</i>	<i>L-L</i>	<i>L-M</i>	<i>L-H</i>
	<i>REMOTE</i>	<i>LOW</i>	<i>MEDIUM</i>	<i>HIGH</i>
	<i>LIKELIHOOD OF OCCURRENCE</i>			



***RISK ASSESSMENT AND
CHARACTERIZATION***

DEFINITION OF RISK (KAPLAN 1981, 1997)

- **WHAT CAN HAPPEN?**
- **HOW LIKELY WILL IT HAPPEN?**
- **WHAT ARE THE CONSEQUENCES?**

FOOD CONSUMPTION

- **SUCCESSFUL SCENARIO**
 - **NOTHING GOES WRONG**

FOOD CONSUMPTION

- **UNSUCCESSFUL SCENARIO**
 - **ACUTE**
 - **FOOD BORNE ILLNESS**
 - **CHEMICAL POISONING**
 - **CHOKING ON A BONE**
 - **CHRONIC**
 - **LONG TERM EFFECTS**
 - **CANCER**
 - **BIRTH DEFECTS**

MORE NARROWLY DEFINING THE SCENARIO

- **THE PROCESS**
 - VIRULENCE FACTORS
 - HOW MUCH CONSUMED, ETC.
- **THE POTENTIAL CONSEQUENCE**
- **THE TARGET**
 - HIGH VS. LOW RISK POPULATION

HOW LIKELY IS IT?

- **CONDITIONS**
- **PROBABILITY ISSUES**

WHAT ARE THE CONSEQUENCES?

- **PROBABILITY OF PROBLEM**

RISK ANALYSIS

- **RISK ASSESSMENT**
- **RISK MANAGEMENT**
- **RISK COMMUNICATION**

HACCP EMPHASIS

- **RISK ASSESSMENT**
- **RISK MANAGEMENT**

RISK ASSESSMENT ELEMENTS (NRC 1983)

- **HAZARD IDENTIFICATION**
- **HAZARD CHARACTERIZATION**
 - **EXPOSURE ASSESSMENT**
 - **DOSE-RESPONSE ASSESSMENT**
- **RISK CHARACTERIZATION**

HAZARD IDENTIFICATION (HI)

- **CONSIDER MANY OUTCOMES OF ADVERSE SCENARIOS**
 - **END-POINTS**
- **SOURCES OF INFORMATION**
 - **TOXICOLOGICAL DATA**
 - **EPIDEMIOLOGICAL DATA**

HAZARD IDENTIFICATION (HI)

- **CLASSIFICATION**
- **EXTRAPOLATION**
 - **CHEMICAL RISK EXTRAPOLATED FROM ANIMAL STUDIES**
 - **PITFALLS OF EPIDEMIOLOGICAL DATA??**

EXPOSURE ASSESSMENT (EA)

- **OCCURRENCE OF HAZARD**
- **LEVEL OF HAZARD**
- **POTENTIAL FOR INGESTION IN FOODS**
- **CONSERVATIVE RATHER THAN UNBIASED MODELS**

EXPOSURE ASSESSMENT (EA)

- **SOURCES OF INFORMATION**
 - **EATING HABITS OF TARGET POPULATIONS**
 - **CONSUMPTION SURVEYS**
 - ***USDA CONTINUING SURVEY OF FOOD INTAKE BY INDIVIDUALS***
 - **PREVALENCE DATA**
 - **MARKET BASKET ANALYSIS SURVEYS**
 - **GROWTH & SURVIVAL STUDIES**
 - **FOOD INOCULATION STUDIES**
 - **EXPERIMENTAL DATA ON SPECIFIC FOODS**

EXPOSURE ASSESSMENT (EA)

- **ADDITIONAL ISSUES**
 - **FOOD CHEMISTRY AND FORMULATION EFFECTS ON HAZARDS**
 - **PROCESSING, HANDLING & PREPARATION**

DOSE-RESPONSE ASSESSMENT (DRA)

- **ASSESSING THE RELATIONSHIP BETWEEN**
 - **SIGNIFICANCE**
 - **SEVERITY**
 - **LIKELIHOOD OF ADVERSE EFFECT**
 - **INFECTIVITY OR PATHOGENICITY OF PATHOGEN**
 - **VULNERABILITY OF HOST**

RISK CHARACTERIZATION (RC)

- **LINKING EXPOSURE ASSESSMENT WITH DOSE-RESPONSE ASSESSMENT**
- **ESTIMATED NUMBERS OF ILLNESSES AND DEATHS**
- **ECONOMIC COSTS**



***MECHANICS OF HACCP
HAZARD ANALYSIS***



HAZARD IDENTIFICATION

HAZARD IDENTIFICATION

- **DEVELOPING HAZARDS LIST**
 - **BIOLOGICAL, CHEMICAL AND PHYSICAL**

BIOLOGICAL HAZARDS

- **BACTERIA**
- **VIRUSES**
- **PARASITES**
- **INSECTS??**

BACTERIA HAZARDS OF MOST CONCERN

- ***C. BOTULINUM***
- ***SALMONELLA***
- ***LISTERIA MONOCYTOGENES***
- ***BACILLUS CEREUS***
- ***STAPHYLOCOCCUS AUREUS***
- ***ESCHERICHIA COLI***
- ***CAMPYLOBACTER JEJUNI***
- ***SHIGELLA***
- ***VIBRIO***
- ***YERSINIA ENTEROCOLITICA***

VIRUSES

- **HEPATITIS A**
- **NORWALK**
- **NORWALK-LIKE**

PARASITES

- ***TAENIA SAGINATA***
- ***DIPHYLLOBOOTHRIUM LATUM***
- ***TRICHINELLA SPIRALIS***

PROTOZOAN PARASITES

- ***CRYPTOSPORIDIUM***
- ***CYCLOSPORA***
- ***TOXOPLASM***
- ***ENTAMOEBIA HISTOLYTICA***

CHEMICAL HAZARDS

- **NATURAL TOXINS**
- **FOOD ADDITIVES/COLOR ADDITIVES**
 - **UNAPPROVED ADDITIVES/RESIDUES**
- **PESTICIDES**
- **DRUG RESIDUES**
- **DECOMPOSITION**
 - **HISTAMINE, ETC.**
- **ALLERGENS**

PHYSICAL HAZARDS

- **METAL, WOOD, GLASS, STONES, ETC.**

SCOPE OF HAZARD IDENTIFICATION

- **RAW MATERIALS/INGREDIENTS**
- **PRODUCT CHARACTERISTICS**
 - **TYPES**
 - **LUMPING/GROUPING??**
- **PROCESSING/HANDLING**
 - **TYPES OF PROCESSES**
 - **EACH PROCESS STEP**
 - **CROSS-REFERENCE FLOW DIAGRAM**
- **PACKAGING**
- **STORAGE**
- **DISTRIBUTION**



HAZARD EVALUATION

PROTOCOL?

- **NO STANDARD PROTOCOL**
- **HACCP TEAM**
- **CONSULT APPROPRIATE SCIENTIFIC LITERATURE**
- **DOCUMENTATION**

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.**

RAW MATERIAL REVIEW

- **PRODUCT DESCRIPTION FORM**
- **INGREDIENT DESCRIPTION FORM**
- **VENDOR & SUPPLIER PROGRAMS**
- **REWORK/RETURN POLICIES**
- **LAB TESTING CAPABILITIES**
- **RAW PRODUCT STORAGE
EFFECTIVENESS**

OPERATIONS REVIEW

- **HACCP FLOW DIAGRAM**
 - LABEL HAZARDS B, C, P
- **OBSERVE PRACTICES**
 - CONFIRM, CONFIRM, CONFIRM

MEASUREMENTS

- **EVALUATE CAPABILITIES**
 - TEMPERATURE/TIME DEVICES, ETC.
- **ANALYSIS OF EXISTING CONTROLS & DATA**
 - HOW DO I USE THE DATA I HAVE?

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

JUSTIFICATION VS. CONTROL

- **SEPARATE COLUMNS ON HAZARD ANALYSIS FORM**
- **CONTROL MEASURE SHOULD NOT BE LISTED IN JUSTIFICATION COLUMN ON HAZARD ANALYSIS FORM!!!!**
- **JUSTIFICATION SHOULD BE SCIENTIFIC JUSTIFICATION AS TO WHETHER HAZARD IS *SIGNIFICANT AND REASONABLY LIKE TO OCCUR IF NOT CONTROLLED***

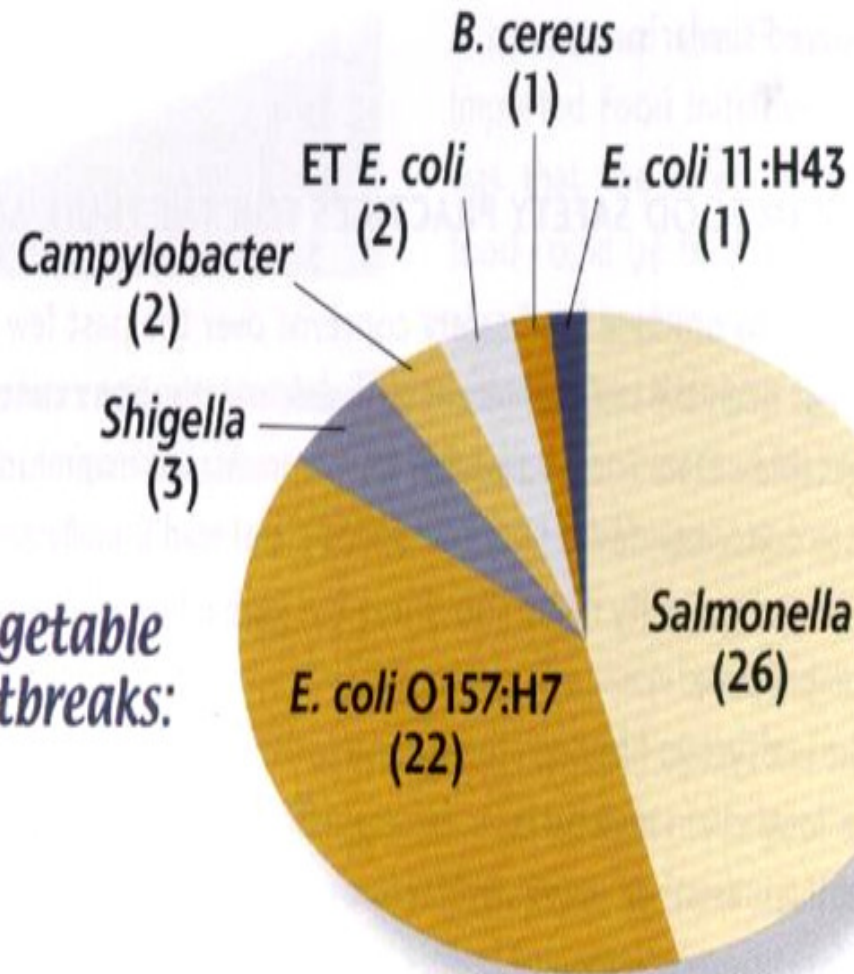
HAZARD JUSTIFICATION – SOURCES OF INFORMATION

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



EXAMPLES OF INFORMATION

***Fruit and Vegetable
Bacterial Outbreaks:
1988-1998***



REGULATORY SOURCES OF INFORMATION

- **FDA & USDA/FSIS**
 - ***ANY BIOLOGICAL, CHEMICAL OR PHYSICAL PROPERTY THAT MAY CAUSE A FOOD TO BE UNSAFE FOR CONSUMPTION***
 - ***REASONABLY LIKELY TO OCCUR***
 - **WWW.FDA.GOV**
 - **WWW.FSIS.USDA.GOV**
- **HAZARD CONTROL GUIDES**
 - **SEAFOOD**
 - **JUICE**

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?**

QUESTIONS TO PONDER ABOUT HACCP HAZARDS

- **DOES EVERY IDENTIFIED HAZARD NEED JUSTIFICATION AS TO SIGNIFICANCE?**
- **HOW MUCH JUSTIFICATION IS NEEDED?**
- **DOES EVERY IDENTIFIED SIGNIFICANT HAZARD NEED TO BE ADDRESSED IN THE HACCP PLAN?**
- **DOES EVERY IDENTIFIED SIGNIFICANT HAZARD NEED TO BE CONTROLLED AT A CRITICAL CONTROL POINT (CCP)?**