



**USAID** | **IRAQ**  
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# USAID-*TIJARA* PROVINCIAL ECONOMIC GROWTH PROGRAM

## SANITARY & PHYTOSANITARY (SPS) TECHNICAL TRANSFER

HAZARD ANALYSIS CRITICAL CONTROL POINTS  
(HACCP) TRAINING MANUAL



December 2012

This report was produced for review by the U.S. Agency for International Development (USAID). It was prepared by The Louis Berger Group, Inc.

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USAID-*Tijara* Provincial Economic Growth Program

Iraq Agricultural Policy Assessment

# USAID-TIJARA PROVINCIAL ECONOMIC GROWTH PROGRAM

DECEMBER 2012

## AGRICULTURAL TRAINING DELIVERABLE REPORT

SPS HACCP FOOD SAFETY TRAINING MANUAL  
BY CHARLES LAMBERT, Ph.D, INTERNATIONAL  
TRADE / WTO ACCESSION, *USAID/TIJARA*

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# ACRONYMS

CY	Calendar Year
GAP	Good Agricultural Practices
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
Gol	Government of Iraq
HACCP	Hazard Analysis Critical Control Points
MoA	Ministry of Agriculture
MoH	Ministry of Health
MoU	Memorandum of Understanding
MoT	Ministry of Trade
Ph. D.	Doctor of Philosophy
SPS	Sanitary & Phytosanitary
SSOP	Sanitary Standard Operating Procedures
STTE	Short Term Training Expert
USAID	United States Agency for International Development
WTO	World Trade Organization



# 1. INTRODUCTION

## 1.1 METHOD OF APPROACH

This report is identified as a deliverable in the *USAID/Tijara* International Trade/WTO Accession Year 5 Work Plan, Activity Reference 4.3: *Training Manual on HACCP Developed*. The stated deliverables follow:

### 1.1.1 DELIVERABLES

- Conduct SPS training workshops to introduce HACCP and Advanced food safety principles to Ministry of Agriculture (MoA) veterinarian food safety officials and Ministry of Health (MoH) officials. Training was in response to requests by *USAID/Tijara* clients -- MoA and MoH official leadership in Baghdad and Erbil.
- Develop a HACCP Training Manual using training materials and lessons learned.

The training programs were co-funded by *USAID/Tijara* and *USAID/Inma*. *USAID/Tijara*'s role was World Trade Organization (WTO) policy communication and providing advance communication with the client, planning and coordination, on-site leadership, translation, meeting rooms, breaks and meals. *USAID/Inma*'s role was technological transfer and providing funding for subject matter experts and rooms for MoA participants.

After the training workshops were complete USAID Deliverables reports for the training sessions were prepared and submitted. This is now the final step in the training process as materials are compiled into a HACCP Training Manual to be provided to MoA, MoH and other interested parties in Iraq.

## 1.2 STRUCTURE OF THIS REPORT

Section 1 provides the Introduction, Method of Approach and Structure of this Report.

Section 2 provides includes discussion about Client Request & Preparation and Information Delivery & Report Writing.

Section 3 provides subsections regarding Background and Training & Way Forward. This material includes an overview of *USAID/Tijara* food safety activities and technical support for MoA

Annex A is the ***SPS HACCP Food Safety Manual for Iraq***

# 2. TRAINING AND WRITING

## 2.1 CLIENT REQUEST AND PREPARATION

This manual is the culmination of client requests from Ministry of Agriculture (MoA) State Veterinary Company senior officials and a follow-up to earlier workshops conducted during May and August 2010 and February, July and December 2011. This series of workshops facilitated preparation among Government of Iraq (GoI) MoA senior officials for implementation of the draft *Plant Quarantine Law* and the *Animal Health Law* from MoA and the draft *Public Health Law* and *Food Safety Regulations* from Ministry of Health (MoH.)

The overall objective for this workshop series has been to develop implementing regulations for SPS legislation that will be administered and enforced uniformly at all Iraqi points of entry. Developing WTO-consistent SPS legislation and regulations and point-of-entry inspection, and administrative infrastructure to uniformly and transparently administer and enforce those regulations, is relevant regardless of when Iraq accedes to the WTO.

## 2.2 INFORMATION DELIVERY AND REPORT WRITING

Participants in these workshops are official decision-makers within MoA responsible for implementation, administration and enforcement of Sanitary/Phytosanitary (SPS) food safety and animal health regulations necessary for WTO Accession. The workshops provided a forum for dialog and input regarding critical needs to improve the inspection infrastructure at points of entry including reference laboratory speed and accuracy.

Two Introductory HACCP Training Seminars and two Advanced HACCP Training Seminars were scheduled; one introductory and one advanced in Baghdad and one of each in Erbil.

(See two earlier USAID Deliverable reports: *“Sanitary & Phytosanitary (SPS) Technical Transfer: Food Safety Training in Hazard Analysis Critical Control Points (HACCP)”* and *“Sanitary & Phytosanitary (SPS) Technical Transfer: Food Safety Training in Advanced Hazard Analysis Critical Control Points (HACCP).”*

This will be the final USAID Deliverable Report in the *USAID/Tijara International Trade/WTO Accession Year 5 Work Plan; Task Area 4: Support Reform for Agriculture and Food Safety to Reduce Barriers to Trade.*

The title of this Deliverable Report is *“SPS HACCP Food Safety Training Manual”*

# 3. SITUATION AND OUTLOOK

## 3.1 BACKGROUND

Safety of imported products, including food safety, is a priority at the highest levels on the agenda for the Government of Iraq (GoI). This is a cross-cutting issue for *USAID/Tijara* and *USAID/Inma* – agriculture needs technological proficiency in HACCP to assure food safety and risk-based inspection to protect human and animal health. WTO accession also requires that the Iraqi inspection system be transparent and based on international guidelines (including HACCP), science and risk.

Iraqi officials are in the initial formative stages of a multiple-year process for developing SPS regulations and an enforcement infrastructure. *USAID/Tijara* and *USAID/Inma* efforts during 2012 will only introduce the topics and help shape the thought process. Actual adoption and future implementation will take place long after funding for current programs ends. Even that scenario depends on an Iraqi political and security environment that is conducive to compromise, transparency and acceptance of international norms.

Given economies of funding and mutual interests, *USAID/Tijara* and *USAID/Inma* agreed to provide a joint HACCP training program and subdivide the costs.

## 3.2 TRAINING MANUAL AND WAY FORWARD

**Training Manual:** This manual compiles training materials from Introductory and Advanced HACCP seminars facilitated by *USAID/Tijara* in Baghdad and Erbil. International Trade/WTO Accession senior advisors have worked with Iraqi MoA and MoH officials since the program began. Specific to animal health and food safety, earlier workshops were conducted during May and August 2010; February, July and December 2011; and July and October 2012.

This series of workshops facilitated preparation among Government of Iraq (GoI) MoA senior officials for implementation of the draft *Plant Quarantine Law* and the *Animal Health Law* from MoA and the draft *Public Health Law* and *Food Safety Regulations* from Ministry of Health (MoH.)

*USAID/Tijara* has distributed these materials to MoA and MoH officials. WTO accession and trade facilitation will indicate the degree to which the information is being used. Ultimately, information disseminated at these Workshops and other capacity building exercises will be developed into GoI Administrative policy and procedures and must be transferred and enforced uniformly in the field.

### **Training Remaining:**

None. Five-year funding for the *USAID/Tijara* program ends January 31, 2013. The International Trade/WTO Accession senior technical advisors will demobilize before the end of December 2012.



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## SPS HACCP FOOD SAFETY MANUAL FOR IRAQ



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Chapter 1: WTO SPS REQUIREMENTS AND IRAQ



## Relationship Between Iraq's WTO Membership, ISO & HACCP

2012 Status



2011



International Trade and WTO



### Implications of Iraq's WTO Membership

**WTO membership is one of the most important ways to strengthen Iraq's economy**

- Mandates **trade reforms** that will influence domestic markets;
- Harmonizes trading practices with **international standards**;
- Mandates trade policies be implemented with domestic laws and regulations that conform to **internationally accepted practices**.



## WTO members as of August 24, 2012



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## Implications of Iraq's WTO Membership

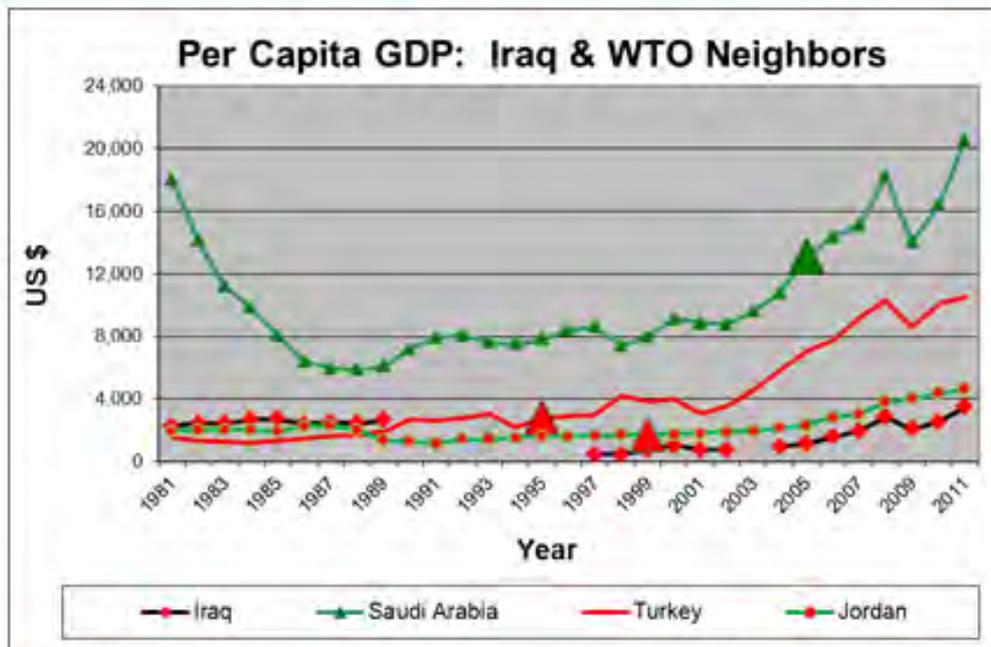
WTO requirements have the direct effect of **increasing transparency, predictability and due process** in economic policy.

WTO membership will: **Improve Iraq's Business and Investment Climate**

- Increased market access to **new technologies**
- Increased **market access** to imports and exports
- **Greater choice** of production and consumption patterns in line with the Law of Comparative Advantage
- **Reduced corruption** through **rule of law** -- less discretion in administering trade-related services and increased accountability among trade-related agencies
- **Increased security** of contracts and intellectual property
- **Reduced cost** of doing business
- **Expanded employment** opportunities
- Improved alignment of domestic wages and prices with **international markets**

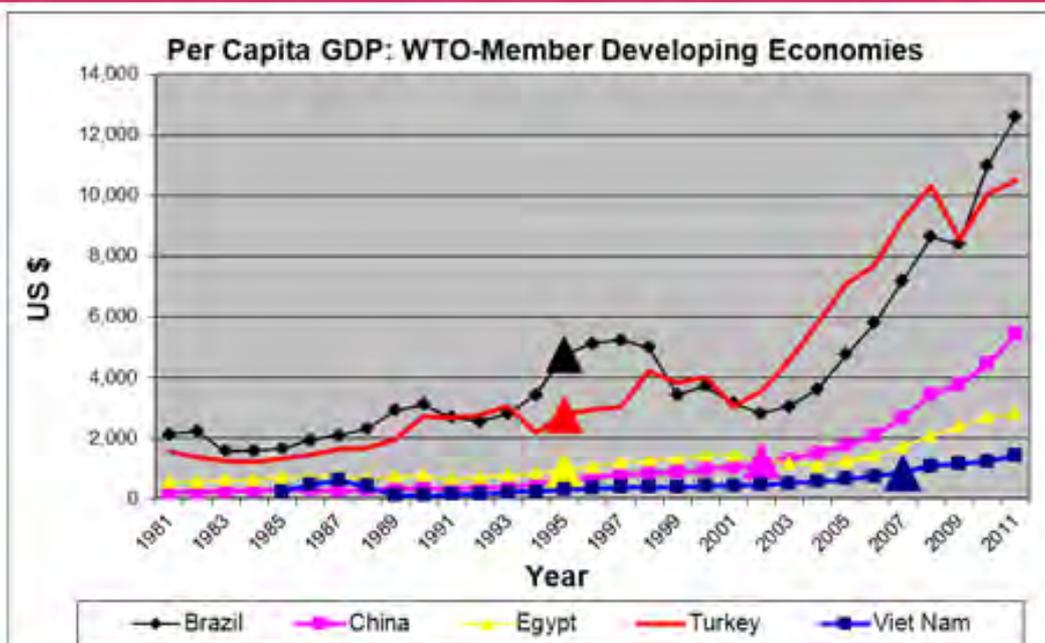
4 WTO Accession Status 2011

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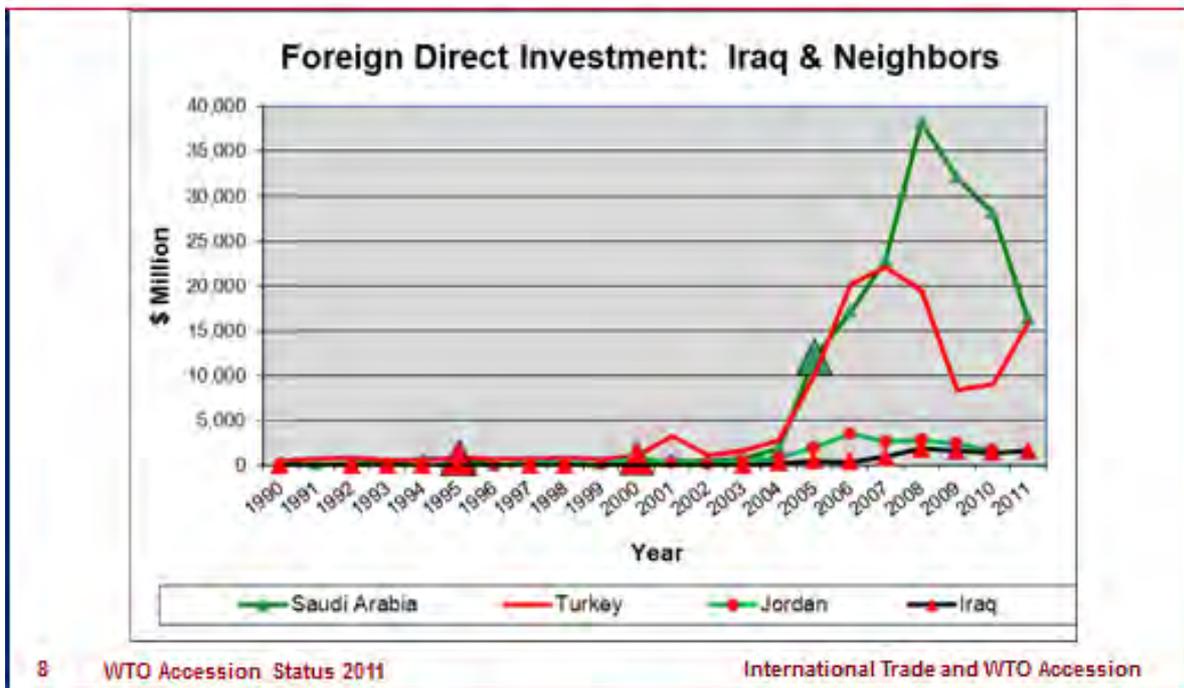
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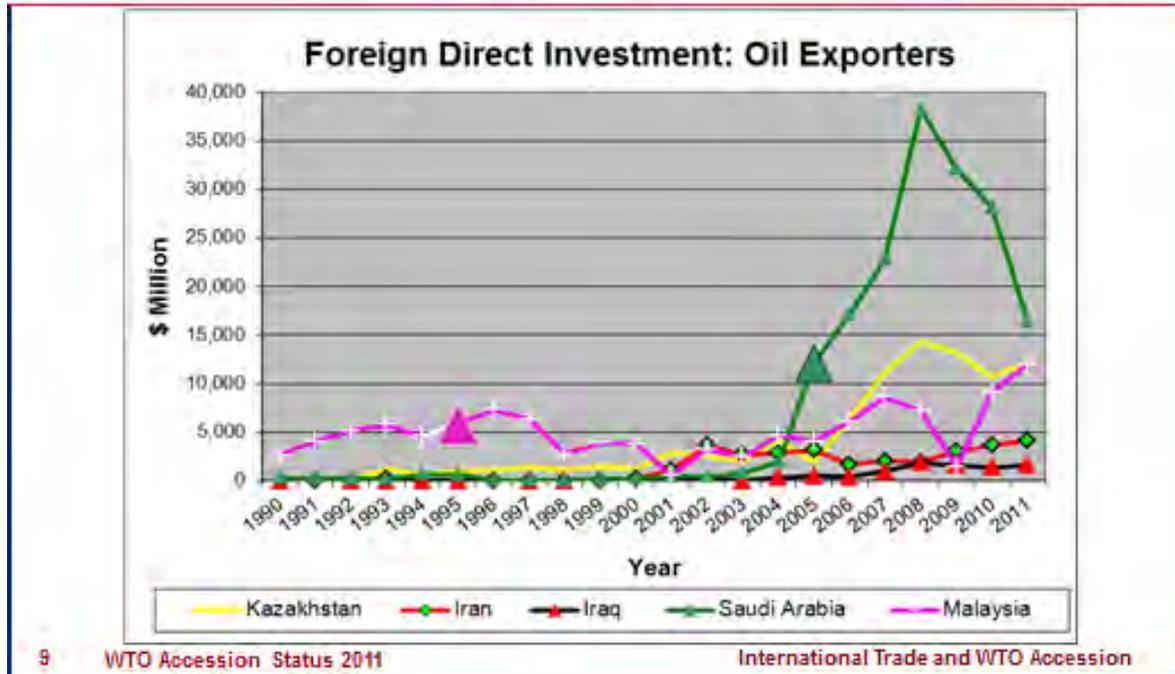
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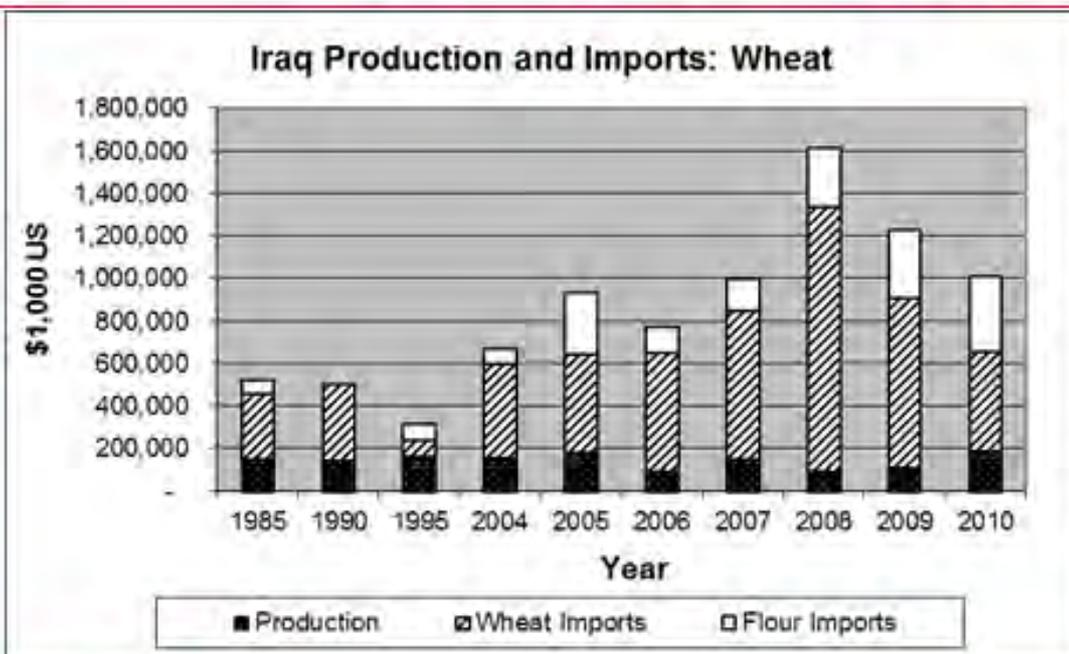
## Main Components of the Accession Process

- **Goods Offer** – A commitment to comply with the provisions of the General Agreement on Tariffs and Trade (GATT) and successive WTO agreements on trade in goods.
- **Intellectual Property Rights Reform** – A commitment to comply with the provisions of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) for protecting property rights for patents, trademarks and copyrights.
- **Services Offer** – A commitment to comply with the provisions of the WTO General Agreement on Trade in Services (GATS) on trade access in 152 services sub-sectors.



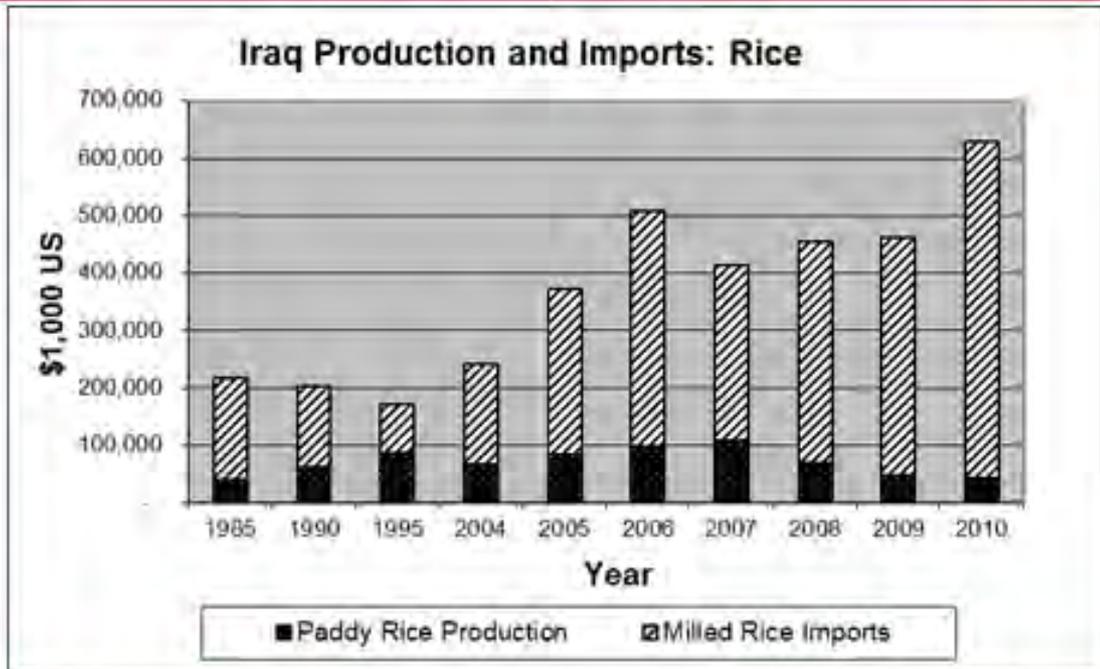
### WTO Accession Roadmap

Key Market Access Issues	Requirements of WTO	Relevant WTO Agreement	Required Actions by Iraq	Conditions for WTO Acceptance
<b>1. Goods Offer – Market Access for Trade in Goods</b>				
Tariffs & Customs		GATT; WTO; Customs Valuation; Pre-shipment Inspection; Rules of Origin; Import Licensing Procedures	Tariff schedule, with concessions to bind rates; legislation, enforcement of tariff and customs procedures; nation treatment – Introduction of Customs reforms through automation	Goods offer negotiated with Members through a series of bi-lateral negotiations. Final Goods Offer submitted
Agriculture		Agriculture	Commitment to bind subsidies exceeding de minimus levels	Commitment negotiated with Members
		Sanitary and Phytosanitary Measures	Legislation, enforcement of plant/animal health, food safety	Not negotiable. Iraq must fully comply with SPS Agreement
Technical Barriers to Trade		Technical Barriers to Trade	Legislation, enforcement of measures preventing technical barriers to trade	WTO accepts commitment on legislation, enforcement
<b>2. Services Offer – Market Access for Trade in Services</b>				
Services		Trade in Services – General Agreement on Trade in Services (GATS), TRIMS	Commitment to increase market access in selected subsectors and national treatment	Services offer negotiated with Members through bilateral negotiations. Final Services Offer submitted
<b>3. Reform of Intellectual Property Rights Regime</b>				
Intellectual Property Rights		Trade Related Aspects of Intellectual Property Rights (TRIPS)	Legislation and enforcement of patents, copyrights, trademarks	WTO accepts commitment on legislation, enforcement





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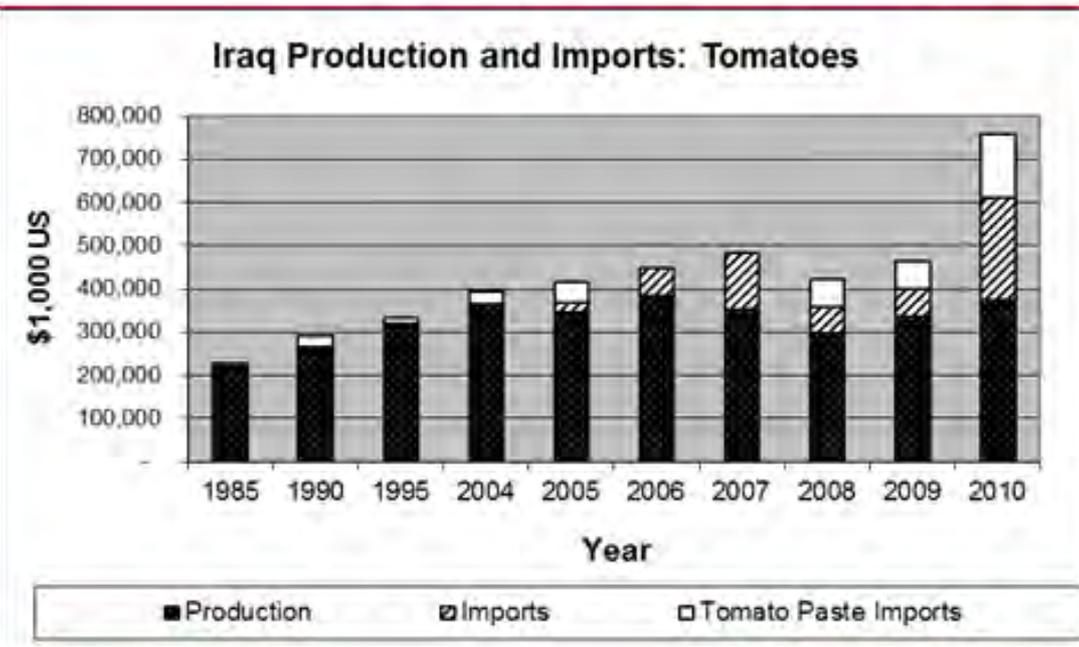


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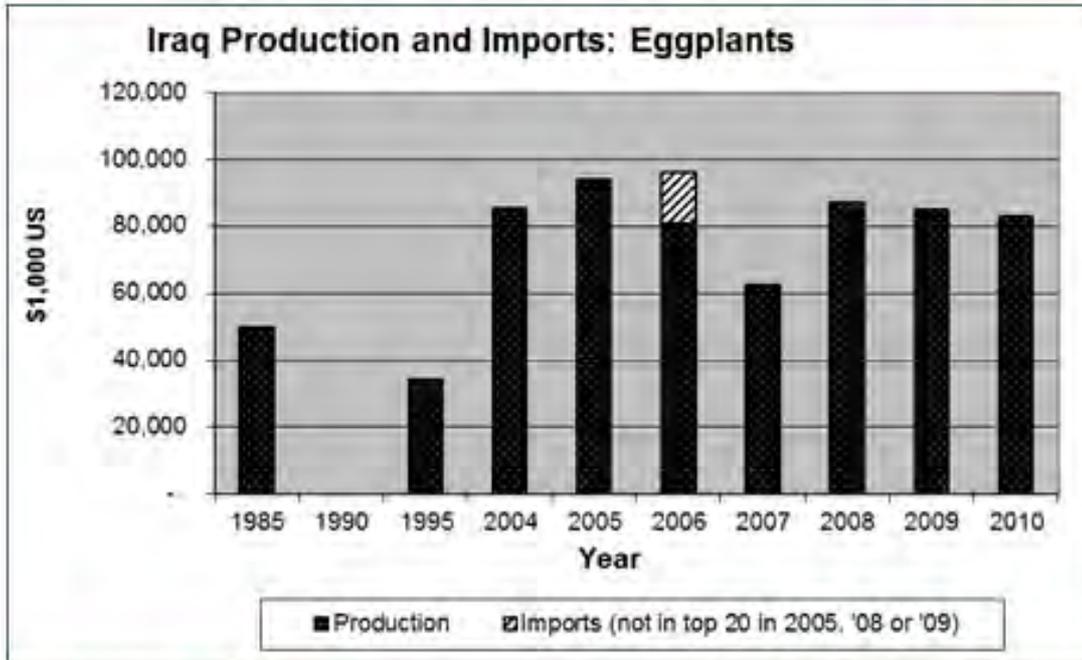


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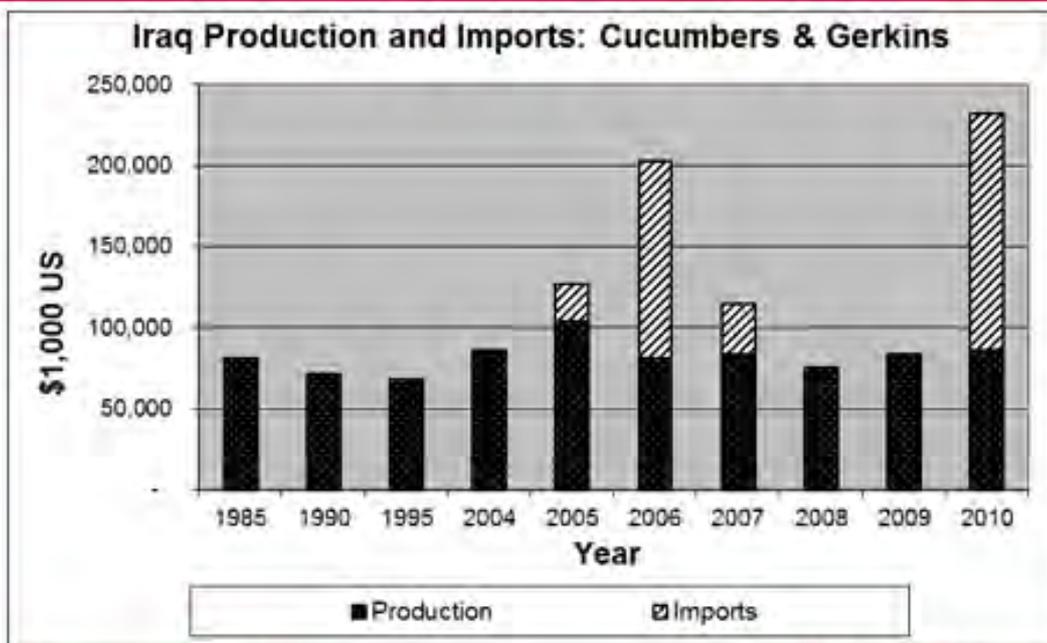
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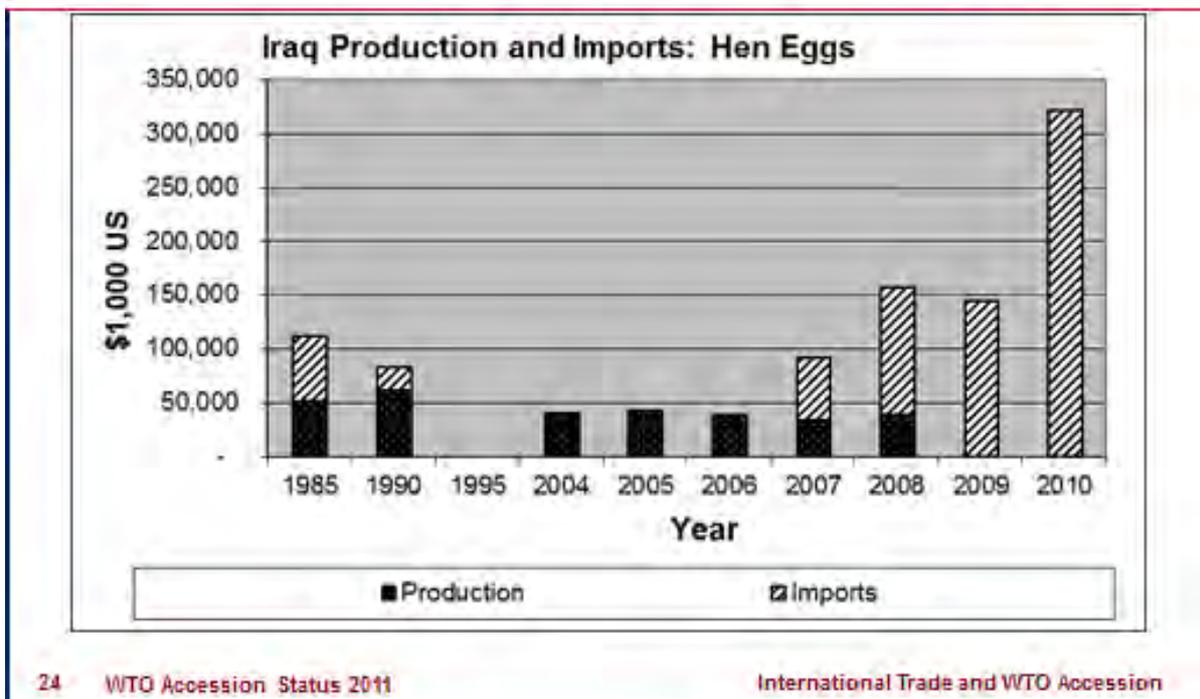
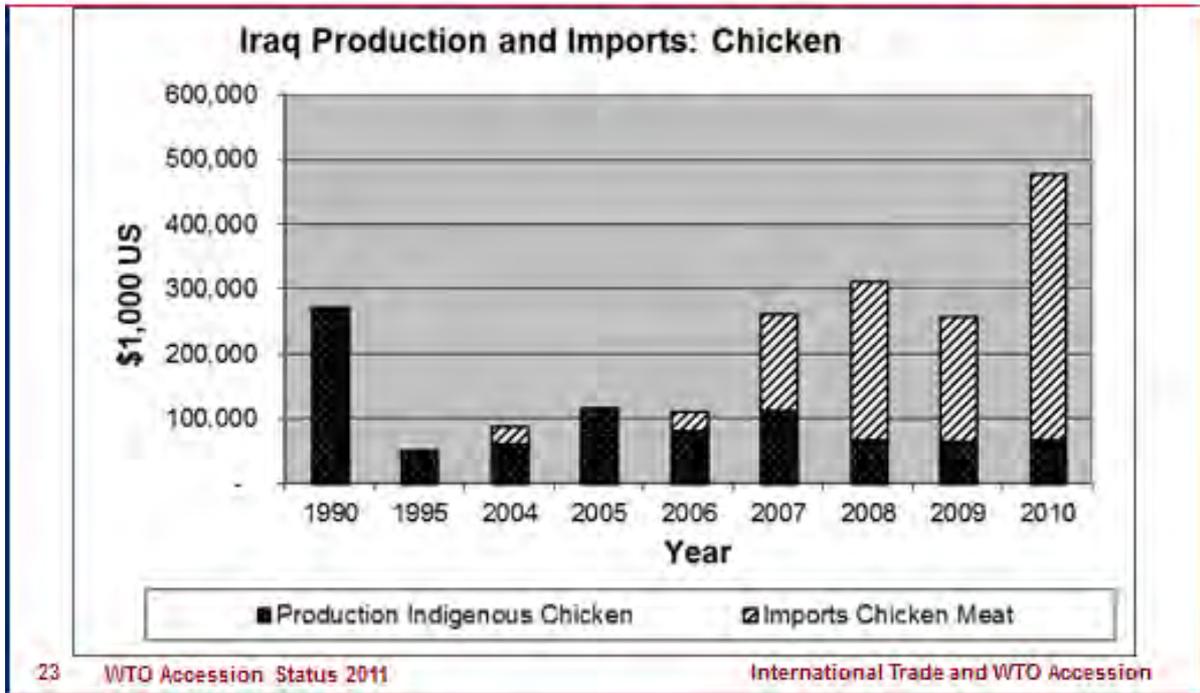
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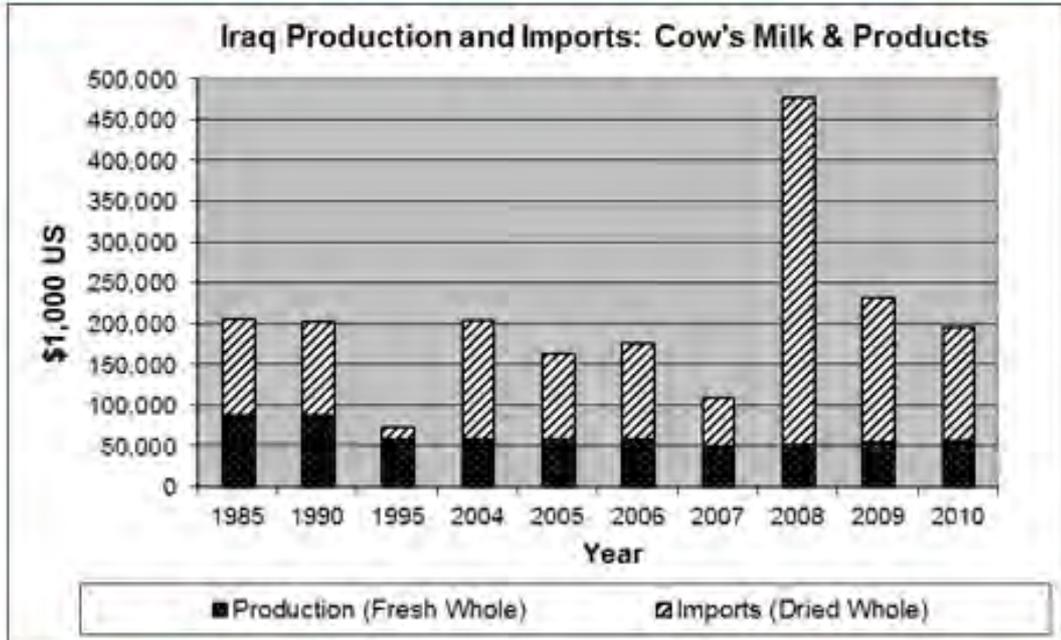
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## Roadmap for Next WTO Working Party Meeting

The following actions are being taken, in anticipation of the 3<sup>rd</sup> WP meeting\* being held during 2012:

1. Revised Legislative Action Plan to cover pending and new legislative actions
2. Submission of the Initial Goods Offer to WTO – another 2-3 years
3. Public awareness events with the private to create a broad understanding of the importance of WTO membership and the status of Iraq's accession process.
4. Preparations for the next Working Party Meeting, including answering new questions prior to the Meeting

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## Agreement on the Application of Sanitary and Phytosanitary Measures

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### Definition of an SPS measure

**to protect:**

**from:**

human or animal

risks arising from additives, contaminants, toxins or disease-causing organisms in food, beverages, feedstuffs

human life

plant- or animal-carried diseases (zoonoses);

animal or plant health

pests, diseases, or disease-causing organisms

a country

damage caused by entry, establishment or spread of pests (including weeds)

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All types of measures with these purposes, including:

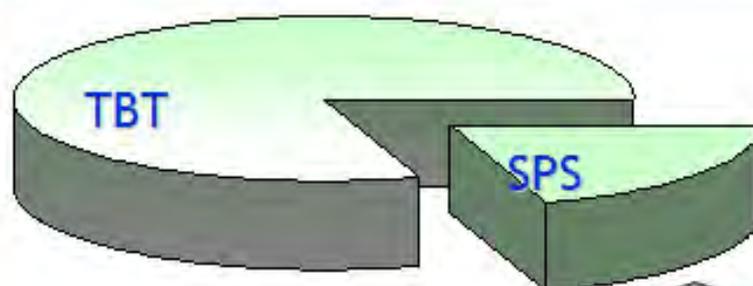
- ✓ product criteria
- ✓ quarantine measures
- ✓ processing requirements
- ✓ certification
- ✓ inspection
- ✓ testing
- ✓ health-related labeling

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TBT Applies To: All Industrial And Agricultural Products



TBT Does Not Apply To: SPS Measures

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SPS Measures	TBT Measures
<ul style="list-style-type: none"> <li>❖ human or animal health from food-borne risks</li> <li>❖ human health from animal- or plant-carried diseases</li> <li>❖ animals and plants from pests or diseases </li> <li>❖ examples:                             <ul style="list-style-type: none"> <li>❖ pesticide residues</li> <li>❖ food additives</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>❖ human disease control (unless it's food safety)</li> <li>❖ nutritional claims</li> <li>❖ food packaging and quality examples:                             <ul style="list-style-type: none"> <li>❖ labelling (unless related to food safety)</li> <li>❖ pesticide handling</li> <li>❖ seat belts</li> </ul> </li> </ul>



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## Key Provisions of the SPS Agreement

1. Non-discrimination
2. Scientific justification
  - harmonization
  - risk assessment
  - consistency
  - least trade-restrictiveness
3. Equivalence
4. Regionalization
5. Transparency
6. Technical assistance/special treatment
7. Control, inspection and approval procedures



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## SPS Agreement: Basic Rights

### Article 2.1

**“Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement”**

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## International Harmonization

- ✓ Encourage the use of international standards
- ✓ Presumption of conformity
- ✓ Right to be more , but the SPS Agreement requires **scientific justification** or a **risk evaluation**.



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## Harmonization

### Standard-setting Organizations

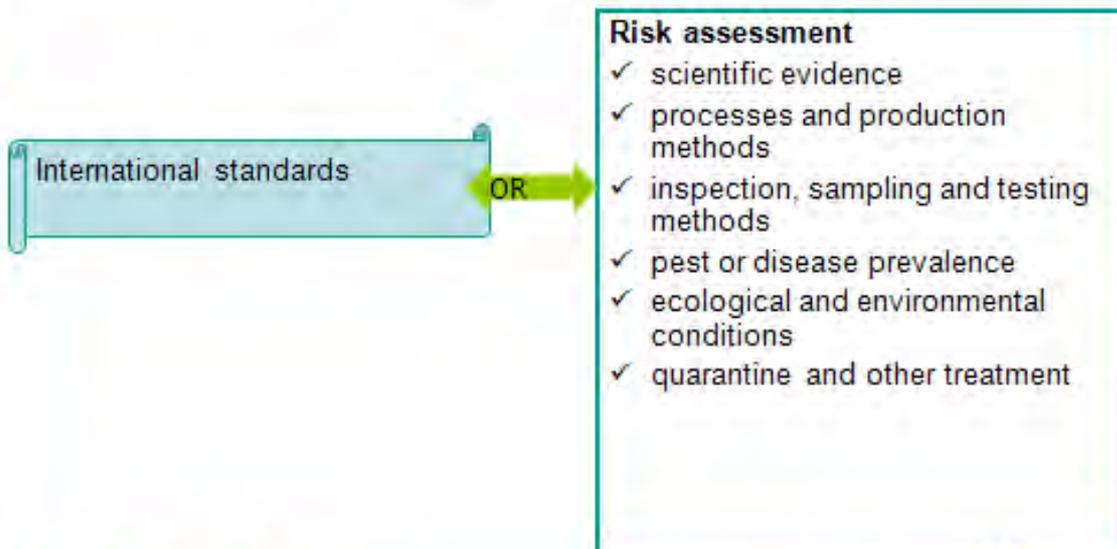


Codex = Joint FAO/WHO Codex Alimentarius Commission  
OIE = World Organization for Animal Health  
IPPC = International Plant Protection Convention (FAO)

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## Scientific Justification



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## Risk Assessment

### Food safety risks

Risks associated with foods, drinks or animal feed



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### Pest or disease risks

- Evaluation of the probability of entry, establishment or dissemination
- As a function of the applied SPS measure
- Possible biological and economic consequences



Loss of production, costs of control or eradication, relative cost-effectiveness of alternative approaches

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## Consistency

Members **shall**

**Avoid arbitrary distinctions**



**in appropriate level of SPS protection (ALOP) considered in different situations**



**if distinctions result in discrimination or disguised restrictions on trade**



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## Least Trade-restrictive

Measures no more trade restrictive than necessary



To obtain the appropriate level of protection



Technically & economically feasible.

## Equivalence

If the exporting country objectively demonstrates that its measures achieve the same ALOP as the importing country



Members shall

Accept SPS measures of other Members as **equivalent**



## Pest or Disease Free Areas

Members **shall** take into account

of exporting  
AND  
importing  
regions

disease prevalence  
guidelines set by  
relevant international  
organizations  
existence of eradication  
programmes



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## Transparency

Members **shall**

Establish an Enquiry Point  
AND  
Designate a Notification Authority\_

Notify other Members of new or changed  
SPS regulations when



no international standard exists  
OR  
the new regulation is different  
than the international standard

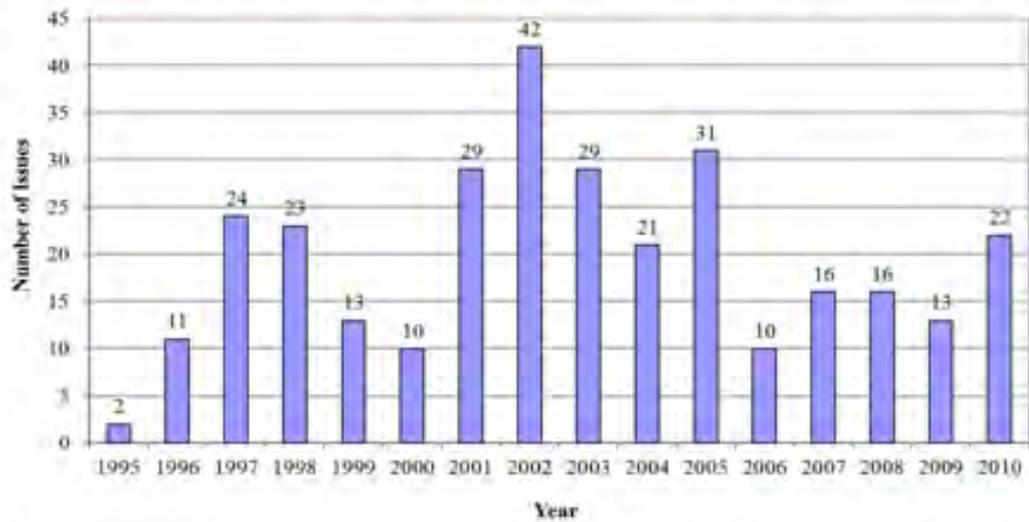
AND  
regulation may  
have significant  
effect on trade

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### Specific Trade Concerns (1995-2010)

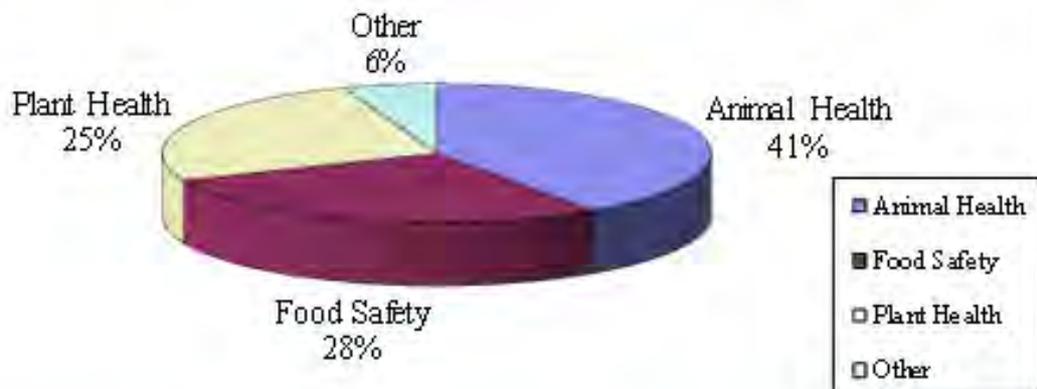


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### Trade Concerns by Subject (1995-2010)

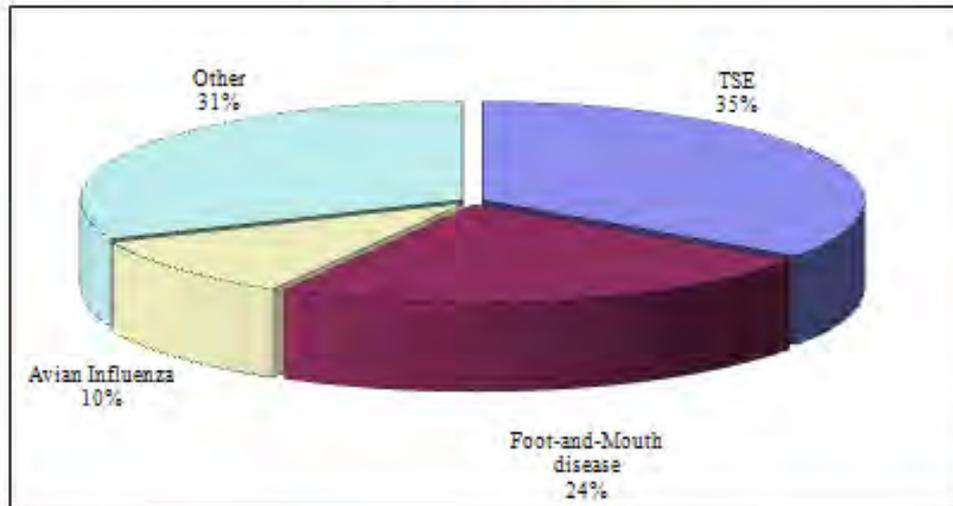


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### Specific Trade Concerns related to Animal Health and Zoonosis



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### Members with Measures Complained Against

Country	Number of measures
European Union	59
United States	28
Japan	22
Australia	16
China	14
Korea, Republic of	12
Brazil	10
Mexico	9
India	8

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## Members Raising Concerns

Country	Number of measures
United States	72
European Union	60
Argentina	33
Canada	22
China	20
Brazil	15
Thailand	9
Australia	8
Chile	7
Switzerland	5

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## Hazard Analysis Critical Control Point (HACCP)

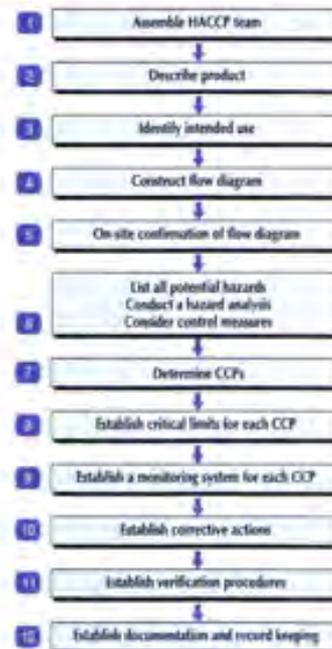
Summer 2012





**Hazard  
Analysis  
Critical  
Control  
Point**

- a system for the processing of safe food
- identifies specific hazards and preventive measures for their control
- requires team approach and full commitment of management and employees



- a dynamic system that can and shall be adjusted to new knowledge and experience
- adjusts to changes in product formulation, manufacturing design and intended use
- an alternative to the food chain from primary producer to the consumer
- applicable to all food producers, small companies as well as multinational food corporations.
- internationally accepted as the most effective system for the production of safe food

• **National Treatment Issues**



# Discussion

## Questions??



**For more information contact:**

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- **Mr. Saif Natiq, Deputy Team Leader**  
[snatiq@tijara-iraq.com](mailto:snatiq@tijara-iraq.com)

Chapter 2: HACCP ORIENTATION

HAZARD ANALYSIS  
AND  
CRITICAL CONTROL  
POINTS



**Why HACCP?**

## **Food**

- **Per capita annual consumption ~ 1,800 #s**
- **A very risky activity**
- **Consequences**
  - **Illness**
  - **Hospitalization**
  - **Death**

## **Consequences of Unsafe Food Production**

- **Illness, hospitalization, death**
- **Product recall, plant closure, job losses**
- **Regulatory action**
- **Fines**
- **Legal liability**

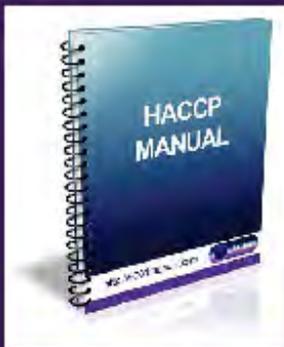
## Foodborne Disease in the U.S.

### Annual Estimated Incidence & Cost

- Foodborne diseases > 600 causes
- Cases: 6.5 - 81 million cases
- 323,000 hospitalizations
- Deaths: 525 - 9,000 deaths
- Costs: \$8 - 23 billion

## HACCP OVERVIEW

☞ HACCP is a tool to assess hazards and establish control systems that focus on preventive measures, rather than relying on end-product testing. HACCP is not a stand-alone program.



## **HACCP Concept**

- **Identifying potential food safety problems**
- **Determining how and where these can be controlled or prevented**
- **Describing what to do and training the personnel**
- **Implementation and recording**
- *All food safety records and data in one place*

## **History of HACCP**

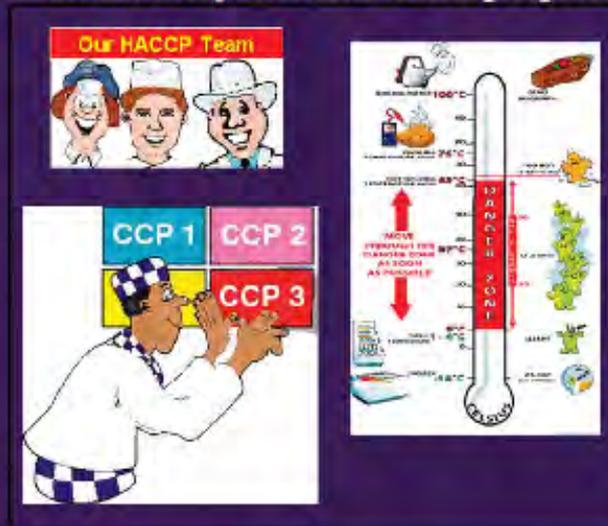
- **HACCP originated in the chemical processing industry, particularly in Great Britain, over sixty years ago.**
- **Then in the 1950's and 60's the US atomic energy commission made extensive use of the HACCP principles to design nuclear power plants.**

## History of HACCP

- **The modern concept of HACCP was developed during space missions in the 1960's by the U.S. Army Laboratories and NASA, mainly to prevent their astronauts from getting sick from the food they were eating in space.**
- **The Pillsbury Company, which was the manufacturer of the food, applied HACCP principles to its food operations to ensure the safety of its products.**

- ♦ **The HACCP system is a logical scientific approach, including the HACCP plan, to controlling safety problems in food production.**
- ♦ **The HACCP plan is a written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.**

- **HACCP plans reflect:**
  - The uniqueness of a food.
  - Its method of processing, and
  - The facility in which it is prepared.



## THE HACCP Food Safety Assurance Pyramid



## VERIFICATION OF HACCP PREREQUISITE PROGRAMS



## PURPOSE OF VERIFICATION

...To Insure that safe food handling practices are Implemented and Maintained

...Practices are Effective in Achieving the Goal of Producing Safe Foods



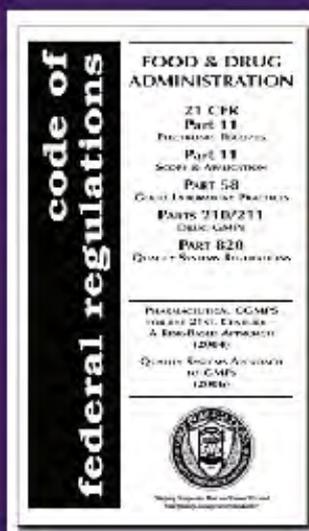
## GOOD MANUFACTURING PRACTICES (GMPS) IN MANUFACTURE, PACKING, OR HOLDING HUMAN FOODS

Originally Published by FDA on April 26, 1969

Major Portion of Regulations Dealing with Food Quality is Included in GMPs



## GMP REGULATIONS



Deal Primarily with Sanitation in Manufacturing Processing, Packing, or Holding Human Food

Established to Define in Clearer Terms What FDA Expects from Food Plants In Order to Meet Provisions of Food, Drug & Cosmetic Act

... Section 402 (a) (4)



## GMPS REGULATIONS

☞ Represent Minimal Sanitary Requirements

... Establishes Basic Rules for Sanitation  
in Food Establishment



## GMPS REGULATIONS

☞ Divided into Several Subparts

... Each Contains Detailed Requirements  
Pertaining to Various Operations or  
Groups of Operations in Food  
Processing Facilities



## GMPS

- ☞ Subpart A - General Provisions
- ☞ Subpart B - Buildings and Facilities
- ☞ Subpart C - Equipment
- ☞ Subpart E - Production and Process Controls
- ☞ Subpart G - Defect Action Levels



## A. GENERAL PROVISIONS

Defines Terms Used in the Regulations in Order to Minimize Misunderstanding

## GENERAL PROVISIONS

### ☞ Summary of Responsibilities Imposed on Plant Management Regarding Plant Personnel

... Criteria for

☞ Disease Control

☞ Cleanliness

... Personal Hygiene

... Dress Code

☞ Education and Training

☞ Supervision



## PURPOSE OF REQUIREMENTS

### ☞ Prevent Spread of Disease

... Worker to Worker

... Workers to Food Processing Area

... Workers to Food Itself



## B. BUILDINGS AND FACILITIES



⌘ Plants and Grounds

⌘ Sanitary Operations

⌘ Sanitary Facilities and Controls

## PLANTS AND GROUNDS



⌘ Methods for Adequate Maintenance of Grounds

⌘ General Principles of Plant Design and Construction Necessary to Protect Foods from Insanitary Conditions

... Recommendations for Separation of Various Operations to Reduce Food Contamination

... Adequate Working Space, Lighting and Ventilation are Required



## SANITARY OPERATIONS



- ☞ Basic Rules for Food Plant Sanitation
  - ... Describe General Requirements for
    - ☞ Maintenance of Physical Facilities
      - ... Building and Equipment
    - ☞ Pest Control
    - ☞ Cleaning and Sanitizing of Equipment and Utensils
    - ☞ Storage and Holding of Cleaned Equipment and Utensil
- ☞ Basic Rules for Food Plant Sanitation
  - ... Proper Use and Storage of Cleaning Compounds, Sanitizers, & Pesticides



## SANITARY FACILITIES AND CONTROLS

- ☞ Minimum Requirements for Sanitary Facilities and Accommodations
  - ... Water
  - ... Plumbing
  - ... Sewage Disposal
  - ... Toilet and Hand-washing Facilities and Supplies
  - ... Rubbish and Offal Disposal





## EQUIPMENT

- ⌘ General Principles of Design, Construction, and Maintenance of Processing Equipment and Utensils - Cleanability is Emphasized
- ⌘ Requirements for Compressed Air and Other Gases Used in Food Processing

## E. PRODUCTION AND PROCESS CONTROLS

- ⌘ Contains Most Detailed Requirements
- ⌘ Rules to Assure the Suitability of Raw Ingredients

**Maintain Integrity of Processed Foods**  
**Protect Finished Foods from Deterioration**

## PROCESS AND CONTROLS SECTION

### ☞ Requires That All Operations Involving Foods

... “Be Conducted in Accordance with Adequate Sanitation Principles” Plant Sanitation

... “Be Under the Supervision of One or More Individuals Assigned Responsibility for this Function”

### ☞ Quality Control Programs

... Required to Insure Compliance with Sanitation Principles and with the FD&C Act



## RAW MATERIALS AND INGREDIENTS SUBSECTION

### ☞ Descriptions of Required Methods and Procedures to Insure Cleanliness and Fitness of These Materials

... Must Not Contain Levels of Microorganisms That Can Cause Foodborne Illness

... Treat Properly to Destroy Pathogens

... Compliance with Regulations on Natural Toxins and Extraneous Materials



## WAREHOUSING AND DISTRIBUTION

☞ Requires that Storage and Transportation of Finished Food

... Be Conducted Under Conditions that Prevent Physical, Chemical and Microbiological Contamination



## G. DEFECT ACTION LEVELS

Defect Levels

Handbook

The Food Defect Action

Levels

Levels of natural or unavoidable defects in foods

foods

that present no health

hazards for humans

http://www.fda.gov/food/guidances/default.htm#q

intended for marketing and

consumption under conditions

as intended for use

☞ Natural or Unavoidable Defects Which Occur in Some Foods

☞ One Time Referred to as Unavoidable Defects Levels

## DEFECT ACTION LEVELS



☞ Current Level of Defects Permitted

... Based Largely on Industry's Ability to Reduce Levels Occurring in Raw Product Through GMP

... Action Level Limit At or Above Which FDA May Take Legal Action to Remove the Commodities from Consumer Market

☞ Cannot be Used as an Excuse for Poor Manufacturing Practices



## SANITATION STANDARD OPERATING PROCEDURES (SSOPS)

⌘ All Federally Inspected Meat and Poultry Plants must have Written SSOPs to Show How They Will Meet Basic Sanitation requirements Every Day

⌘ Each Plant Must Assume Responsibility for Identifying and Addressing Sanitation Deficiencies

## SANITATION STANDARD OPERATING PROCEDURES (SSOP)



- ☞ Plants Will Document and Maintain Daily Records of
  - ... Completed Sanitation Procedures
  - ... Corrective and Preventive Actions
- ☞ Records Will Be Made Available to USDA Inspectors for Review and Verification



## PERIODIC INSPECTION TASKS

- ☞ Verifying SSOPs Meet Regulation's Requirements
- ☞ SSOPs are Implemented and Maintained
- ☞ SSOPs are Effective in Producing Sanitary Conditions





## SSOP

- ☞ Describes How Plant Will Meet Basic Sanitation Requirements Every Day
- ☞ Document and Maintain Daily Records of Completed Sanitation Procedures, Correction and Preventive Actions
- ... Make Available to USDA Inspector for Review and Verification



## PARTS OF SSOPS

- ☞ Pre-operational Sanitation
- ☞ Operational Sanitation
- ☞ Implementing and Monitoring SSOPs
- ☞ Corrective Actions



## PRE-OPERATIONAL SANITATION

⌘ Describe Daily, Routine Pre-Operational Sanitary Procedures to Prevent Direct Product Contamination or Adulteration

*Include Cleaning of Product Contact Surfaces of Facilities, Equipment and Utensils*

## ADDITIONAL SANITARY PROCEDURES



- ⌘ Descriptions of
  - ... Equipment Disassembly
  - ... Equipment Reassembly After Cleaning
  - ... Cleaning Techniques
- ⌘ Use of Acceptable Chemicals According to Label Directions



## OPERATIONAL SANITATION

⌘ Describe Daily, Routine Sanitary Procedures That the Establishment Will Conduct During Operations to Prevent Direct Product Contamination or Adulteration



## OPERATIONAL PROCEDURES

- ⌘ Cleaning, Sanitizing, and Disinfecting Equipment and Utensil
  - ... During Production
  - ... As Appropriate
    - ⌘ At Breaks
    - ⌘ Between Shifts
    - ⌘ At Mid-shift Cleanup
- ⌘ Product Handling in Raw and in Cooked Product Areas



## OPERATIONAL SANITATION



### ☞ Employee Hygiene

- ... Personal Hygiene
- ... Cleanliness of Outer Garments and Gloves
- ... Hair Restraints
- ... Hand Washing
- ... Health



## IMPLEMENTING AND MONITORING SSOP

- ⌘ Specify Method, Frequency, and Record-keeping Processes Associated With Monitoring
- ⌘ Identify Establishment Positions Responsible for Implementation and Maintenance of SSOP
- ⌘ Identify Employees/Positions to Monitor and Evaluate Effectiveness of SSOP

## PRE-OPERATIONAL SANITATION MONITORING

- ☞ Evaluate and Document the Effective Cleaning of All Direct Product Contact Facilities, Equipment, and/or Utensils That Are to Be Used at Start of Production



## OPERATIONAL SANITATION MONITORING

- ☞ Document Adherence to SOP
  - ... Actions That Identify and Correct Instances or Circumstances of Direct Product Contamination Which Occur From
    - ☞ Environmental Sources (Facilities, Equipment, Pests, etc.)
    - ☞ Employee Practices (Personal Hygiene, Product Handling, etc.)

## CORRECTIVE ACTIONS



⌘ Action Taken To Correct and Prevent Direct Product Contamination or Adulteration When Deviations Occur

⌘ Provide Instructions to Employees and Management Officials for Documenting Corrective Actions

⌘ Actions Must Be Recorded

## VERIFICATION

⌘ FSIS Inspectors

*Review SSOP's*

*Daily Records*

⌘ Conduct of Procedures Specified in SSOP's

*Sanitary Conditions Themselves*



# QUESTIONS?



## Five Preliminary HACCP Steps

- ☞ **STEP 1: Bring Together HACCP Resources Including the HACCP Team.**
  - ... **The HACCP team is a group of people who are responsible for developing a HACCP plan.**
  - ... **The team should consist of individuals who have specific knowledge and expertise appropriate to the product and process.**
  - ... **The HACCP team should be multi-disciplinary.**

## STEP 1: Bring Together HACCP Resources Including the HACCP Team.

- ∅ Outside experts who are knowledgeable in public health associated with the product and process may be required.
- ∅ There is no specific number of individuals required for the HACCP team - in very small plants, the HACCP team may only consist of one or two individuals.

## HACCP Team Members

- ∅ The HACCP team members should have the knowledge and experience to correctly:
  - ... Identify potential hazards;
  - ... Recommend controls, criteria, and procedures for monitoring and verification;
  - ... Recommend appropriate corrective actions when a deviation occurs;
  - ... Recommend research related to the HACCP plan if important information is not known; and
  - ... Predict the success of the HACCP plan.

## **Step 2: Describe The Product and Its Method of Distribution**

- ∅ Give the common name.
- ∅ Describe how it is to be used.
- ∅ Describe how it is packaged.
- ∅ Tell the shelf life and at what temperature.
- ∅ Describe where it will be sold.
- ∅ Describe labeling instructions.
- ∅ Describe special distribution controls that are needed.

## **MEAT PRODUCT CATEGORIES**

- ∅ Raw Ground Meat and Poultry Products
- ∅ Beef Slaughter, Pork Slaughter, and Poultry Slaughter.
- ∅ Mechanically Separated (Species)/Mechanically Deboned Poultry
- ∅ Thermally Processed Commercially Sterile Meat and Poultry
- ∅ Irradiation

## MEAT PRODUCT CATEGORIES

- Ø Meat and Poultry Products with Secondary Inhibitors, Not Shelf Stable
- Ø Heat Treated, Shelf Stable Meat and Poultry Products
- Ø Not Shelf Stable Heat Treated, Not Fully Cooked, Meat and Poultry Products
- Ø Fully Cooked, Not Shelf Stable Meat and Poultry Products
- Ø Not Heat Treated, Shelf Stable Meat and Poultry Products

### *Product Description*

*Product Category: Raw, Ground*

*Product Example: Ground Beef*

**THE FOLLOWING QUESTIONS NEED TO BE ANSWERED WHEN DEVELOPING THE PRODUCT DESCRIPTION:**

- |   |  |
|---|--|
| 1. COMMON NAME?                               | Ground Beef  |
| 2. HOW IS IT USED?                            | Cooked and consumed.   |
| 3. TYPE OF PACKAGE?                           | Bulk-packed (e.g., plastic bag, vacuum packaged), layer or stack packed, pattie packed.  |
| 4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE? | 3-6 months at 0 °F or below, 7 days at 40 °F.  |
| 5. WHERE WILL IT BE SOLD? CONSUMERS?          | Retail and HRI, wholesale General public - may include hospitals.  |
| 6. LABELING INSTRUCTIONS?                     | KEEP FROZEN; COOKING INSTRUCTIONS (Minimum Internal Temperature for Cooking); THAWING INSTRUCTIONS; KEEP REFRIGERATED; SAFE FOOD HANDLING LABEL. |
| 7. IS SPECIAL DISTRIBUTION CONTROL NEEDED?    | KEEP FROZEN, KEEP REFRIGERATED.  |

DATE: \_\_\_\_\_ APPROVED BY: \_\_\_\_\_

## STEP 3: Develop a Complete List of All Ingredients and Raw Materials Used in the Product.

- ∅ The list should include all of the meat items used in the product.
- ∅ Each non-meat ingredient should be listed individually. Pre-blended items may be listed by blend (mix) name.



### Product & Ingredients

*PRODUCT CATEGORY:*

*Raw, Ground*

*PRODUCT EXAMPLE:*

*Fresh Pork Sausage*

#### ∅ MEAT

- ... Pork shoulder
- ... Pork trimmings
- ... Edible casings



#### ∅ INGREDIENTS

- ... Water
- ... Salt
- ... Spice mix
- ... Sugar

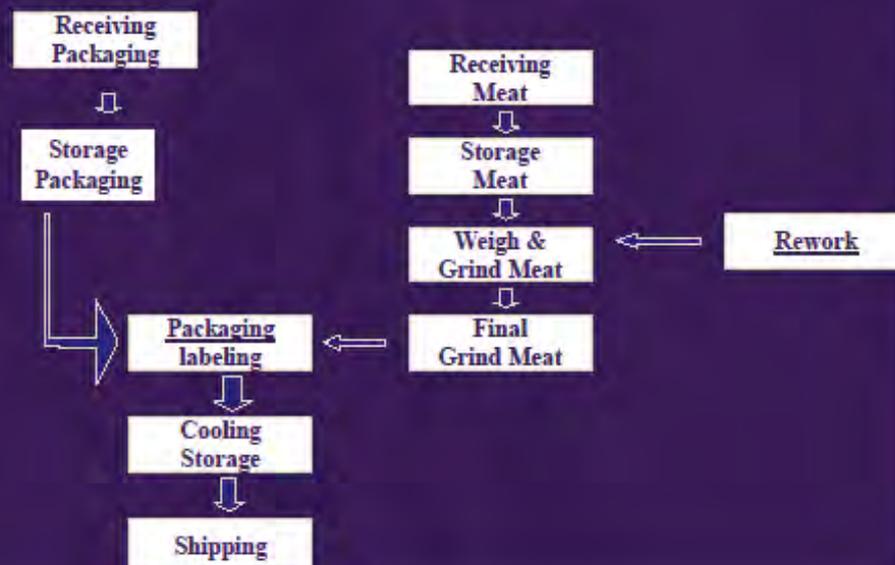


## STEP 4: Develop A Process Flow Diagram.

- ∞ The process flow diagram should include ALL of the steps involved in the preparation of the product from receiving to shipping.
- ∞ The purpose of the process flow diagram is to provide a clear and simple description of ALL steps involved in the process, and to serve as a guide in performing the process hazard analysis in HACCP Principle 1.

### PROCESS FLOW DIAGRAM

PROCESS CATEGORY: Raw, Ground  
PRODUCT: Ground Beef



## **STEP 5: Verify The Process Flow Diagram**

- ☞ The HACCP team should review (walk through) the operation to verify the accuracy and completeness of the flow diagram.
- ☞ It may be helpful to have someone not familiar with the operation, who may see a step that the HACCP team does not, accompany the HACCP team.

## **The 7 Principles of HACCP**

## The 7 Principles of HACCP

1. Conduct a Hazard Analysis
2. Identify Critical Control Points
3. Establish Critical Limits for each CCP
4. Establish CCP Monitoring Requirements
5. Establish Corrective Actions
6. Establish Record Keeping Procedures
7. Verify the HACCP Plan is working

### Principle # 1

#### ☞ CONDUCT A HAZARD ANALYSIS

#### ☞ Flow chart

#### ☞ Identify areas within the flow chart where significant hazards can occur

... Chemical

... Physical

... Biological

#### ☞ Describe preventative measures

## HAZARD

- ⌘ Unacceptable Contamination of Biological, Chemical or Physical Nature
- ⌘ Unacceptable Production or Persistence in Foods of Toxins or other Undesirable Products of Microbial Metabolism
- ⌘ Is it reasonably likely to occur?

## Types of Hazards

### ⌘ Biological

#### ... Infectious or Toxigenic Organisms

- ⌘ Bacteria, Rickettsia, Viruses, Molds
- ⌘ Parasites
- ⌘ Toxic Plants
- ⌘ Fish and Shellfish
- ⌘ Allergenic ingredients

32 3333 3333

3 Determine Hazardous Biological Agents  
Inherently Associated With Any Ingredients

- ... *Salmonella* in Raw Chicken
- ... Various Pathogens in Raw Milk
- ... *Listeria* in Raw Meat
- ... *C. Botulinum* in Vegetables
- ... Histamine in Fish With High Histidine Levels
- ... Various Pathogens and Parasites in Untreated Water

32 3333 3333

3 Are Any Ingredients or Finished  
Product Capable of Supporting  
Pathogens or Otherwise  
Susceptible to Biological Hazards  
Due to Contamination or  
Mishandling?





التهديدات الكيميائية الزراعية والمواد الكيميائية المحظورة

☞ **الكيمياء الزراعية**

- ... مبيدات
- ... فطريات
- ... أسمدة
- ... مبيدات الحشرات
- ... مضادات حيوية
- ... هرمونات النمو

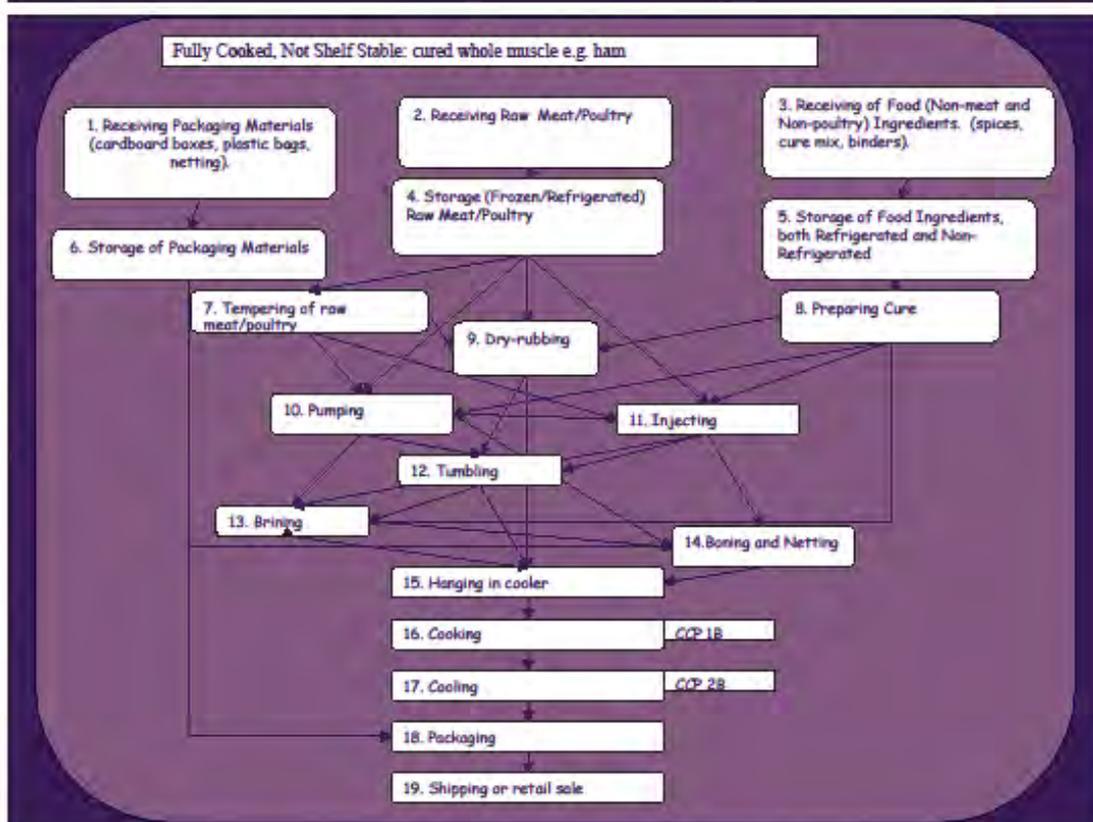
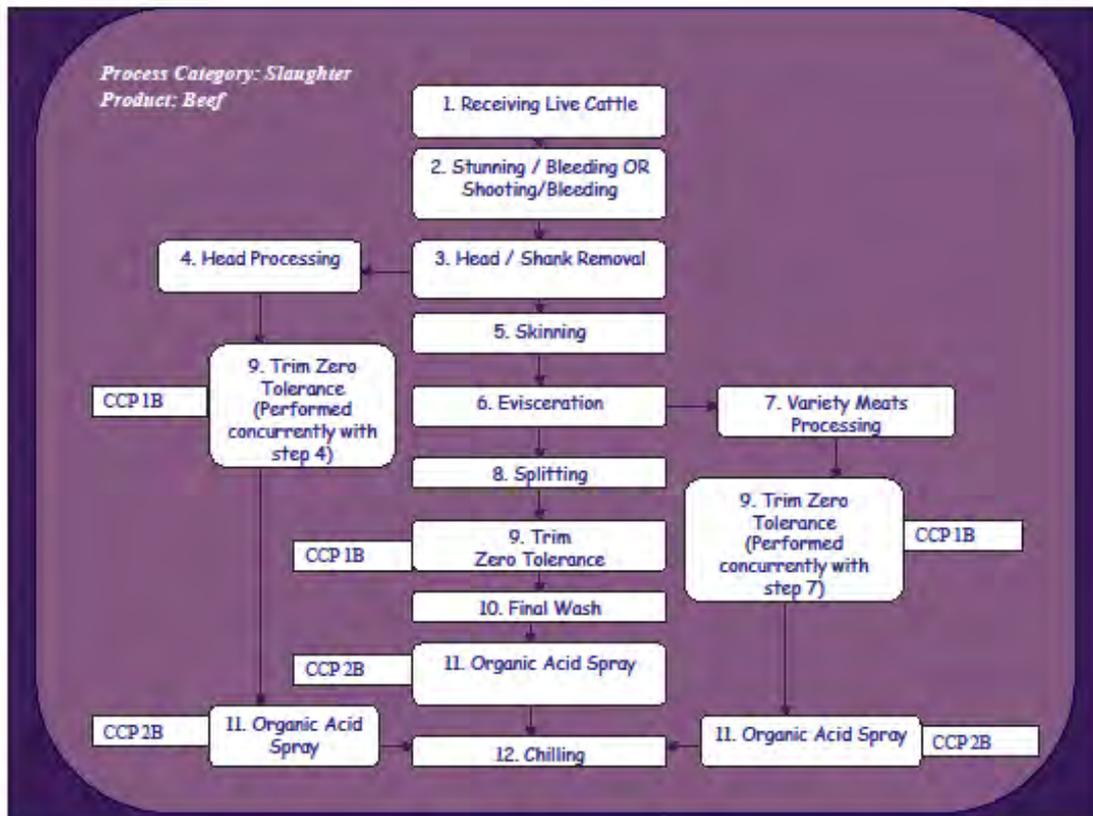
☞ **المواد المحظورة**

- ☞ **عناصر سامة ومركبات**
- ☞ **مكونات غذائية**
- ☞ **مكونات لونية**
- ☞ **مواد كيميائية مضافة عمداً**

**أنواع المخاطر**

☞ **فيزيائية**

- ... **أجزاء معدنية**
- ... **زجاج**
- ... **شظايا خشب**
- ... **حجارة**



**HAZARD ANALYSIS – BEEF SLAUGHTER – Carcass halves and quarters, head meat, heart, liver, tongue**

1. Process Step	2. Food Safety Hazard	3. Reasonably likely to occur	4. Basis of Reasonably likely to occur	5. If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	6. Critical Control Point
1. Receiving live cattle	Biological - Pathogens (Salmonella, Escherichia coli O157:H7) carried on hide and in intestinal tract., Prions (if animal has BSE).	Yes (Pathogens) No (Prions)	Cattle are a known source of Salmonella. Elder et al data (supplied by FSIS) states that E. coli O157:H7 is reasonably likely to occur in beef cattle. Non-ambulatory animals are not accepted for slaughter, per 9 CFR 309.3(e).	Trim Zero Tolerance and Organic Acid Spray steps (CCP's later in the process) control pathogens.	
	Chemical - Drug residues	No	Low risk according to USDA Residue Monitoring Program		
	Physical - Buckshot, needles, bullets	No	No reported incidences at this facility (must be supported with evidence); visual observation for foreign materials during processing, inspection of equipment during cleaning make hazard unlikely.		

## Principle #2

### IDENTIFY THE CRITICAL CONTROL POINTS IN THE PROCESS

- ... Control Point = any step where biological, physical, or chemical contamination can occur
- ... Critical Control Point = a step in the flow chart where control can be applied to prevent, eliminate, or reduce to acceptable levels

## Principle #2

- CCP decision tree
- A series of questions
- Example:
- Q1. Do preventative measures exist?

Yes

No; not a CCP

Q2. Does this step eliminate or reduce the likely occurrence of a hazard to an acceptable level?

Yes

No; not a CCP

## Principle #2

Q3. Could contamination with identified hazard occur in excess of acceptable levels or could these increase to unacceptable levels?

Yes

No; not a CCP

Q4. Will subsequent step, prior to consuming food eliminate hazard or reduce?

Yes, not a CCP

No; a CCP

## What do you mean “Control Point”?

### ☞ Examples of Control Points

- ... Temperature
- ... Pasteurizers
- ... Canning Retorts
- ... pH (acidification)
- ... Water Activity (Aw)
- ... Magnets for metal fragments
- ... Cooking

## Principle # 3

### ☞ ESTABLISH CRITICAL LIMITS FOR EACH CCP

- ... Minimum or maximum
- ... Temperature
- ... PPM, PPB
- ... Logs/ CFU
- ... Zero Tolerance

## Principle # 3

☞ These values must be backed up by science

- ... Peer-reviewed Papers
- ... CFR or other government documents
- ... Appendix A & B
- ... Validation studies

☞ The internet can be a good source, but make sure they fit into the above criteria

## Principle # 4

☞ ESTABLISH CCP MONITORING REQUIREMENTS

- ... Above or below a temperature
- ... Time; cooking time
- ... Physical measurements; pH, Aw, Logs/CFU, salt content
- ... Frequency of monitoring
- ... Documentation for each
- ... Lot testing

## Principle No. 4

- ☞ Establish Procedures for Monitoring and Using the Results of Monitoring to adjust the Process and Maintain Control

### Monitoring Critical Control Point Critical Limits

- ☞ What is monitoring?
- ☞ Why do we monitor?
- ☞ How do we monitor?
- ☞ Where do we monitor?
- ☞ Who monitors?
- ☞ When do we monitor?

## Monitoring

- ∞ Planned Sequence of Observations or Measurements to assess Whether a Processing or Handling Procedure at each CCP is Under Control

## Purposes of Monitoring

- ∞ Tracks System's Operation
  - ... Essential to Food Safety management
- ∞ Determines Loss of Control and Deviation at a CCP
- ∞ Provides Written Documentation for Use in Verification of HACCP Plan

## Examples of Monitoring

- ☞ Visual Observation
- ☞ Temperature
- ☞ pH
- ☞ Salt Concentration
- ☞ Moisture Levels
- ☞ Food Sample analysis

## Examples of Monitoring

- ☞ Visual Observations
  - ... Handling Practices
  - ... Cleaning Procedures
  - ... Physical Hazards
- ☞ Measurements
  - ... Time/Temperature
  - ... pH
  - ... Water Activity
  - ... Detergent/Sanitizer Concentration
  - ... Container/Package Condition

## Where do we Monitor?

- ☞ At the CCP location or vicinity

## Types of Monitoring

- ☞ Continuous Monitoring – constant surveillance of CCP's
  - ... Temperature
- ☞ Discontinuous Monitoring – intermittent surveillance of CCP's
  - ... Statistical Testing
  - ... Lot Testing

## What is a Lot?

∞ Lots can be:

- ... A months production
- ... A weeks production
- ... A days production
- ... A shifts production
- ... An hours production
- ... A carcass or an individual item

## Some tips

∞ Continuous Monitoring

- ... Temperature loggers, pH, etc

∞ Discontinuous Monitoring

- ... Find the coldest spot in your smokehouse, cooker, etc
- ... Monitor the temperature in the largest item
- ... The warmest part of the cooler or the location that has the least air flow

## Principle # 5

### ☞ ESTABLISH CORECTIVE ACTIONS

#### ☞ What will you do if CCP is “out”

... Temperature; could leave until temperature is reached (HOLD)

... Bacterial; “tank”, “new home”, find ways to reduce numbers

#### ☞ Modify step

## Principle #6

### ☞ ESTABLISH RECORDKEEPING PROCEDURES

#### ☞ Proves the system is working

#### ☞ All should contain:

... Title

... Date

... Product

... Operation

... Limits

... Corrective action taken

... Name

## Principle # 5

### ☞ ESTABLISH CORECTIVE ACTIONS

#### ☞ What will you do if CCP is “out”

... Temperature; could leave until temperature is reached (HOLD)

... Bacterial; “tank”, “new home”, find ways to reduce numbers

#### ☞ Modify step

## Principle #6

### ☞ ESTABLISH RECORDKEEPING PROCEDURES

☞ Proves the system is working

☞ All should contain:

... Title

... Date

... Product

... Operation

... Limits

... Corrective action taken

... Name

## **Principle #6**

### **☞ Why?**

... Evidence

### **☞ Types?**

... CCP Records

... Establishment of Critical Limits

... Monitoring CCP

... Deviations

## **Principle #7**

### **☞ VERIFICATION THAT THE HACCP SYSTEM IS WORKING**

... Evaluate

... Revise

... Review

### **☞ External Verification**

... USDA-FSIS (EIAO)

## FOOD SAFETY MODERNIZATION ACT(FSMA)



January 2011

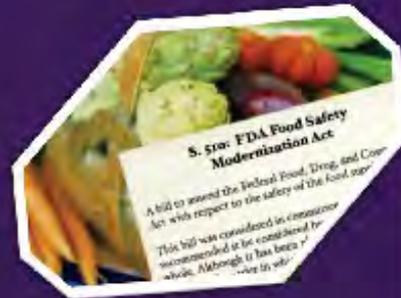


The FSMA is the first major amendment in almost 75 years to the food safety regulations of the Food Drug and Cosmetic Act (FD&C)



✎ The FSMA governs food products regulated by the FDA; it does not apply to meat, poultry or egg products regulated by the USDA. The new law grants additional power to, and also places additional requirements on, the FDA

- ☞ Mandatory Recalls Authority
- ☞ Inspections
- ☞ Administrative Detentions
- ☞ Facility Registration
- ☞ Suspension of Registration
- ☞ Imported Products
- ☞ Import Certification
- ☞ Performance Standards
- ☞ Develop and Implement HACCP plans



## Imported Products

- ☞ Food importers must perform risk based foreign supplier verification activities to verify that the food imported is not adulterated.

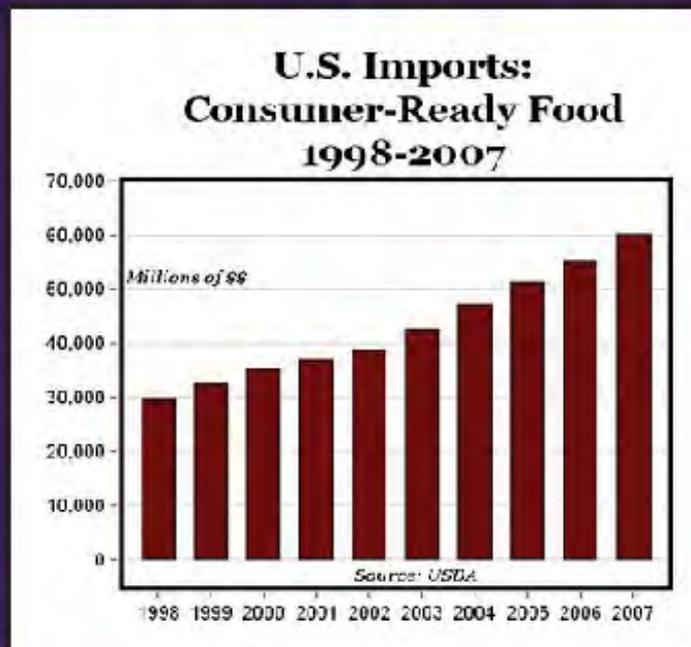
☞ **Effective January 2013.**

## Import Certification



☞ FDA may require importers to provide a safety certification from an accredited third-party auditor as a condition of granting admission.

## Importance of Imported Food



## Traceability Door is Open?



Although the new law doesn't establish new traceability requirements for food ingredients it directs FDA to collaborate with food manufactures to develop mechanisms to rapidly identify recipients of food that may have been contaminated.

Paving the way for future traceability requirements

## Questions



### Chapter 3: TECHNICAL TRAINING IN GAP

# On-farm Food Safety: Guide to Good Agricultural Practices (GAPs)

Safe produce begins with the production and handling practices on the farm. Produce that is grown and sold with little biological contamination is less likely to result in health hazards caused by poor handling during later preparation stages. Producers and their employees have the critical job of minimizing product contamination by learning about potential sources of contamination and by using Good Agricultural Practices (GAPs).

Food safety concerns are increasing as once unheard of illness-causing microorganisms become more prevalent and as products previously considered safe cause an increasing number of illnesses each year. Produce, recently thought of as a safe product, has been identified as a cause of major foodborne illness outbreaks in recent years.

Illnesses are primarily caused by bacteria, viruses, parasites, and fungi. These microorganisms, often referred to as pathogens or biological hazards, also are associated with ground beef, poultry, eggs, and seafood. Cooking is a common method of easily killing most pathogens in those foods. However, fresh produce is often consumed raw.

In addition, produce is exposed to naturally occurring, biological hazards in the soil, water, and air. The potential risk for contamination is increased by production practices using manure for fertilizer and human handling of products.

Developing a safety plan helps food producers manage the safety component of their operation by organizing the action steps identified as key to reducing those risks. Documenting of current practices and any changes over time allows for monitoring the safety of the food product.

This publication provides some background about GAPs and how they relate to the development of a food safety plan. Resources for other produce production GAPs and food safety information also are provided.

## Good Agricultural Practices (GAPs)

Good Agricultural Practices, more commonly referred to as GAPs, are a set of recommendations that can help improve the quality and safety of the produce grown. These general guidelines can be adapted and/or incorporated into any production system. GAPs focus on four primary components of production and processing: soil, water, hands, and surfaces.

**Soil**—Maintaining “clean soil” reduces the risk of contaminating produce with illness-causing microorganisms found in soil during stages of growth and harvesting. Illness-causing microbes always are present in the soil, but their populations and resulting risk of product contamination can be increased tremendously by improper manure management and application.

Although manure is a good form of fertilizer, all manure contains pathogens. Some pathogen levels in the soil will decrease over time due to competition from other bacteria in the soil or because of less-than-desirable conditions.

PM 1974a      October 2004

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## GAPs improve the quality and safety of your produce

The following steps are recommended to minimize risks from manure.

**Hands**—Having “clean hands” refers to the human element involved in food safety during production and processing. The food producer and handler each have an important role in ensuring the safety and quality of foods grown and processed. Poor hygiene and health, unclean clothing or shoes, or unsafe practices on the part of workers can threaten food safety. Providing clean and appropriately stocked rest-room and handwashing facilities to field and processing employees helps prevent product contamination. A lack of restrooms results in unnecessary product contaminants in the field. The publication “On-farm Food Safety: Guide to Food Handling” (PM 1974b) provides more details about managing the human impact on product quality and safety.

**Surfaces**—Produce items will have physical contact with many surfaces during harvest and processing. These may include harvest equipment and containers, transport bins, knives and other utensils, sorting and packaging tables, product packaging, and storage areas. Basic GAPs to help ensure clean surfaces include the following:

- Keep potential contaminants, such as soil and manure, out of the processing area or facility.
- Cull soiled produce in the field and damaged produce prior to processing.
- Use plastic containers and totes that are suitable for routine and efficient cleaning and sanitizing.
- Clean and sanitize equipment and facilities daily.
- Consider including a sanitizer in produce rinse water to reduce bacterial contamination.
- Control animal contamination sources, including pets, wildlife, birds, insects, and rodents.
- Develop guidelines for product storage and transportation.

•••

Incorporate manure or use cover mulch after application to reduce the risk of physical contamination of product from rain or irrigation splash.

Reduce microbes through high temperature, aerobic composting. Apply manure to cover crops in the fall.

Apply manure in the spring two weeks before planting and preferably on grain crops or perennials. Allow a minimum of 120 days between manure application and fruit or vegetable harvest.

**Water**—Water used for irrigation, cooling, processing, or for cleaning equipment and facilities should be free of microbial contaminants. Water quality and safety can be dependent on the water source. Municipal water usually has the best quality because of previous testing and safety requirements. Ground or well water will have fewer pathogens than surface water (such as ponds, streams, or rivers) because there is less chance of contamination.

Regularly testing water sources provides documentation that the water is not a source of contamination. The frequency of water testing is dependent on the type of water source and the time of year. Water quality becomes more important as harvest approaches and water contact with the product occurs or increases.

The method and timing of water use also has an effect on its contribution to product contamination. Using drip irrigation instead of sprinklers helps prevent contamination from soil splash and from product contact.

Management steps that are taken to improve product quality can also improve product safety. Product spoilage also is caused by bacteria and molds, so whatever practices are implemented to control product loss from spoilage also will control pathogens. Refer to the publication “On-farm Food Safety: Guide to Cleaning and Sanitizing” (PM 1974c) for additional information about appropriate cleaning and sanitizing procedures.

## Food Safety Plan

The food safety plan developed for your operation is a roadmap for actively reducing risks that may jeopardize product safety. The plan also includes checkpoints and monitoring mechanisms to verify that the steps taken or changes made actually help maintain or improve product quality and safety. A comprehensive food safety plan describes procedures for all aspects of production and processing, including manure management; water management; product handling; cleaning and sanitation; employee training; and crisis management.

**Developing a plan**—The best way to start developing a food safety plan is to review your current production practices.

1. Start by listing the steps from preparation for planting to post-packaging product handling.
2. During this assessment, identify areas where product quality and safety may be affected.
3. Identify how you can measure or monitor this risk. Various audit forms have been developed. Refer to the reference list at the end of this material for specific Internet addresses of these resources.
4. Once areas of potential product safety problems have been identified, the next step is to modify your practices to reduce or eliminate these risks. Consider modifications that will reduce risks and are economically feasible. Keep in mind the cost may be more than the initial monetary investment to make the change; it also can include time to implement, time to perform once implemented, recurring costs of new practices, and can affect efficiency.
5. While making modifications to reduce contamination risks, document all steps of the changes, including how practices were previously carried out, what the changes included, and how you will measure or monitor the potential risk. See the following scenario for an example.

**Updating the food safety plan**— Having a food safety plan in place is a good first step, but just like a business or marketing plan, the food safety plan requires revisions and updates to stay current with your operation.

## A food safety plan documents your risk reduction efforts

The best time to give your food safety plan a thorough review is during the off season when you are preparing for your next growing season. Part of this review is looking at the monitoring or tracking records kept from the previous year. These documents can help identify areas needing improvement going into the next growing season.

As you make changes to your operation based on the previous year's experience, be sure to update your food safety plan. The plan then serves as a written guide or reference.

Changes to the plan, however, can and should be made anytime throughout the year. If something occurs during the season that causes changes in your operating practices, then change your food safety plan too.

**Sample Food Safety Plan Steps 1-2.** While assessing your storage facility, you identify the cold storage temperature as a potential risk of promoting bacterial growth.

**Step 3.** Measuring and recording the temperature routinely is a way of monitoring this risk.

**Steps 4-5.** Start monitoring and recording temperatures. This is a modification that easily can be implemented with minimal expense and time commitment.

**Benefits of a Food Safety Plan** • Provides operational roadmap for food safety risk reduction • Offers mechanism for monitoring effectiveness of changes to improve product safety and quality

- Provides structure through which assessment of an operation can occur
- Creates a documentation process to verify production and processing changes
- Serves as a reference for all employees during training and throughout the season

**Summary:** Producers and their employees have the critical job of minimizing product contamination by learning about potential sources of contamination and by using Good Agricultural Practices (GAPs).

After identifying the risks that may exist within a producer's specific operation, a series of action steps can be developed to measure, monitor, and, if necessary, modify procedures designed to reduce these risks.

By using a food safety plan that tracks and documents procedures, a producer has a series of records that demonstrates progress toward the reduction of risks for the operation.

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### References and Resources

More information about general produce food safety, GAPs, and food safety plans is available at the following Web sites.

Local Foods: From Farm to Foodservice, Hotel, Restaurant, and Institution Management, Extension, Iowa State University <http://www.extension.iastate.edu/hrim/localfoods>

Foodborne Illness Education Information Center, USDA/FDA

<http://peaches.nal.usda.gov/foodborne/fbindex/Produce.asp>

FoodSafe Program, University of California, Davis

<http://foodsafety.ucdavis.edu>

Good Agricultural Practices, New England Extension Food Safety Consortium

<http://www.hort.uconn.edu/IPM/foodsafety/index.htm>

Good Agricultural Practices, University of California

[http://groups.ucanr.org/UC\\_GAPs/](http://groups.ucanr.org/UC_GAPs/)

Good Agricultural Practices Project, Cornell University

<http://www.gaps.cornell.edu>

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration <http://vm.cfsan.fda.gov/~dms/prodguid.html>

HACCP: Hazard Analysis Critical Control Point Information Center, Iowa State University Extension

<http://www.iowahaccp.iastate.edu/sections/farmfoodsafety.cfm?action=resources>

ISU Extension publications-

<http://www.extension.iastate.edu/pubs>

On-Farm Food Safety for Fruit and Vegetable Growers, Ministry of Agriculture and Food, Ontario, Canada

<http://www.gov.on.ca/OMAFRA/english/offers/growers.htm>

Postharvest Technology Research and Information Center, University of California, Davis

<http://postharvest.ucdavis.edu>

Vegetable Research and Information Center, University of California Cooperative Extension

<http://vric.ucdavis.edu>

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## GAP Requirements for Selected Fruits



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## Preparing Farms to Meet Sanitary Standards

Farms should be managed according to good agricultural practices to maintain sanitation, avoid toxic chemical exposure, and contact with fecal matter. Must maintain records for traceability



## **GAP – Improving Quality and Safety of Produce**

- Food handler must be clean
- Surfaces – all surfaces that come in contact with produce must be clean
- Water – any water used for irrigation, cooling or processing must be free of contaminants
- Soil – must be free of pathogens including manure



## **GAP – Food Handler Must Be Clean**

1. Wash hands when handling food
2. Food handler must be healthy – hepatitis can be transferred via food
3. Clothing must be clean and free from contamination
4. Should have good personal hygiene – no runny noses



## **GAP – Surfaces Must Be Clean**

1. Should be washed daily with disinfectant such as chlorinated water or to kill bacteria
2. Should be smooth and easily cleaned without crevasses where contaminants can lodge
3. Use plastic containers that are easily washed and sanitized
4. Should use crates and totes for transportation and storage of produce



## **GAP – Water Must Be Clean**

1. Clean water should be used to clean fruit
2. Water should be treated with a mild disinfectant such as Chlorine (eg 50 ppm)



## **GAP – Soil Must Be Free From Contamination**

1. Soil should be maintained with the least amount of contaminants
2. Manure should be managed with care so that crop contamination from pathogens does not take place



## **GAP – Food Safety Plan**

1. List steps from planting to post harvest
2. Identify areas where safety may be affected-protect crops from contamination from animals
3. Identify how to monitor and measure risk
4. Modify practices to reduce or eliminate this risk
5. Document all steps and changes made (important for inspectors)



## Obtaining Certification for the Farm

1. Preliminary Audit – A team determines whether any requirements have already been met
2. Documentation Audit – Team examines documents to determine if they concur with GAP requirements
3. Audit – Farmer/owner demonstrates how food system meets requirements in practice
4. Issue of Certificate – issued if farm meets all requirements (Good for three years)
5. Compliance inspected annually



## GAP- Figs

Soil	Figs can grow in sandy, clay and loamy soils, but the best soil is sandy loam soils .
Spacing	6*6 m (400 trees/ha)
Training and pruning	Modified open center system, light pruning and topping during initial years
Irrigation	Figs need less water than the other fruit trees. One month before harvest time, irrigation is very important for better quality figs.
Fertilizers application	Figs needs NPK fertilizers, but depends on the usage of the figs. For fresh consumption needs more N. Proper requirement is 80 kg N, 50 kg P and 50 kg K/ha.
Tillage and orchards care	Mulch and till to make weed free. Avoid inter-row cultivation to prevent damage to the shallow root system



## GAP-Fig Cont...

<b>Harvest</b>	<b>Normally, picked from the tree or gathered after falling to the ground. Mechanical sweepers can be used for those on the ground</b>
Storage	Up to 30 days at low temperatures at 0-2°C
Diseases	Fig rust: it is controlling by cultural practices such as removing of the disease leaves, branches from the orchards. It could be also controlled by application of 1g zenib/lit water in December.
Pests and insects	Fig scales: it can be controlled by cultural control such as removing infested branches from the trees and orchard area if the infestation is severe then use of 0.5% chlorophosphorus 2 ml/lit water will control the scales.
Sanitary consideration	Hands, picking materials and all equipments that are using for handling of figs must be sanitized.



## GAP-Apricots

<b>Soil</b>	<b>The best soil for growing apricots is well drained and soft sandy soils</b>
Spacing	6*6 m (400 trees/ha)
Training and pruning	Train as Vase or open center. Prune to encourage annual growth. Best to do annual pruning after danger of frost has passed. Then prune heavily if the crop is too heavy, less heavily if the crop is light.
Irrigation	Apricots needs for irrigation before and during vegetative growth as well as after harvesting. Avoid from continues surface irrigation and apply periodic deep irrigation.
Fertilizers application	For 3 years old trees or more than that 1 kg/tree of urea during vegetative growth, potassium merit 1-2kg/tree and super phosphate 10kg/tree before vegetative growth.
Tillage and orchards care	Grassed alleyways often used. Keep surface around trees clean.



## GAP - Apricots Cont...

Harvest	Hand harvest. Get best flavor when picked mature.
Storage	1-2 weeks at 0-2°C
Diseases	<p>Brown rot: the best way to reduce and avoid further growth of this disease is that as soon as possible remove diseased branches, leaves, and fruits from the tree.</p> <p>Bacterial canker: pruning should be done in winter time, application of micro-elements such as zinc and boron during vegetative growth, as well as can help in reduction of this disease</p>
Pests and insects	<p>Aphids: weeds control, avoidance of too much application of N, and removing of infested branches and leaves, can help to reduce the aphids population,</p> <p>Peach twig borer: the best way to eliminate this insect is application of Spinosad at dormant stage of the plant or early stage of the plant growth.</p>
Sanitary consideration	Hands, picking materials and all equipments that are using for handling of apricots must be sanitized.



## GAP-Grapes

Soil	The best soil for growing apricots is well drained and deep sandy soils
Spacing	Depends on variety, consumption (fresh/dried) and soil fertility, usually in Afghanistan 2*3 m
Training and pruning	Keep the canopy open to reduce disease problems and facilitate crop and vine management. Training: Various options– e.g., Vertical shoot positioned. Prune while dormant. The aim is to keep the canopy open to reduce humidity and disease problems
Irrigation	In Kandhar in Helmand 10 times/growing season, because there is only 250mm of rain per year.
Fertilizers application	For 6 years trees fertilizers application is Urea 170 g/tree during vegetative growth, 150 g/tree DAP and 270 g/tree potassium chloride after harvest and during vegetative growth.
Tillage and vineyards care	Keep surface between and around vines clean. Grow cover crops, if adequate water - to reduce dust and associated mite problems.



## GAP-Grapes Cont...

<b>Harvest</b>	<b>Machine harvest for juice. Hand pick for table grapes and raisins.</b>
Storage	3-6 months at 1°C
Diseases	<p>Powdery mildew: removing of weeds from vineyards, growing of resistance varieties and application of lime sulfur in dormant stage of the vines.</p> <p>Anthraxnose: application of lime sulfur as well as zineb 250g/ha during winter time, and copravit blue 4g/lit water 2-3 times per season.</p>
Pests and insects	Branches and twig borers: To manage branch and twig borers in vineyards, prevent their invasion and establishment with cultural methods. Completely remove wood brush piles of any trees or shrubs from the vineyard or burn them before emergence of adult beetles. Remove and destroy dead or dying portions of vine by pruning that should not remain in the vineyard
Sanitary consideration	Hands, picking materials and all equipments that are using for handling of apricots must be sanitized.



## GAP-Almond

<b>Soil</b>	<b>The best soil for growing almond is well drained, deep/ soft sandy and fertile soils</b>
Spacing	6*6.6 to 6.6*6.6 m
Training and pruning	Both vase shaped and with central leader systems
Irrigation	New saplings requires 11.4-18.9 litter/week. Young trees must be irrigated after 3-5 days.
Fertilizers application	N 91 kg/ha, phosphate 34 kg/ha and K 114 kg/ha. Half of mentioned fertilizers should apply at spring time and the remains half of them 30 days after the first application.
Tillage and orchards care	Grassed alleyways. Surface around trees clean.



## GAP-Almond Cont...

Harvest	Hand or machine (Shake and then sweep)
Storage	Remove nuts from shell and keep cool and dry as soon as possible
Diseases	Anthracnose: application of lime sulfur during winter season can control efficiently. Bacterial canker: pruning should be done in winter and/or fall season after collection of fruits.
Pests and insects	Peach twig borer: the best way to eliminate this insect is application of Spinosad and lime sulfur at dormant stage of the plant or early stage of the plant growth.
Sanitary consideration	Hands, picking materials and all equipments that are using for handling of apricots must be sanitized.



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**Chapter 4: TECHNICAL TRAINING IN GMP**

## **Good Manufacturing Practices(GMP)**

**Follow USFDA  
Code of Federal Regulation  
CFR21,Part 110 for detail**

### **GMP requirement**

- **Personnel hygiene enforced**
- **Building and facility design for sanitation**
- **Equipment and utensil sanitation observed**
- **Process and production control regulated**
- **Rodent and insect proofing established**
- **Visitor policy and limited plant access enforced.**

## Details of GMP

### Personnel hygiene

- Check employee health and cleanliness
- Guard against communicable diseases
- Avoid bacteria and virus on clothes
- Clean contaminants on body parts
- Cover hair as a source of contamination
- Stow away jewelry as contaminant
- Cover and sanitize shoes, they may carry germs

## Building and facilities

- These should be constructed to help in sanitation:
  1. Floors should be smooth and washable
  2. Walls should have safe paints and some areas covered with tiles or plastic
  3. Ceilings should be smooth and cleanable
  4. Doors and windows should be made of materials that are easily cleaned
  5. See the pictures in the following slides.

## Building and facilities ( continued)

- Fixtures should be protected such as :
  1. Electrical distribution systems made fire and explosion proof
  2. Distribution panels should be located away from manufacturing areas
  3. Pipes with elbows and joints should have traps that can be easily cleaned
  4. Areas should have sufficient lighting.

## Equipment , Production and Process Critical for GMP

1. All equipment and utensils should meet sanitary standards and be made of non-toxic materials.
2. Materials like wooden tables and chairs should be avoided that can absorb bacteria/mold
3. Food handling and safety during use of all processing methods should be maintained and recorded.
4. Production areas should be well ventilated with filtered air
5. Process water should be potable and treated.







Chapter 5: GMP & HACCP FOR IRAQ'S PRODUCE



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# **Good Manufacturing Practices and Hazard Analysis for Critical Control Points**

## **FOOD PROCESSING PLANTS IN IRAQ FRESH FRUIT AND VEGETABLE PACKING**

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## Introduction

Food processing plant owners have a social responsibility to insure that the food they produce and sell to the general public will not damage consumers' health. Responsible plant owners take many steps to make sure that the food they produce is healthy and wholesome for human consumption. The cumulative steps result in a food quality assurance system that includes:

- Good Manufacturing Practices (GMP) and
- Hazard Analysis and Critical Control Points (HACCP).

The purpose of this manual is to assist owners and managers of fruit and vegetable processing plants in Iraq obtain a basic understanding of these components of a responsible food quality assurance system and alert them to important issues to consider when installing and operating these systems.

The manual will discuss basic concepts and suggest the food safety and quality assurance system that should be implemented in food processing plants in Iraq. The actual procedures and programs for fresh fruit and vegetable processing plants in Iraq should be developed and installed with the help of food safety experts, employed either by the individual plant owners or through some organization of plant owners.

## **Good Manufacturing Practices (GMP)**

Good manufacturing practices are the procedures that should be followed during plant construction and operation to assure food wholesomeness. GMP refers to the minimum sanitary and processing conditions required in a properly built processing plant.

GMP contains cleanliness and sanitary requirements for personnel, building and facilities, equipment and utensils, in addition to food processing requirements and controls. Cleaning and sanitation is a multi-step procedure that involves first cleaning and then sanitizing in the processing plant. Food processing refers to the actual manufacturing operations, such as cleaning, sorting, grading and packaging that are applied to the fresh or processed food products. When implemented properly, GMP not only reduces new forms of biological, chemical and physical contamination, but eliminates existing contamination.

Food processing plants or packing sheds must be constructed with these practices in mind. To comply with U.S. and European standards, processing facilities must be constructed with approved materials and maintained under hygienic and sanitary conditions. Construction materials should be safe, non-toxic and approved for use in a processing facility. All of the equipment, walls, floors, doors, windows, and fixtures must meet approved standards. The plant layout should be such that it can avoid accumulating dirt and can be easily cleaned and sanitized.

## **PLANT AND GROUNDS**

The design of the plant layout should include the following points:

- The ground selected should be above the road level and water drainage system.
- The building should be a few feet above ground level for cleaning water to flow out.
- Adequate protection should be provided against rain and dust storms.
- Areas for incoming raw material and outgoing finished goods should be segregated.
- Plumbing must be of adequate size and design to:
  - Supply enough water to areas in the plant where it is needed.
  - Properly convey sewage or disposable liquid waste from the plant.
- Not create a source of contamination or unsanitary condition.
  - Provide adequate floor drainage where hosing-type cleaning is done or where operations discharge water or liquid waste onto the floor; floor drains must be designed to trap material that could clog the drainage system; floor drains must be designed for easy cleaning to remove trapped material. Where practical, any solid material that can clog the drains should be removed prior to disposal.

- Water supply for the plant should be tested to see if it is potable. High bacterial count and excessive mineral content should be eliminated by treatment with chlorine and filtration or ion exchange system.
- Used process water should also be treated before disposal to reduce biological and chemical oxygen in the effluent.
- There should be no backflow from cross-connections between piping systems that discharge waste water or sewage and those that carry water for fruits and vegetables.
- Air filters should be used to clean air for in-plant use. Any emission of air with high polluting materials should be filtered or scrubbed prior to its discharge.
- Electricity should be supplied through a distribution switch board. Proper safety switches and fuse boxes should be installed to avoid overload and electrical fires. Wiring inside the plant should be protected with
- In some cases stand by generators may be needed for refrigerators and freezers to avoid spoilage due to electrical interruptions.
- Lighting and ventilation systems should be adequate for visibility and safety.
- All entry points to the building should be secured against insects, rodents and other animals.

- The doors, windows, walls, floors and ceilings should be made of smooth surfaces that can be easily wiped and cleaned.
- Materials used in construction of floors and walls should be non-toxic.
  - Cement walls and floors are acceptable if they are smooth enough without rough corners and crevices. Special plastic wall covers such as “Kimlite” panels may be ideal because they can be easily washed and wiped.
  - Wooden doors and windows may be covered with thin stainless steel sheets; but, if metal doors and windows are available they are preferable.
- Toxic materials such as lead paint must not be used. Asbestos sheet ceilings should be absolutely avoided. Some plants use galvanized iron sheets as roofs. This would require a false ceiling of plastic material to cover the iron sheets from the inside and waterproof covering that can be wiped during clean up.

## **DESIGN OF EQUIPMENT AND UTENSILS**

Equipment and utensils must be designed for easy cleaning and sanitation.

Equipment and utensils must be made from non-corrosive materials.

## **SANITATION FACILITIES AND CONTROL**

- Toilet, hand-washing, ablution and locker-room facilities:
  - Toilets and hand-washing facilities must be provided inside the processing centre;

- Toilet tissue must be provided;
- Toilets must be kept sanitary and in good repair;
- Signs must be posted that direct employees to wash their hands with soap or detergent after using the toilet.
- Toilet rooms must have self-closing doors;
- Toilet rooms must not open directly into areas where processed products are exposed unless steps have been taken to prevent airborne contamination (example: double doors, positive airflow, etc.);
- Hand-washing facilities must provide:
  - Running water at a suitable temperature;
  - Effective hand-cleaning and hand-sanitizing preparations;
  - Clean towel service or suitable drying devices;
  - Easily cleanable waste receptacle;
  - Water control valves designed and constructed to protect against recontamination of clean, sanitized hands;
  - Signs directing employees handling unprotected fruits and vegetables to wash and, if appropriate, sanitize their hands before starting work, after each absence from the workstation, and any other time when the hands have become soiled or contaminated.

## **SANITARY OPERATIONS**

### **HOUSEKEEPING**

The plant must develop Standard Operating Procedures (SOPs) and Standard Sanitary Operating Procedures (SSOPs) relative to all cleaning and sanitizing of the plant facilities and equipment. Cleaning operations must be conducted in a manner that will minimize the possibility of contaminating fruits and vegetables and equipment surfaces that contact them. Cleaning removes the visible soil and organic matter and most of the harmful bacteria.

Plant personnel use brooms, brushes, high pressure air, low and high pressure water to remove visible soil and organic matter from:

- Plant floors
- Plant walls
- Equipment and utensils, which must be kept in a sanitary condition through frequent cleaning and, when necessary, sanitizing. If necessary, such equipment must be taken apart for thorough cleaning.

Cleaning is done on a pre-planned, regular schedule. Most cleaning operations are conducted at the end of the work day or at a prescribed time before the shift begins.

Sanitation requires that a sanitizing compound such as chlorine be applied to the cleaned surfaces so that the level of bacteria can be reduced to an acceptable level. Sanitation is done at different times for various parts of the plant. The following is a recommended schedule of sanitation for the various parts of a processing plant:

- Plant floors every day and during mid-shift

- Plant walls every day before each shift
- Equipment before use for every batch
- Other utensils prior to use

## **PEST CONTROL**

Food plants must have structures to control insects, rodents, birds, cats and other animals. Flies, bees, rats and mice invade the food plants in search of food. Cats and other animals enter the plant in search of rats and mice. All structures and equipment should be secured against them.

Doors, windows and other openings must be secured. Openings that are typically left open for ventilation should be screened. Installation of air curtains, fans and electrocutors at strategic locations will be extremely helpful. Snap traps, glue boards and bait stations must be placed around the immediate building exterior and interior walls.

## **PROCESSES AND CONTROLS**

### **RAW MATERIALS AND CONTAINERS**

Raw product and finished product must be stored in segregated areas under conditions that prevent contamination and the growth of undesirable microorganisms. Product flow zones must be protected from all sources of contamination.

### **FOOD PROCESSING**

It is necessary to process, package and store fruits and vegetables under conditions that will minimize the potential for undesirable microbiological growth, toxin formation, deterioration or contamination. This will require

careful monitoring (via a HACCP program described below) of such factors as time, temperature, humidity, pressure, flow rate, etc. The object is to assure that mechanical breakdowns, time delays, temperature fluctuations or other factors do not allow the fruits and vegetables to decompose or become contaminated. Good manufacturing practices include the following:

- Fruits and vegetables must be held under conditions that prevent contamination and the growth of microorganisms.
- Mechanical manufacturing steps such as shelling and packaging, etc. must be performed in a manner that:
  - provides adequate protection from contaminants that may drip, drain or be drawn into the products,
  - adequately cleans and sanitizes all contact surfaces
  - uses materials for fruit and vegetable containers and packaging materials that are safe and suitable
  - Implements a HACCP program to check for possible contamination and assure that GMPs are being followed.
- Measures such as sieves, traps, or metal detectors must be used to protect against the inclusion of metal or other extraneous material in food;
- Measures such as sterilizing, irradiating, or pasteurizing must be adequate to destroy or prevent the growth of undesirable microorganisms.
- Equipment, containers and utensils must be constructed, handled and maintained to protect against contamination.

- Fruits and vegetables that are adulterated must be disposed of without contaminating others.

### **PACKAGING, CODING AND FINISHED FOOD PRODUCTS**

- A coding system should be utilized that will allow positive lot identification in the event it is necessary to identify and segregate lots of fruits and vegetables that may be contaminated.
- Records should be kept for a period of time that exceeds the shelf life of the product.

### **PERSONNEL**

Employee sanitation requires that plant personnel use personal hygiene to insure that food products do not become contaminated. Personal hygiene for processing plant personnel includes:

- Use of protective clothing, shoes, hair-nets, beard guards, etc. approved by management.
- Washing and sanitizing of hands and body parts that may come in contact with the food during preparation.
- Food processing personnel should not wear jewelry while processing food. The owner of the processing plant should establish strict jewelry rules so that watches, rings, earrings etc. are not worn by processing personnel and may not contaminate the products. The plant owner should provide a place for plant personnel to safely store their jewelry prior to entering the processing areas.

- All personnel should be screened regularly for any illness that can be transmitted to food.

## **Hazard Analysis for Critical Control Points (HACCP)**

HAACP is a system for monitoring food-processing plants to insure that all established procedures for maintaining food quality are followed. It establishes a series of scheduled inspections in the plant at critical points of manufacture. Physical, chemical and biological tests are performed at the critical points. When results are acceptable, food processing/manufacturing continues; when the results of tests are unacceptable, food processing ceases until the problems are corrected.

HACCP is not a stand-alone system. It requires GMP to be in place before HACCP can be applied. It is now used extensively in the food industries all over the world for making sure that processed foods are prevented from contamination with hazardous elements, pathogenic microorganisms, physical objects like glass, metal or bone, and chemicals like toxins, heavy metals or pesticide residues. It helps monitor strict adherence to processing and storage parameters.

### **DEFINITION OF TERMS USED IN HACCP**

Many terms used in discussion of HACCP must be clearly understood to effectively develop and implement a plan. The following definitions are provided for clarity:

- Acceptable level means the amount of a hazard that is unlikely to cause a health risk.
- Control point means any point where loss of control does not lead to an unacceptable health risk.
- Critical control point, as defined in the Food Code, means a point at which loss of control may result in an unacceptable health risk.
- Critical limit, as defined in the Food Code of the FDA, means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled.
- Deviation means failure to meet a required critical limit for a critical control point.
- HACCP plan, as defined in the Food Code, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.
- Hazard, as defined in the Food Code, means a biological, chemical, or physical property that may cause an unacceptable consumer health risks.
- Monitoring means a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.
- Preventive measure means an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination.
- Risk means an estimate of the likely occurrence of a hazard.

- Sensitive ingredient means any ingredient historically associated with a known microbiological hazard that causes or contributes to production of a potentially hazardous food as defined in the Food Code of the FDA.
- Verification means methods, procedures, and tests used to determine the HACCP system to be in compliance.

<b>Step 1</b>	Receiving raw materials in the bulk storage bins at the plant
<b>Step 2</b>	Fumigation of raw materials to kill insects and molds prior to processing , if required
<b>Step 3</b>	Storage of fumigated raw materials in the processing area
<b>Step 4</b>	Cleaning and removing undesirable fruits and vegetables and Drying
<b>Step 5</b>	Sizing, sorting and grading
<b>Step 6</b>	Pass through color sorter if necessary
<b>Step 7</b>	Initial quality check to observe any visible defects
<b>Step 8</b>	Quality control tests for moisture, density, firmness, color and flavor
<b>Step 9</b>	Pass through check point to isolate off quality fruits and vegetables
<b>Step 10</b>	Final quality check for physical, chemical and sensory tests
<b>Step 11</b>	Bagging and boxing
<b>Step 12</b>	Random batch tests of packaged products for quality assurance
<b>Step 13</b>	Final check of packaged finished goods to avoid any recontamination with insects and molds
<b>Step 14</b>	Storage of finished packaged products in a cool dry place
<b>Step 15</b>	Shipping of products in bags, boxes and large containers with batch control for any recall of product from the market

## **SEVEN PRINCIPLES OF HACCP**

Seven principles are applied to establish an HACCP program. They are given below with reference to fresh fruit and vegetable processing industries.

1. Perform analysis of hazard (type of physical, chemical and biological hazard in fruits and vegetables)
2. Determine critical control points (locate the areas during handling and processing of fruits and vegetables)
3. Establish limits for the critical control points (establish the safety limits acceptable at the points)
4. Monitor critical control points (check and re-check the occurrence of hazards at the points)
5. Take corrective action (establish procedures to eliminate the hazards through treatments)
6. Keep records (maintain the history of events that includes observation, action and results )
7. Verify that the system works (check and re-check that the procedures are updated and functioning).

## **CRITICAL STEPS FOR DEVELOPMENT OF HACCP**

The following steps are essential for consideration at the time of establishing a HACCP program:

- Assemble a multi-disciplinary team that includes managers, scientists, process workers, engineers and book keepers so that intelligent input can be provided at periodic HACCP meetings. In the case of fruit and vegetable processing, people with knowledge of growing, handling, storage and distribution should be included to provide input of the local conditions.
- Engage an external safety consultant with technical knowledge to provide guidance at the HACCP meetings. The consultant can co-ordinate the external testing and laboratory services and discuss test results and corrective measures.
- Prepare a flow chart of the operation of processing. This should be a step by step flow chart.
- Examine the steps and identify the hazards at each step.
- Determine curative measures such as cleaning the surfaces in contact with the product or reducing water and airflow on the produce that can contaminate them.
- Establish tests to measure the elimination of contaminants.
- Record all sources of ingredients to establish traceable connections and eliminate hazard sources.
- Display the critical control points and repeat the review of actions taken periodically, like daily, weekly and monthly.

- Standardize procedures and update them as frequently as possible with new techniques.
- Make sure that the management approves and signs records of inspections regularly.

## **THE HAZARD ANALYSIS PROCESS**

The hazard analysis process consists of asking a series of questions at each operational step in the processing of the product as it flows through the plant. The analysis examines the effect of a variety of factors upon the safety of the food. Sample questions are given below.

### **INGREDIENTS**

- Does the produce contain any sensitive ingredients that are likely to present microbiological hazards (e.g., Salmonella, Staphylococcus aureus), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide.)
- What is the normal microbial content of the food stored under proper conditions?
- Does the microbial population change while the food is stored before consumption?
- Does that change in microbial population alter the safety of the food?

### **FACILITY DESIGN**

- Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?

- Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
- Is the traffic pattern for people and moving equipment a potentially significant source of contamination?

## **EQUIPMENT DESIGN**

- Will the equipment provide the time and temperature control that is necessary for safe food?
- Is the equipment properly sized for the volume of produce that will be package?
- Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
- Is the equipment reliable or is it prone to frequent breakdowns?
- Is the equipment designed so that it can be cleaned and sanitized?
- Is there a chance for product contamination with hazardous substances?
- What product safety devices, such as time and temperature integrators, are used to enhance consumer safety?

## **PACKAGING**

- Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
- Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

- Is the package clearly labeled “Keep Refrigerated” if this is required for safety?
- Does the package include instructions for the safe handling and preparation of the food by the consumer?
- Are tamper-evident packaging features used?
- Is each package legibly and accurately coded to indicate production lot?
- Does each package contain the proper label?

## **DETERMINATION OF THE CRITICAL CONTROL POINTS (CCP)**

Determination of the Critical Control Points (CCP) is made by analyzing each operational step in the flow of product through the plant to evaluate the potential for contamination by biological, chemical and physical vectors. The table below provides an example of the analysis of the flow of product through a typical food processing plant. At each step in the processing plant the potential for biological, chemical or physical contamination is analyzed. Critical Control Points (CCP) are identified where the potential for contamination is significant.

**HACCP Flow Chart of Food Processing Plant with examples of CCP**

<b>Operation</b>	<b>Biological Control Point</b>	<b>Chemical Control Point</b>	<b>Physical Control Point</b>	<b>Remedy</b>	<b>Critical Control Point</b>
<b>Receiving</b>	Check bacteria, mold	Check pesticide & insecticide	Check dirt, debris & filth	Treatment to remove them	Yes
<b>Fumigation if required</b>	Kill insects, mold	Check for residue	Check for insect fragments	Treat and remove physically	Yes
<b>Culling/ Removing</b>	Check for bacteria and mold	Check for chemical residue	Check for discolored fruits etc.	Remove the discolored fruits	Yes
<b>Sizing &amp; Grading</b>	Quality Check	Quality check	Quality check	Remove blemished and off grade fruits	No for food safety
<b>Line &amp; QC Inspection</b>	Final line check for bacteria and mold	Final line check for any chemical residue	Final line check for any foreign material	Eliminate the off grade items and clean fruits	Yes
<b>Packing</b>	Check packaging materials for bacteria	Check packaging materials for chemicals	Check any damage and tear	Eliminate damaged packaging materials and cartons	Yes
<b>Storage</b>	Check storage area	Check storage area	Check storage area	Make sure the storage area is clean and dry	Yes
<b>Shipping</b>	Check shipping condition	Check shipping condition	Check shipping condition	Clean the shipping vehicles	Yes

Note: The sizing and grading operation may not be directly related to health hazards but for quality of fruit size and grade, the operation is critical.

Tests will have to be performed regularly in the plant. Some examples of tests are given below.

- For visual tests, magnifiers, microscopes and UV lights will be needed.
- For color control of the fruits, color charts or electronic eyes for color comparison may be needed.
- For microbiological examination, equipment will be needed for incubation and plate count
- For physical debris and filth removal, cleaning devices, cyclones and dust removal equipment will be needed.

## **General Management Principles**

Management support and involvement are extremely important in achieving success. The following points for record keeping and plant policies are of paramount importance.

### **RECORD KEEPING**

The procedure of testing and re-testing requires record keeping in an archive that is chronological, permanent and readily accessible. It should be maintained by the management in a safe and secured place. This will also help product recalls if they are needed.

## **MANAGEMENT POLICIES FOR PLANTS**

All policies regarding the hygiene of employees and visitors should be posted in prominent places. They should be strictly enforced. Safety of material handling should also be monitored with great care.

### **References**

<sup>1</sup>Refer to the *United States Food and Drug Administration (FDA) codes*

<sup>2</sup>Refer to the *United States Food and Drug Administration (FDA) codes in Section 21 of the Code of Federal Regulations, Part 110 for further detail*

<sup>3</sup>For further detail on flow chart and critical control points for HACCP consult the *HACCP User's Manual by D.A. Corlett,Jr. 1988. Aspen Press, Gaithersburg, MD, USA.*

# **INSPECTION FOR SMALL PROCESSING PLANTS CHECKLIST**

This checklist was developed for the North Carolina Department of Agriculture and Consumer Services (NCDA&CS), Meat and Poultry Inspection Division. It has been adapted for Iraq.

## **GUIDELINES FOR NEW PROCESSING PLANTS**

### **I. THE COURTESY REVIEW**

#### **A. Structure**

- Interior walls and ceiling of waterproof materials
- Joints tight fitting (wall-ceiling and wall-floor)
- Adequate ceiling height
- Metal doors (tight fitting)
- Floor (concrete slanting to floor drains)
- Covering (at the wall-floor juncture)
- Drains (in floor (four inch) with traps)
- Adequate square footage for production and equipment
- No exposed wood
- Ventilation adequate for space and function
- Correct traffic flow

#### **B. Equipment**

- Product wash/recondition sink
- Hand wash sink with foot or knee valve
- Equipment wash sink (3 compartments)
- Hot water supply

- Soap and single service towel dispensers
- Approved grinders, choppers, stuffers, cookers, saws, pots, lugs, knives, racks, stands, tables, cutting boards
- No exposed wood on tables, shelves, racks
- Hose and hose rack

### **C. Lighting**

- Adequate lighting (50 foot candles at work level)
- Shatter proof bulbs or light covers with ends
- Plastic or stainless fixtures (do not rust)
- Waterproof switches for lights in processing
- Must have lighting in coolers, freezers, dry storage

### **D. Coolers**

- Four inch floor drains
- Waterproof walls, floor and ceiling
- Metal racks 12 inches up off the floor
- Tight fitting metal door
- Accurate thermometer
- Cooling unit with fan covers and drain pan
- Adequate lighting
- Separate cooler for chilling cooked product

### **E. Welfare**

- Number of restrooms adequate for number of employees
- Equipped with hand wash sink, soap and towel dispenser
- Hot water supply
- Must not enter directly into processing
- Provide space for lockers, hangers, and boot racks

## **F. Dry Storage**

- Metal racks, stands, cabinets for wrap, spices, labels
- Adequate space for volume
- Tight fitting construction
- Adequate lighting

## **G. Office Space**

- Metal table or desk
- File drawer or cabinet (lockable)
- Metal chair
- Trash receptacle
- Dedicated phone line

## **H. Entrance-Traffic Flow**

- No direct entrance from outside into processing
- Vestibule on outside entrance
- Concrete pad at loading area
- “Employee Only” sign on processing door

## **I. Separation**

- Finished goods and raw product should be separated
- Inspected and custom product must be separated
- Retail and inspected areas must be separated

## **J. Chemicals**

- Approved chemicals, cleaners only
- Must be stored away from processing area in designated area
- Material safety data sheets (MSDS) for all chemicals
- Storage cabinets for flammables

### **K. Safety**

- Lighted exit signs
- Exit diagram
- Fire extinguishers
- Approved electrical boxes with grounded circuits
- Water proof socket covers
- Evacuation plan
- No spliced wires or undersized extension cords
- All fans must have covers and moving parts must have guards
- Safety glasses should be provided
- Hazard communication program in inspector file
- Lockout Tag out program

### **L. Water and Sewer**

- Water and sewer systems must be approved
- Water samples must be submitted regularly
- Hot water heater of adequate size and volume

### **M. Plant File**

- Approved labels
- Approved blue prints
- MSDS sheets
- Evacuation plan
- Water and sewer letter
- Processing reports
- Operating hours
- Activity report

- Equipment List
- Letters of guarantee
- Inedible letter
- Pest control letter
- Chemicals list
- Formulations if any
- Plant profile
- Application and grant of inspection

**N. Exterior**

- Graded drive to prevent standing water
- Concrete pad at loading door
- Weed control around plant
- Fly fans and electrocuters where indicated
- Control of rust and flaking paint

**O. Employees**

- Trained in basic hygiene practices
- Clean work smocks and aprons
- Head covers (hard hats or caps)
- No smoking, eating or chewing in processing areas
- Hair and beards should be trimmed
- Frequent hand washing and clean nails
- All cuts and health problems should be cared for promptly
- Safety boots should be provided
- No rings, watches, bracelets worn by employees in plant working areas

## **P. Transportation**

- Clean, enclosed vehicle
- Refrigeration

### **PRE-OP CHECKLIST :**

Through cleaning of facilities, equipment and containers

- Hot water must be available
- Cooler must be operating within required limits
- Lighting must be adequate
- No signs of insects or rodents
- No buildup of blood, oil, tissue, or dirt on cutters, choppers, dicers, tables, cutting boards or containers
- Check equipment for wear of blades, loose fittings to reduce chances of metal contamination
- Trays, boxes, wrap and other direct contact material checked for cleanliness and
- Foreign material contamination
- Hand sanitizers and/or sterilizers available with proper strength and approved chemicals
- All chemicals and cleaning materials should be removed from the processing area Coats, hats, boots, and aprons should be checked for cleanliness and wear
- All lugs and food containers should be checked for cleanliness and cracks
- All floor drains should be functional and free from odor
- Check for flaking paint and rust on all metal including fans
- Check all raw products for expiration date, spoilage, species, and freshness
- Disassembled equipment should be inspected before use

## **PROCESSING UNCOOKED RAW PRODUCT**

- During processing only authorized employees are allowed in the processing area
- Hands should be thoroughly cleaned with soap and water; nails should be clean
- Knives should be sanitized or sterilized
- Clothing such as coat sleeves should not be allowed to contact raw product
- Do not put product containers on the floor; use stands twelve inches off floor
- While cutting examine raw product for foreign material (paper, plastic, wire, dirt, bone, insects, and other abnormalities)
- If foreign material is found, processing should be stopped and the entire lot should be examined and identified
- If you are unsure about the source or safety of raw product, put the product in the retained area of the cooler for examination
- Accurate certified scales should be used for net weights
- All products should be labeled with an approved label. Safe handling labels and nutritional labels when required
- Raw product must be cooled, refrigerated, or frozen immediately after processing
- Raw product should be transported in clean containers under refrigeration
- All additives should be measured and used in accordance with formulations and regulations
- Inedible material should be denatured and stored in containers with lids marked “inedible”

## **PROCESSING / COOKING**

- All preparatory procedures listed under raw product apply
- Cookers are examined for cleanliness and proper function
- Cooking time and temperatures are mandated by regulations and must be carefully followed
- Cook charts showing temperature and time should be kept
- Cooked product should be rapidly cooled in accordance with regulations and cooling guidelines
- A cooling time chart should be kept
- Measurements of temperature should be made with a good probe type thermometer
- Cooked product should be kept separate from raw product
- Shrink test should be done where applicable
- Restricted ingredients must be carefully monitored
- Accurate inventories should be kept on any restricted ingredients
- Identification of lots should be maintained at all stages of processing

## **TRANSPORTATION**

- Check all products to be shipped to be sure that it is properly packaged and correctly labeled before it leaves the plant
- The transportation vehicle should be clean and cooled prior to loading
- The vehicle should be equipped with a thermometer
- If an accident occurs, call the inspector
- Do not distribute product to public unless cleared by the quality inspection service
- Transportation boxes must be clean and of the appropriate type
- Do not use boxes with another establishment's legend or label

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Chapter 6: TRACEABILITY IN THE FOOD CHAIN



## Traceability in the Food Chain

Supply Chain Seminar

HACCP Workshop

July 2012



*Why?*



As economies change the need for more sophisticated controls become necessary.

This is most noticeable in the agricultural sectors of emerging countries. The need for traceability is, therefore, a most important factor in the marketing arsenal of agricultural and food businesses. Without it businesses can easily be by-passed.



## *What it means*

- In the food chain, traceability means the ability to trace and follow a food, feed, food producing animal or substance through all stages of production and distribution.
- Stages of production and distribution means any stage through the supply chain starting from primary production via processor, trader (including import/export) and supermarket or any other point of sale to the final consumer.



## *EU – Legislation – an example*

- **The EU has issued new guidelines to facilitate the traceability of food products across all member states.**
- **This follows the passing of the General Food Law, which entered into force on 01/01/2005 (EU Directive 2001/95/EC on General Product Safety, EU Regulation 178/2002 on Food Safety).**



## *EU - Legislation*

The specific requirements include:

- the traceability of food products
- withdrawal of dangerous food products from the market
- operator responsibilities
- requirements applicable to imports and exports



## *Priorities*

The first priority of product traceability and incident management processes is to protect the consumer and ensure a fast product withdrawal or recall



## *Priorities*

The second priority of product traceability is to manage the economic aspects related to the company and this is best achieved through the precise identification and location of all non-conforming products.



## *Traceability System*

Information on the name, address of producer, nature of products and date of transaction must be systematically registered within each operator's traceability system.

This information must be kept for a period of five years and on request, it must immediately be made available to the competent authorities.



## *Supply chain*

Traceability in wholesale distribution means knowing where the products have come from and to whom you've sold product on a lot code basis.



## *Incoming register*

Incoming register for each business partner in the food chain must contain:

- Nature of the incoming product
- Identification of this product
- Quantity of this product
- Date of reception
- Identification of the supplier
- Other data described by other authorities



## *Outgoing register*

Outgoing register for each business partner in the food chain must contain:

- Nature of the incoming product
- Identification of this product
- Quantity of this product
- Delivery date
- Identification of the client
- Other data described by other authorities



## *International trade (Europe)*

Under the EU General Food Law regulation, importers and exporters of bulk goods will not need to be able to demonstrate traceability back to the primary producer.

Traceability can only be required from the EU border, so that only the direct supplier to an importer, based in the EU, would need to be identified by law.



## *International trade (Europe)*

Suppliers dealing in retail chains are already required to demonstrate traceability, if requested, back to the level of an individual farmer, even one outside the EU.



## *Summary*

Traceability is not negotiable

- Mandatory requirement
- Throughout the supply chain
  - Known Suppliers
  - Known Standards
  - Known Sources
- Partnership throughout the supply chain
- Optional design (paper, electronic, colour, bar code, passport etc), but functionality must be demonstrable
- Trigger information quality is critical

Chapter 7: FDA FOOD SAFETY MODERNIZATION ACT



## Focus on Imports

# FDA Food Safety Modernization Act

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# Food Safety Modernization Act

"I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action."



*Margaret A. Hamburg, M.D.,  
Commissioner of Food and Drugs*

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## Agenda

- The public health imperative
- Why is the law needed?
- Provisions of the law; focus on imports
- Implementation

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## Why is the law needed?

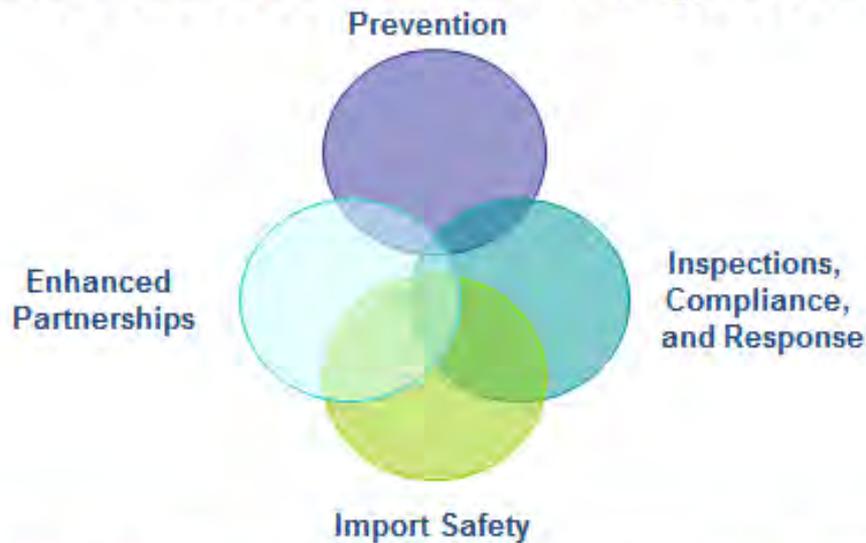
- Globalization
  - 15 percent of U.S. food supply is imported
- Food supply more high-tech and complex
  - More foods in the marketplace
  - New hazards in foods not previously seen
- Shifting demographics
  - Growing population (about 30%) of individuals are especially “at risk” for foodborne illness

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## Main Themes of the Legislation



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## Import Safety: Most Groundbreaking Shift

- Current reliance on port-of-entry inspection cannot handle increase in imported food.
- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- Requires food from abroad to be as safe as domestic

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## Import Safety Mandates

### **Sec. 301. Foreign supplier verification program**

- Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements.

### **Sec. 302. Voluntary qualified importer program**

- Allows for expedited review and entry; facility certification required

### **Sec. 303. Certification for high-risk food imports**

- FDA has discretionary authority to require assurances of compliance for high-risk foods

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## Import Safety Mandates

### **Sec. 304. Prior notice of imported food shipments**

- Requires information on prior refusals to be added to prior notice submission

### **Sec. 305. Capacity building**

- FDA mandate to work with foreign governments to build food safety capacity

### **Sec. 306. Inspection of foreign food facilities**

- Can deny entry if FDA access for inspection is denied

### **Sec. 201. Targeting of inspection resources**

- Increased inspection of foreign as well as domestic facilities

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## Import Safety Mandates

### **Sec. 307. Accreditation of third-party auditors**

- FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements

### **Sec. 308. Foreign Offices of the Food and Drug Administration.**

- Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.

### **Sec. 309. Smuggled Food**

- In coordination with DHS, better identify and prevent entry of smuggled food

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## Role of Third-Party Certification Programs

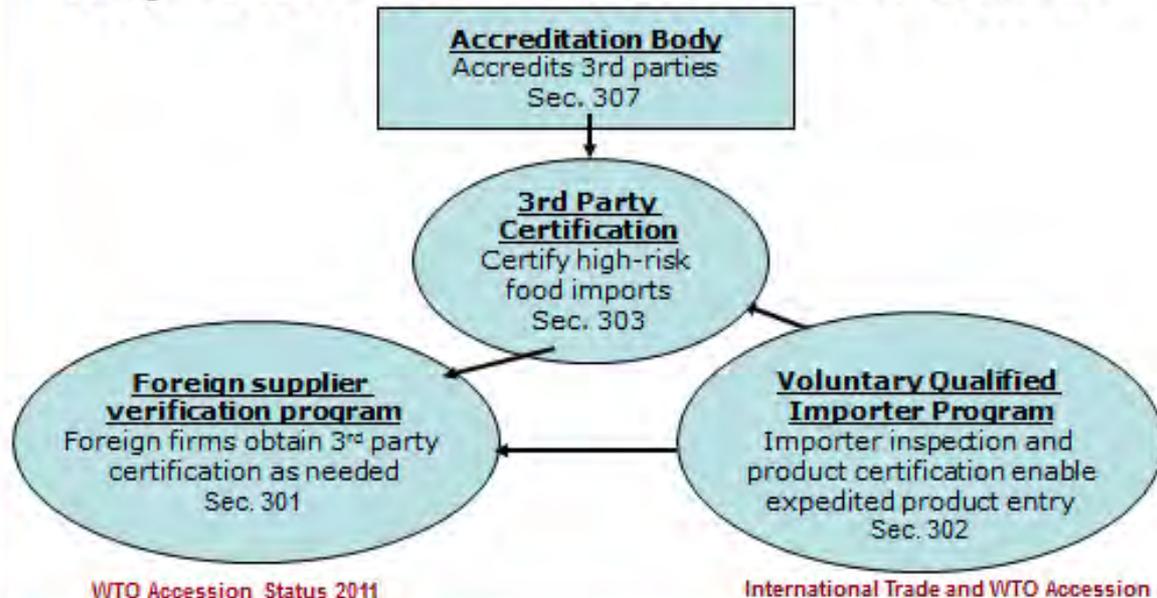
- Tool for importers to obtain needed assurances to meet their obligations for the foreign supplier verification program (sec. 301)
- A way for importers to participate in the voluntary qualified importer program to expedite movement of food through the import process (sec. 302)
- Can be required by FDA to accompany high-risk foods (sec. 303)

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## Import Provisions Work as a Whole



## Enhanced Partnerships: Vital to Success

International capacity building

- FDA has mandate to work with foreign governments to build their food safety capacity
- Allows FDA to rely more heavily on foreign government oversight
- Capacity building helps to prevent problems before products reach the U.S. port of entry

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## Trade Agreements

- Section 404, Compliance with International Agreements, explicitly notes that FSMA must be consistent with our agreement with the World Trade Organization (WTO) and any other treaty or international agreement.
- At each stage of the implementation process, we will make every effort to ensure that our proposed activities, policies, and measures are consistent with the WTO.

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## Implementation Approach

- Implementation already underway
- Coalition needed
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to implement provisions

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## But, many challenges

- Enormous workload
  - 50 new rules, guidance documents, reports in 3 years
- Tight deadlines
- Changes won't appear overnight
  - Building new system will be a long-range process
- Resources

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## Import Projects Completed (as of July 2011)

- Updated list and more information can be found at <http://www.fda.gov/fsma>
  - Sec. 304. Prior notice of imported food shipments
    - Requires information on prior refusals to be added to prior notice submission
    - Effective July 3, 2011
  - Sec. 309. Anti-Smuggling Strategy
    - Issued July 3, 2011

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## Outreach

- Public Meeting on Imports (March 29, 2011)
- Public Hearing on Comparability and Import Practices (March 30-31, 2011)
- 40 listening sessions, meetings to date
- Foreign government outreach through embassy briefings

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## Rulemaking Process

- Rulemaking is open and public.
- Draft rules are published on <http://www.regulations.gov>.
- Time is allowed for public comment, and FDA is required to consider significant comments during the rulemaking process.
- Check <http://www.fda.gov/fsma> to find out what is open for comment.

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FROM THE AMERICAN PEOPLE



## For more information



- Web site is at: <http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to [FSMA@fda.hhs.gov](mailto:FSMA@fda.hhs.gov)

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## For more information contact:

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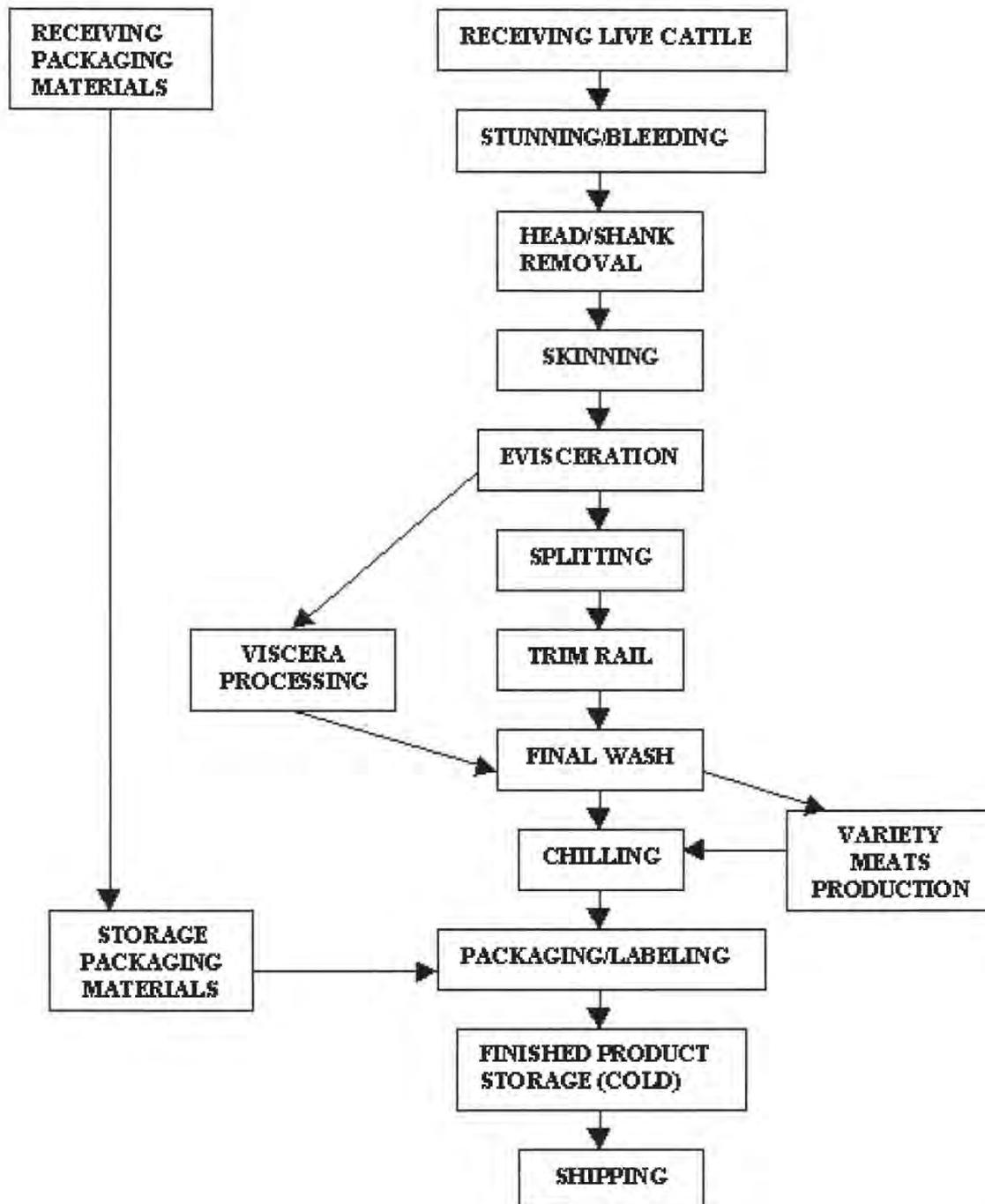
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Chapter 8: HAZARDS AND CONTROL POINTS FOR MEAT

Cattle (also Sheep and Goats) Slaughter



## BEEF, SHEEP & GOAT FLOW CHART – IRAQ

Red = Risks: B = Biological, C = Chemical and P = Physical  
Green = Control Measures





**Receive and Hold Livestock**



## Halal Slaughter and Complete Draining of Blood



### Remove Hide and Washing



## Evisceration and Veterinary Inspection for Disease Symptoms



### Chilling and Additional Trimming at Control Point



**Inspected Lamb Carcasses in Cooler and Food Safety Inspection Stamp**



**Deboned Beef for Tika and Cleaned Grinding Equipment**



**Smoked Processed Product and Cold Storage Conditions**

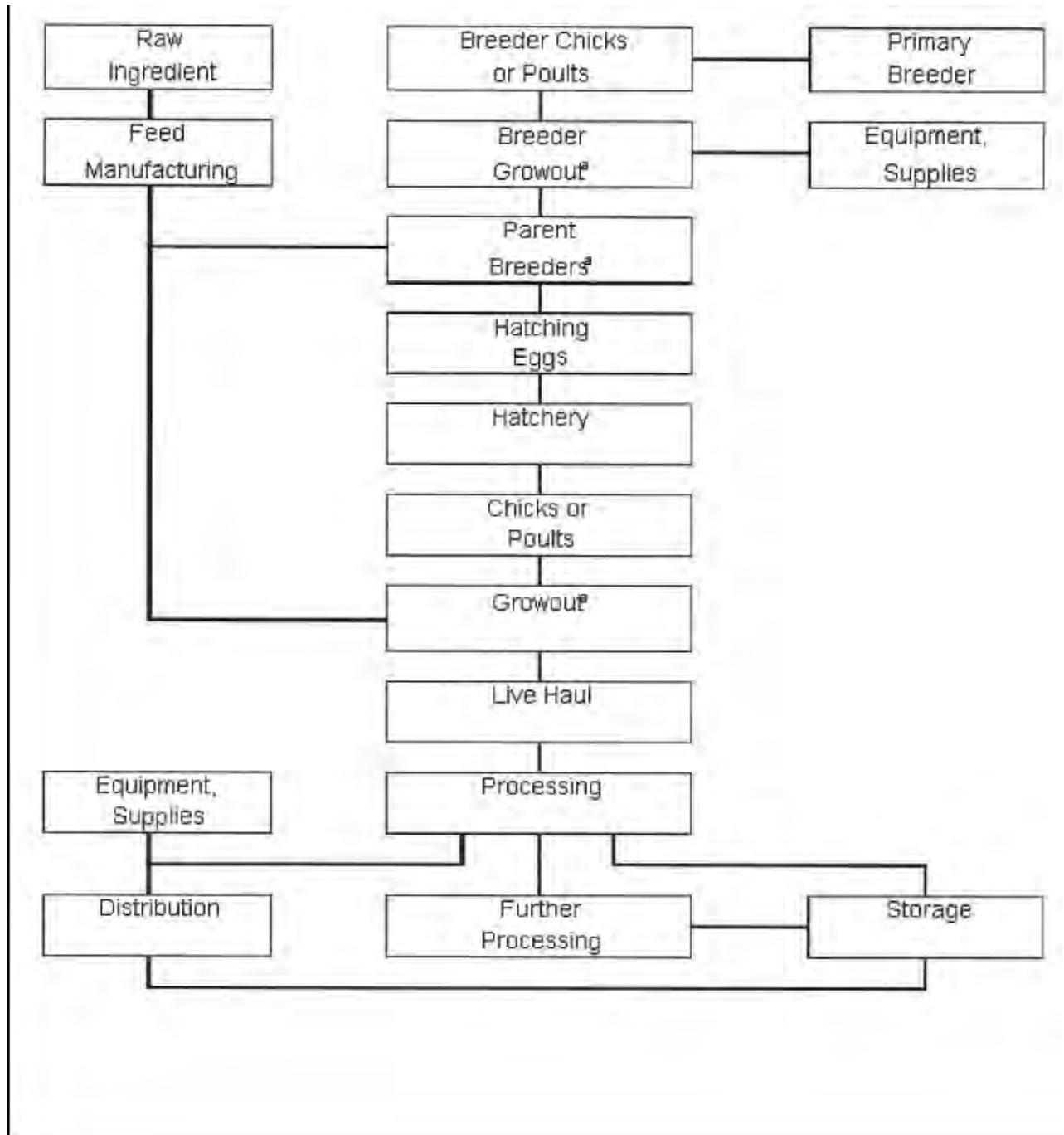


Labeled Product with Bar Coding for Traceability

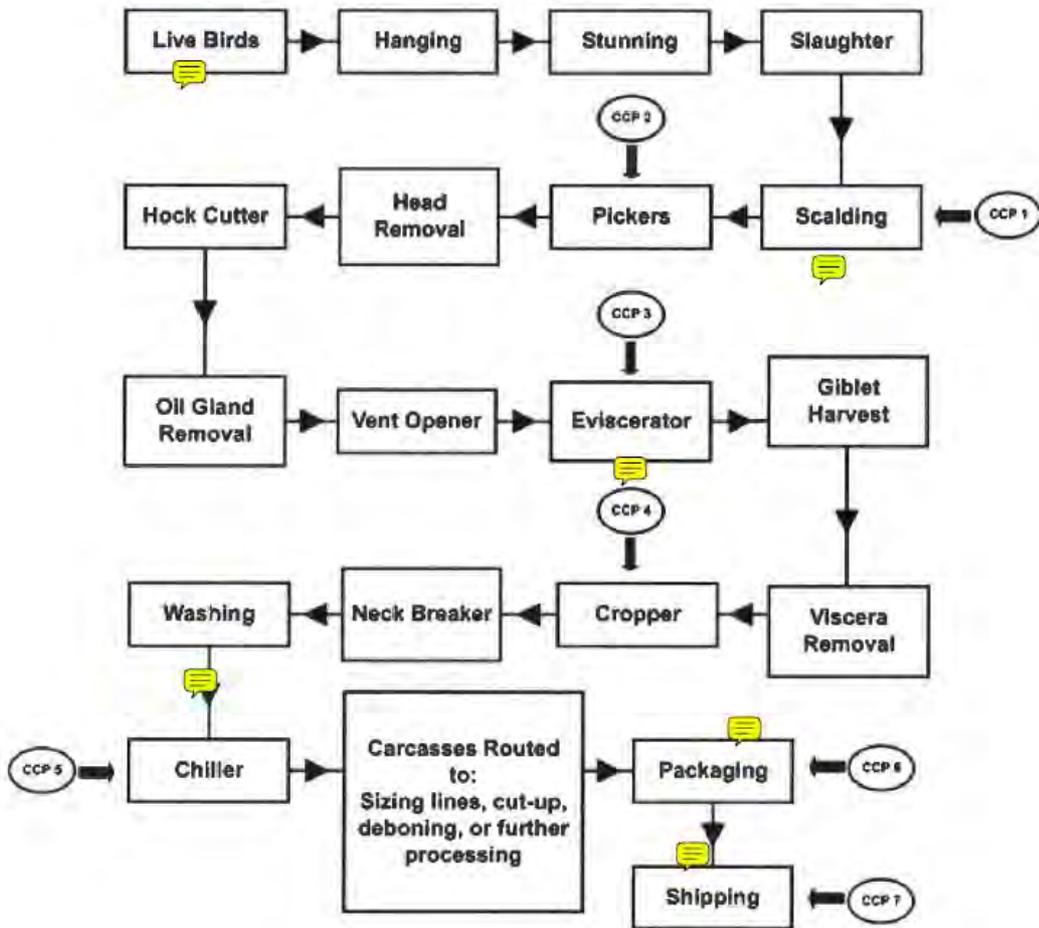


L to R: Benjy Mikel, KRG Meat Inspector, Chuck Lambert

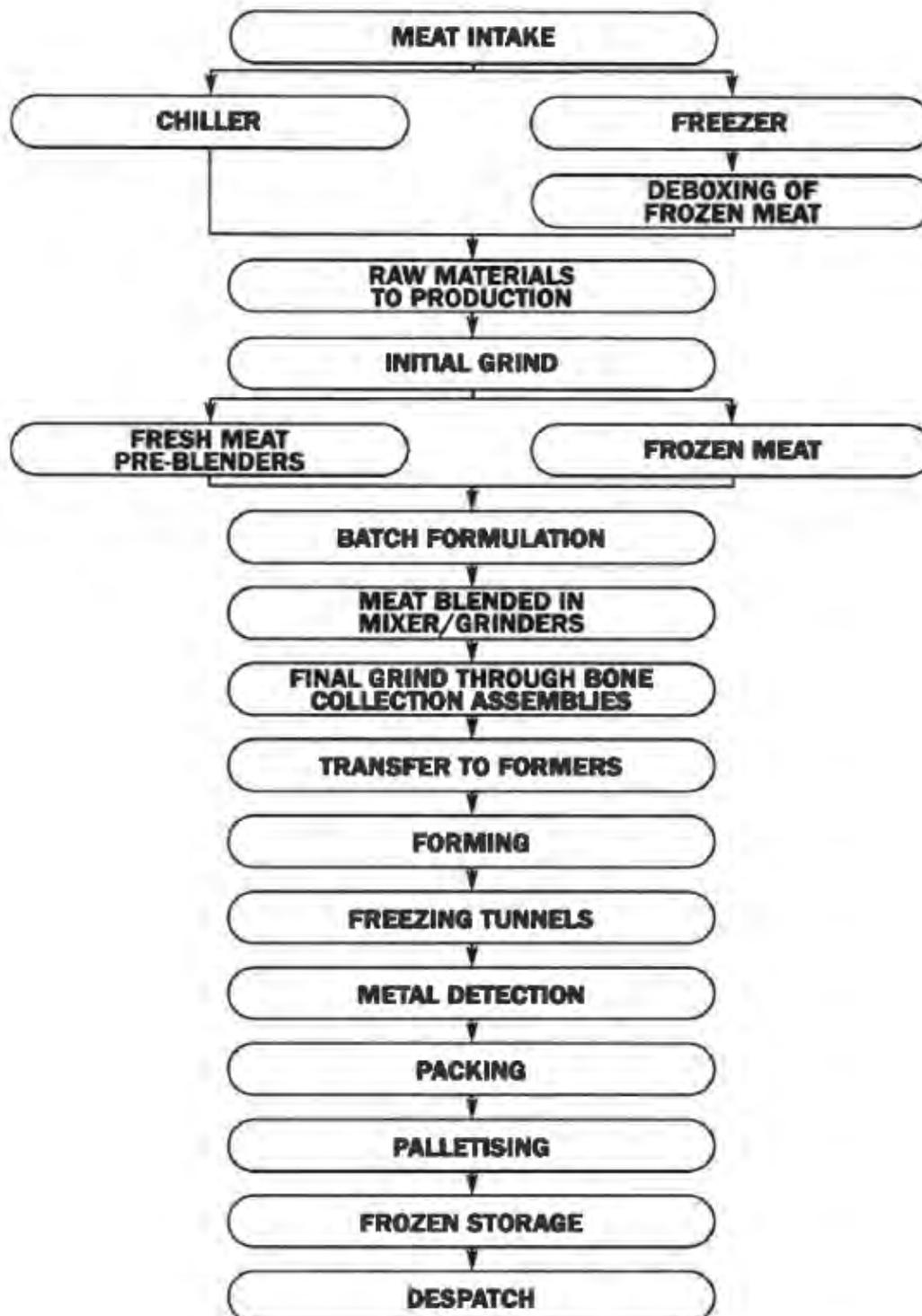
### Flow Chart for Integrated Poultry Production



### Flow Chart for Poultry Slaughter and Processing



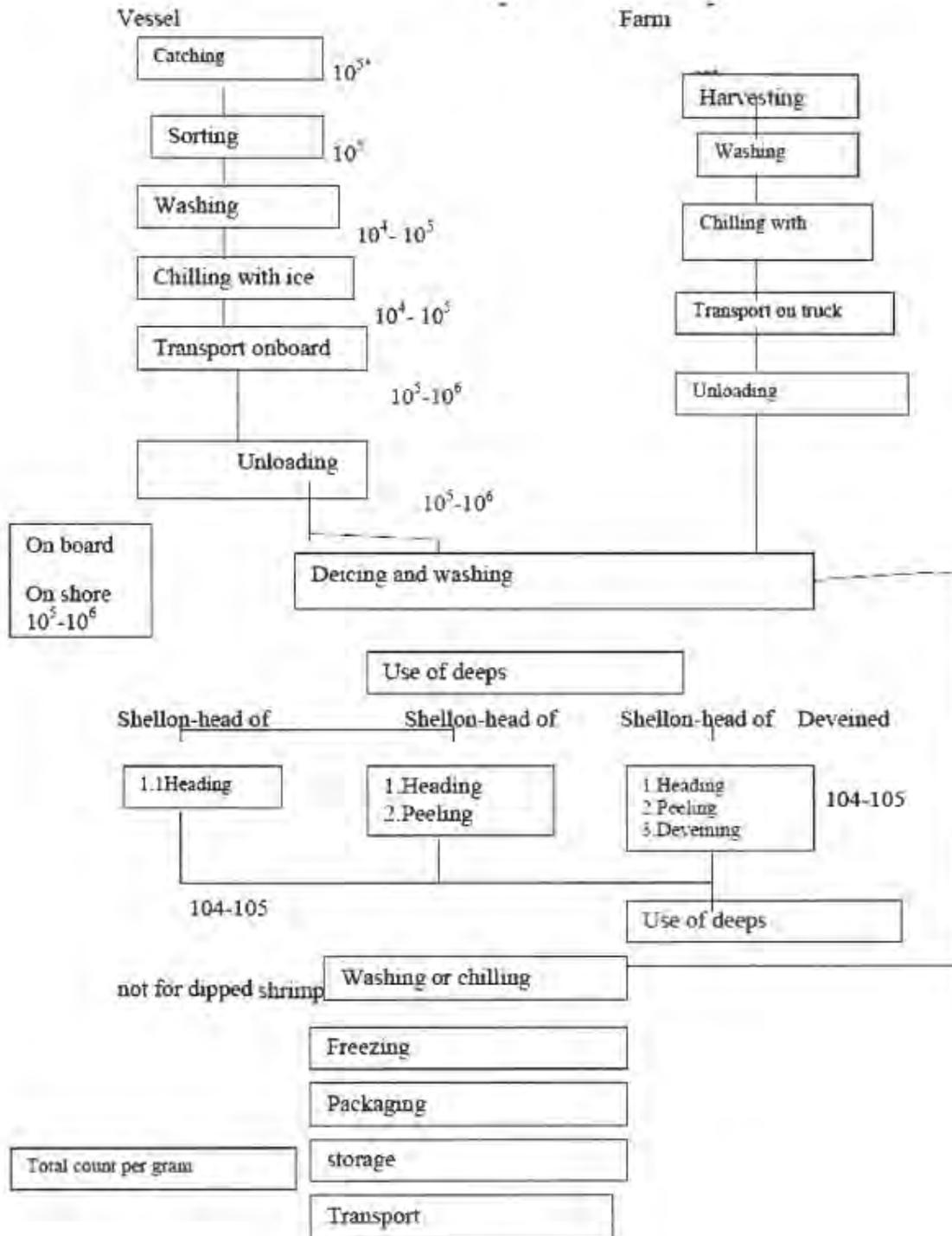
## Flow Chart for Making Further Processed Red Meat and Poultry Products



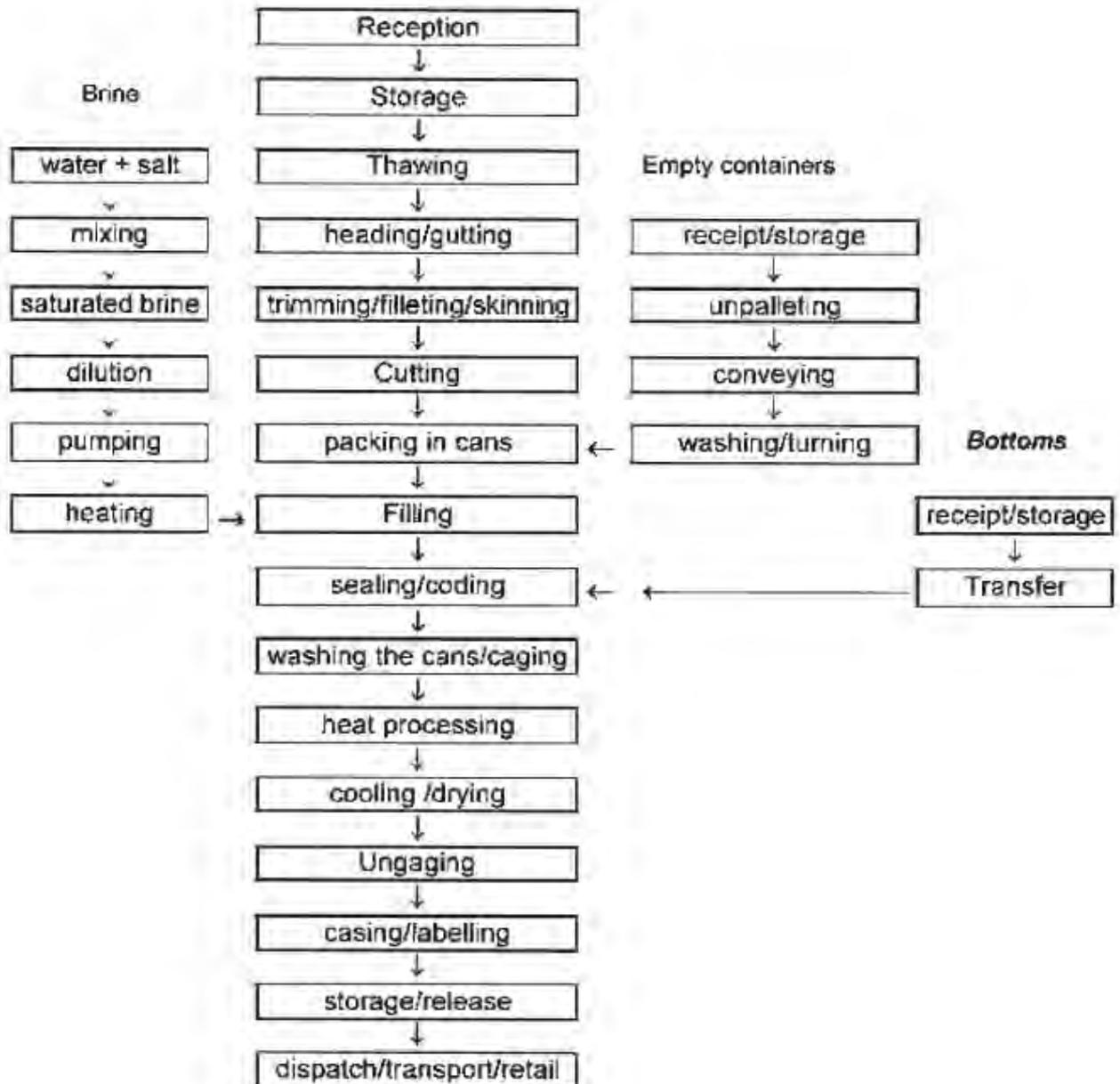


Frozen Hamburger Patties and Product in Frozen Storage

### Flow Chart for Wild-Caught or Farm-Raised Fish



### Flow Chart for Fish Further Processing and Canning



## Carp (Most Prevalent Iraqi Fish) Hazards

**TABLE 3-2**

**POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS**

Note: You should identify pathogens from the harvest area as a potential species-related hazard if you know or have reason to know that the fish will be consumed without a process sufficient to kill pathogens, or if you represent, label, or intend for the product to be so consumed. (See Chapter 4 for guidance on controlling pathogens from the harvest area.)

MARKET NAMES	LATIN NAMES	HAZARDS				
		PARASITES	NATURAL TOXINS	SCOMBROTOXIN (HISTAMINE)	ENVIRONMENTAL CHEMICALS	AQUACULTURE DRUGS
		CHP 5	CHP 6	CHP 7	CHP 9	CHP 11
CARP	<i>Barbonymus spp.</i>				√	
	<i>Cyprinus carpio</i>				√	
	<i>Hypophthalmichthys molitrix</i>				√	
	<i>Hypophthalmichthys nobilis</i>				√	
	<i>Carassius carassius</i>				√	
CARP, AQUACULTURED	<i>Cyprinus carpio</i>				√	√
	<i>Hypophthalmichthys molitrix</i>				√	√
	<i>Hypophthalmichthys nobilis</i>				√	√
	<i>Carassius carassius</i>				√	√



## Chapter 9: HACCP FOR DAIRY FARMS & PRODUCTS

### What's HACCP ?



- Hazard Analysis
  - A threat to food safety categorized from 3 areas: biological, chemical or physical
- Critical Control Points
  - CCP- (Critical Control Point) a point, step or procedure where a control can be used and a food hazard can be prevented, eliminated or reduced to acceptable levels.

### HACCP



- To **protect the food supply** and **assure food safety**, the FDA has adopted HACCP as the food safety system
- First developed nearly 30 years ago for astronauts
- **Systematic approach** to be used in food production as a means to **assure food safety**
- **Endorsed** by many national and international scientific groups, corporations, government, agencies and academic organizations

## HACCP

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- HACCP focuses on preventing hazards in the food industry, not on catching them when it's too late
- *Think of it as a pro-active solution instead of after-the-fact-fix*

## HACCP Plan and System

---

- Five preliminary steps and seven principles
  - Preliminary Steps -
    - Assemble the HACCP team.
    - Describe the food and the method of its distribution.
    - Identify the intended use and consumers of the food.
    - Develop a flow diagram which describes the process.
    - Verify the flow diagram.

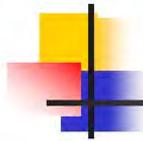




## HACCP: Principles

---

- Principles
  - **Principle No. 1.** Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.
  - **Principle No. 2.** Identify the critical control points (CCPs) in the process.
  - **Principle No. 3.** Establish critical limits for preventive measures associated with each identified CCP.



## HACCP: Principles

---

- **Principle No. 4.** Establish CCP monitoring requirements.
- **Principle No. 5.** Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.
- **Principle No. 6.** Establish effective record-keeping procedures that document the HACCP system.
- **Principle No. 7.** Establish procedures for verification that the HACCP system is working correctly.

## HACCP: steps 1-3

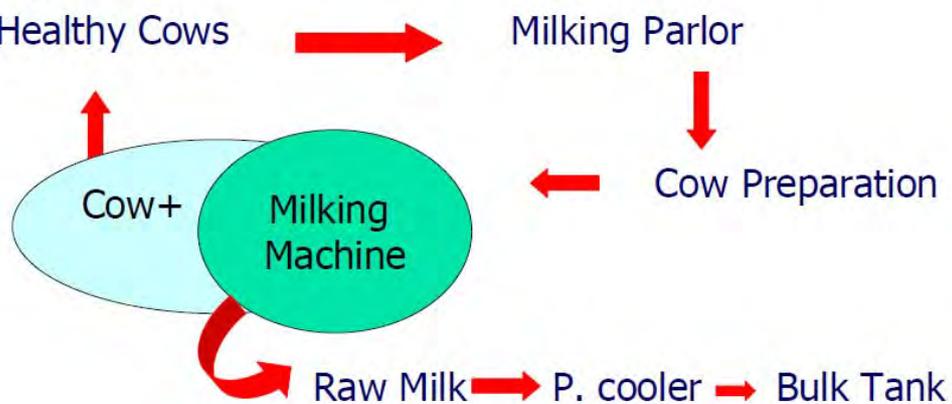
- Assemble the HACCP team.
- Describe the food and the method of its distribution.
- Identify the intended use and consumers of the food



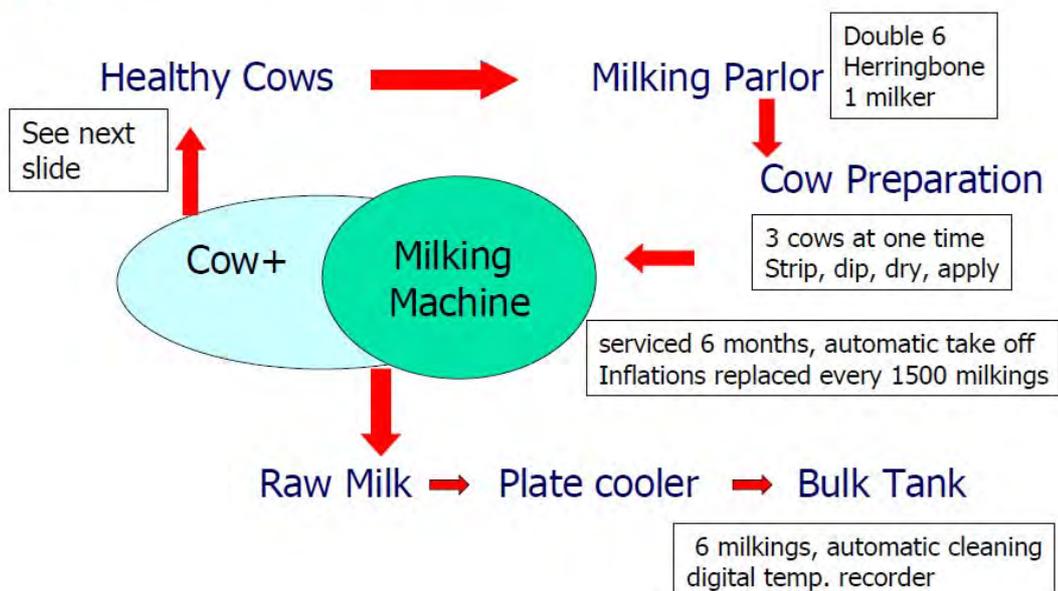
- RAW FLUID MILK
  - BTSCC ~ 250,000 CELLS/ML
  - Lac = 4.8, Pro = 3.3, Fat = 3.8
  - Temp ~ 40 F
  - SPC = ~ 5000 cfu/ml
  - Coliforms – NIL
  - PIC = < 3 x 4 SPC
- MILK COOPERATIVE
- Human consumption following pasteurization

## HACCP: steps 4

- Develop a flow diagram which describes the process



## HACCP: step 5



## HACCP: principles

- **Principle No. 1.** Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.
  - **Cows** (mastitis, SCC, udder condition)
  - **Parlor** (hazardous const. Stray voltage)
  - **Milker** (training and supervision)
  - **Cow Preparation** (written protocols in practice)
  - **Milking System** (service and maintenance protocols)
  - **Bulk Tank** (bulk tank temp, and recording device)

## HACCP: principles

- **Principle No. 2.** Identify the critical control points

- **Cows**

Criteria	Ideal udder health targets
Bulk Milk Somatic Cell Count	< 250,000 cells/ml
Herd average ( actual)	< 200,000 SCC
Herd average ( DHI Linear Score)	< 3.0 LS SCC
100% of first calvers (DHI)	< 100,000 SCC
> 85% of herd	< 200,000 SCC
> 95% of herd	< 500,000 SCC
Incidence of Clinical Mastitis	< 25 cows /100 cows / year
# of culls due to udder health	< 5 cows/ 100 cows/ year

## HACCP: principles

- **Principle No. 2.** Identify the critical control points

- **Parlor**

- Floor - Cleaned and sanitized after every milking
- Drop hoses - Periodically sanitized and replaced
- Stray voltage - Checked periodically every 6 months
- Light - 150 lux units
- Ventilation -150 cubic feet/ min of air exchange
- Milking pit - Cleaned, sanitized after every milking



## HACCP: principles

---

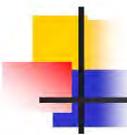
- **Principle No. 2.** Identify the critical control points
  - **Milker**
    - **Cow handling**
    - **Detecting mastitic cows, identifying and reporting**
    - **Recognizing the importance of cows treated with antibiotics**
    - **Proper milking procedures**
      - Cow preparation
      - Milking process
    - **Milking system**
      - Daily checks on system function
      - Basic understanding on the working of milking machine



## HACCP: principles

---

- **Principle No. 2.** Identify the critical control points
  - **Cow Preparation**
    - **Udder, teat and teat end condition**
      - Cleanliness ( manure, feed, bedding)
      - Dry (Wet, chapped)
      - **Teat teat end condition** (warts, injury)
    - **Milking process**
      - **Strip**
      - **Dip** (prep-dip, dip cup)
      - **Dry** (through cleaning, including teat ends)
      - **Apply** (apply post-dip)
      - Other factors: **Consistency and repeatability** on each cow
      - Milking time on each cow



## HACCP: principles

---

- **Principle No. 2.** Identify the critical control points
  - **Milking System**
    - **Checked daily**
    - **Inspected every 6 months**
    - **Serviced every year**
    - **Inflations replaced after 1500 milkings**
    - **Sanitizer and acid rinse containers inspected and periodically replaced**
    - **Gaskets and liners inspected periodically and replaced**
    - **Water temp. recorded periodically**



## HACCP: principles

---

- **Principle No. 2.** Identify the critical control points
  - **Bulk Tank**
    - **Bulk tank temperature**, monitored daily
    - Temperature must **reach 40 F within 2 h of milking** and hold
    - Milk agitator

Estimates of percent infected quarters and losses in milk production due to elevated BTSCC

<b>BTSCC/ml</b>	<b>Percent Quarters Infected</b>	<b>Percent Production Loss</b>
<b>200,000</b>	<b>6</b>	<b>0</b>
<b>500,000</b>	<b>16</b>	<b>6</b>
<b>1,000,000</b>	<b>32</b>	<b>18</b>
<b>1,500,000</b>	<b>48</b>	<b>29</b>



## HACCP- principles

**Principle No. 3** Establish critical limits for preventive measures associated with each identified CCP

<b>Criteria: COWS</b>	<b>Critical Limit</b>	<b>Preventive Measure</b>
Cows treated with antibiotics	ZERO LIMIT	Label cows and milk them separately not in the parlor
Cows with chronic mastitis milked along with healthy cows	UNDEFINED Contagious mastitis pathogens in bulk tank milk ?	Cows will be identified and milked last Sanitize teat cups between milking

## HACCP- principles

<b>Criteria:Cows</b>	<b>Critical Limit</b>	<b>Preventive Measure</b>
Dirty & Soiled Cows	UNDEFINED HIGH SPC and PIC counts	Flame udders Improve farm hygiene and sanitation
Cows high SCC	< 5 % of all cows in the herd should be ~ 500,000 cells/ml	Identify cows with high SCC, and determine their importance in the herd All fresh cows will be examined by CMT on the 6 <sup>th</sup> milking All cows before drying off will be CMT 7 days before drying off

## HACCP- principles

<b>Criteria:Parlor</b>	<b>Critical Limit</b>	<b>Preventive Measure</b>
Hygiene (Teat claws falling on the floor of the parlor)	Milk SPC > 5000 cfu/ml	Through cleaning and sanitization
<b>Criteria:Milker</b>	<b>Critical Limit</b>	<b>Preventive Measure</b>
Handling and Milking cows	UNDEFINED	Wear gloves

## HACCP- principles

<b>Criteria:Cow Preparation</b>	<b>Critical Limit</b>	<b>Preventive Measure</b>
Cleaning of teat ends	SPC > 5000 cfu/ml PIC > 3 to 4 x SPC SSLO > 100 cfu/ml CNS > 1000 cfu/ml Coliforms > 100 cfu/ml	Thorough cleaning of teat & teat ends using an approved pre-dip Fore-strip cows before pre-dipping

## HACCP- principles

<b>Criteria:Milking System</b>	<b>Critical Limit</b>	<b>Preventive Measure</b>
Function	DEFINED	Call service agent
Hygiene	DEFINED SPC > 5000 cfu/ml PIC > 3 to 4 x SPC Coliforms > 100 cfu/ml	Call sanitarian/ service agent
<b>Criteria:Bulk Tank</b>	<b>Critical Limit</b>	<b>Preventive Measure</b>
Temperature	SPC > 5000 cfu/ml PIC > 3 to 4 x SPC	Monitor bulk tank milk temperature

## HACCP-principles

### **Principle No. 4.** Establish CCP monitoring requirements

<b>Criteria: bulk tank milk</b>	<b>Limit</b>
BTSCC	< 250,000
SPC	< 10,000 cfu/ml
PIC	< 4 to 4 x SPC
LPC	< 100 cfu/ml
Coliforms	< 50 cfu/ml
Staph aureus	ZERO
Strep. ag	ZERO
Mycoplasma	ZERO
SSLO	~ 1000 CFU/ML
CNS	~ 1000 CFU/ML

## HACCP-principles

- **Principle No. 5.** Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

## Bulk Tank Milk Analysis:

A tool for improving milk quality and troubleshooting mastitis in a dairy herd



PENNSSTATE



## Somatic Cells

SCC	Count
ideal	200,000
4/16	141,000
5/2	225,000
5/19	173,000
6/5	325,000

## Somatic Cells

- **Corrective action**
  - Identify cows with high SCC
    - Early and late lactation
    - Cows with subclinical mastitis
      - CMT all suspect cows
  - CMT all fresh cows by 6<sup>th</sup> milking
  - CMT all cows 7 days before drying off
  - Make a decision to keep cows in the herd with high SCC

## Standard Plate Count

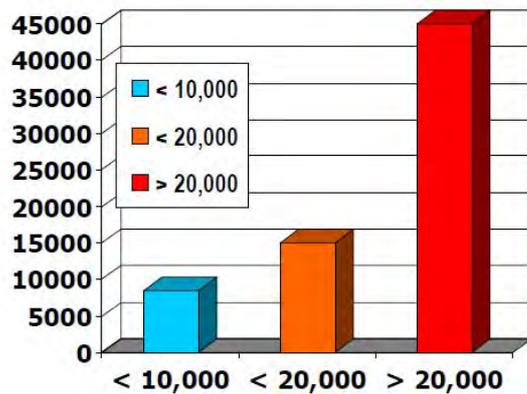
<b>SPC</b>	<b>Count</b>
ideal	10,000
4/16	1,320
5/2	1,040
5/19	1,360
6/5	1,040

## Standard Plate Count

Rating based on cfu/ml

**Good**   **Acceptable**   **Concern**  
(low)   (medium)   (high)

< 10,000   < 20,000   > 20,000



BTM SPC of < 1000 cfu /ml is an indication that milk is from clean and healthy cows

SPC counts of less than 5000 cfu/ml can be achieved

SPC of < 10,000 can be achieved by most farms

## Preliminary Incubation Count

PIC	Count
ideal	10,000
4/16	1,600
5/2	4,800
5/19	14,000
6/5	2,000

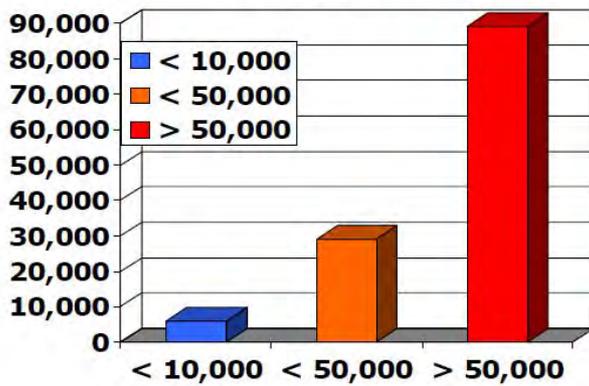
## PI Counts



### Rating based on cfu/ml

Good (low)	Acceptable (medium)	Concern (high)
10,000	< 50,000	> 50,000
	or	or
	< 3-4 x SPC	> 3-4 x SPC

Doc ?  
Why are my PI counts high ?

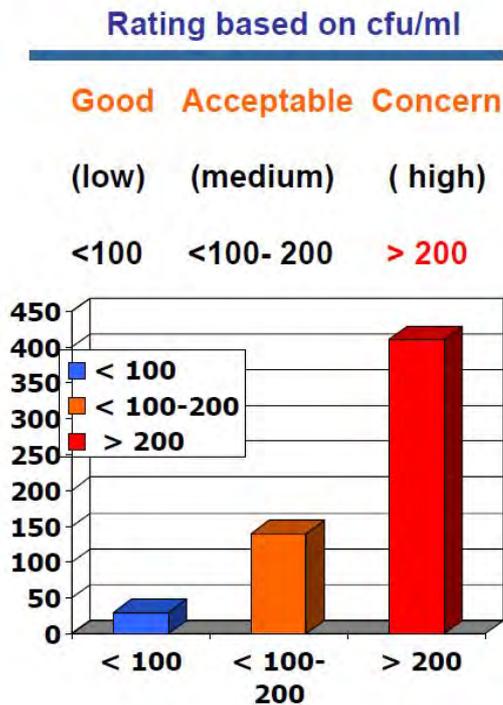


1. Cleaning and sanitation of the milking system
2. Poor udder preparation before milking
3. Failure to cool milk rapidly
4. Prolonged storage times

## Laboratory Pasteurization Count

LPC	Count
ideal	100
4/16	20
5/2	20
5/19	0
6/5	0

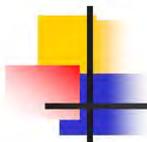
## LP Count



Unclean milking equipment

Faulty milking machine or worn out parts

Extremely dirty cows



## What causes mastitis ?



- Bacteria ( ~ 70%)
- Yeasts and molds ( ~ 2%)
- Unknown ( ~ 28%)
  - physical
    - trauma
    - weather extremes



## Contagious Mastitis Pathogens

	<b>Staph. aureus</b>	<b>Strep. Ag.</b>	<b>Mycoplasma</b>
<b>ideal</b>	<b>0</b>	<b>0</b>	<b>0</b>
4/16	40	Not detected	Not detected
5/2	20	Not detected	Not detected
5/19	20	Not detected	Not detected
6/5	0	Not detected	Not detected

### *Staphylococcus aureus*

**Type of herd:** **closed herd**, suggests the presence of chronic infection; **open herd**, suggests the likelihood of newly purchased animals as one of the possible source of *Staph. aureus*.

**BTSCC** in a herd with high *Staph. aureus* infection, generally ranges from 350,000 - 1000,000 cells/ ml (most occasions 500,000- 600,000 cells/ml).

**Management practices** that allow spread of *Staph. aureus* in the herd:

1. Milking cows without gloves
2. Cloth towels reused without proper cleaning
3. Milking infected cows along with uninfected cows
4. Poor fly control during summer
5. During winter, milking cows with chapped teats
6. Milking cows with teat and teat end injuries



## ***Streptococcus agalactiae***

**Type of herd:** **closed herd**, suggests presence of chronic infection; **open herd**, suggests both the likelihood of newly purchased animals bringing in the infection.

**BTSCC** in a herd with high *Strep. agalactiae* infection, BTSCC count generally ranges from 500,000- 600,000 cells/ml, with high SPC ( 50,000 to > 100,000 cfu/ml).

**Management practices** that allow spread of *Strep. agalactiae* in the herd:

1. Milking cows without gloves
2. Cloth towels reused without proper cleaning
3. Milking infected cows along with uninfected cows
4. No or inadequate teat-dipping practices

## ***Mycoplasma***

**Type of herd:** **closed herd**, suggests the presence of chronic infections in the herd that would include animals of all ages; **open herd**, suggests the likelihood of newly purchased animals as one of the possible source of Mycoplasma

**BTSCC** is generally > 500,000 cells/ ml when there are more than 5 to 10% of the cows with Mycoplasma infection.

**Management practices:**

1. poor herd health management practices with a history of Mycoplasma pneumonia in the herd including calves
2. hygroma in adult cattle; cows treated for clinical mastitis do not respond to treatment;
3. Cloth towels and cannulas are reused without proper cleaning and disinfection.



## Environmental Mastitis Pathogens

	CNS	SSLO	Coliforms	Non-coliforms
<b>Ideal</b>	<b>1,000</b>	<b>1,000</b>	<b>50</b>	<b>1,000</b>
4/16	620	620	20	0
5/2	960	240	0	0
5/19	900	520	20	180
6/5	480	1,000	0	20



## Environmental Mastitis Pathogens

### **BTSCC:**

Streptococci and Strep-like organisms: 250,000- 450,000 cells/ml.

CNS: 350,000 - 500,000 cells/ml

Coliforms: < 300,000 cells/ml

Non-coliforms: No data

### **Milking Procedures:**

No established milking protocol(varies from milker to milker )

Poor udder surface (clipping or flaming not done)

Teat and teat ends not thoroughly cleaned

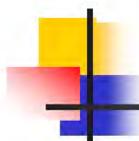
Milking done on wet teats

Cloth towels reused without cleaning

### **Farm Hygiene**

Poor bedding management

Manure removal not done regularly



## HACCP- principles

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- **Principle No. 6.** Establish effective record-keeping procedures that document the HACCP system.
  
- Daily Check lists and records
  - Example: bulk tank milk temperature
- Monthly Check lists and records
  - Example: BTSCC and individual cow SCC
- Six Monthly Check lists and records
  - Example: Milking system inspection



## HACCP- principles

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- **Principle No. 7.** Establish procedures for verification that the HACCP system is working correctly.
  
- Monthly bulk tank milk reports

## DAIRY QUALITY ASSURANCE PROGRAM



**Lawrence Hutchinson**

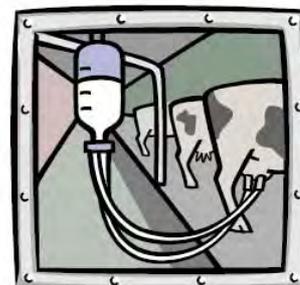
Extension Veterinarian

Department of Veterinary Science  
The Pennsylvania State University  
University Park



## NON-MILKING TIME EVALUATION

- Equipment cleaning procedures
- Equipment evaluation
  - Pump
  - Pulsators
  - Regulators
  - Inflatons
- Parlor sanitation
- Employee training



## CLINICAL MASTITIS

- Organism ?
- Severity ?
- Stage of Lactation
- Parity
- Treatment Response



## RISK ASSESSMENT

- Systematic evaluation of farm
  - By groups
  - By area of concern
- Identification and quantitation of potential problem, or risk areas

## STEPS TO SOLVE MILK QUALITY AND MASTITIS PROBLEMS

- Records
- Milking-time evaluation
- Non-milking time evaluation
- Clinical mastitis
- Risk assessment

### RECORDS

- Individual Cow
  - Production level
  - SCC
  - Culture
- Bulk Tank
  - SCC
  - Culture
  - Bacteria types and concentration
- Treatment Protocols
- Treatment Records
- Standard Operating Procedures



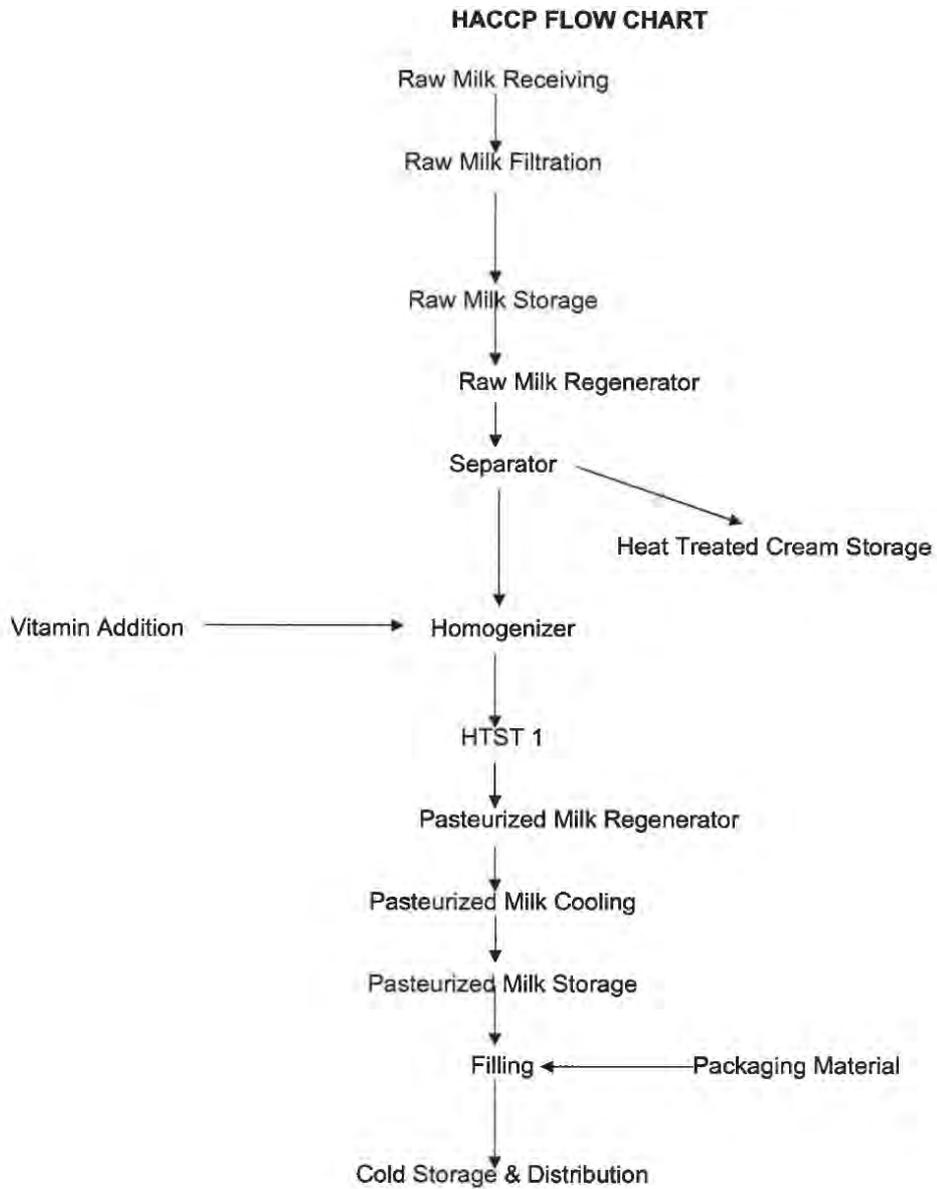


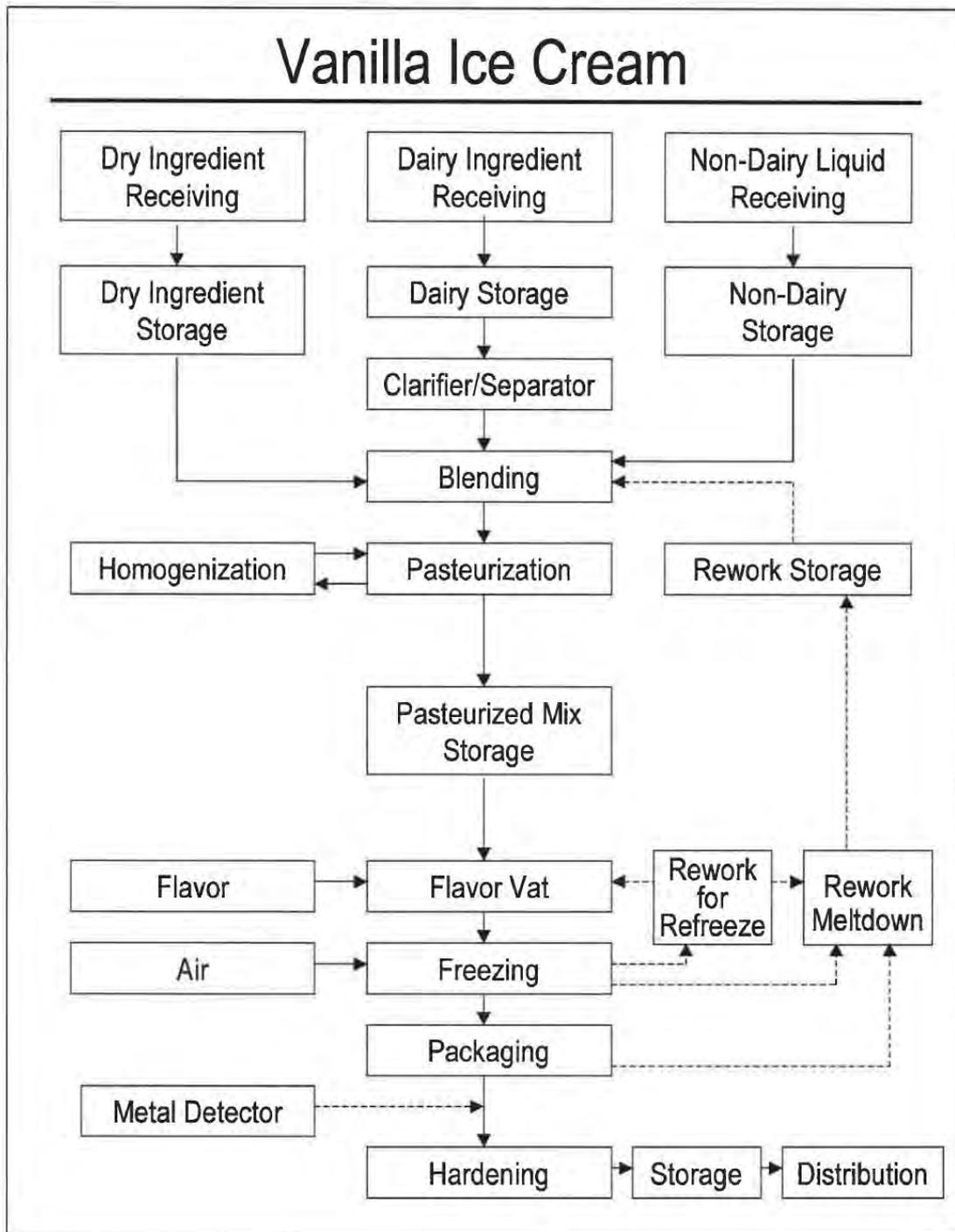
## MILKING TIME EVALUATION

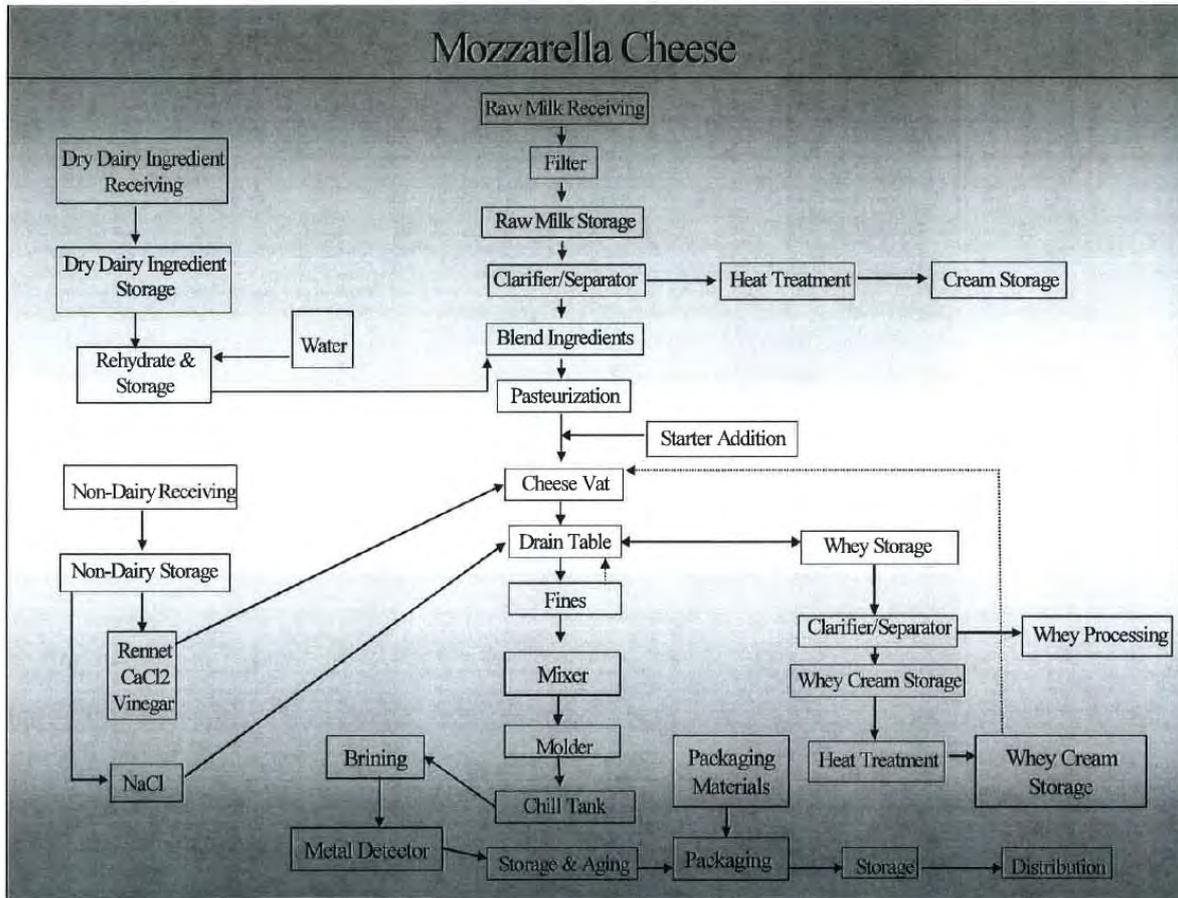
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- Sanitation
- Cow-handling
- Teat preparation
- Unit-on time
- Post-milking:teat dip

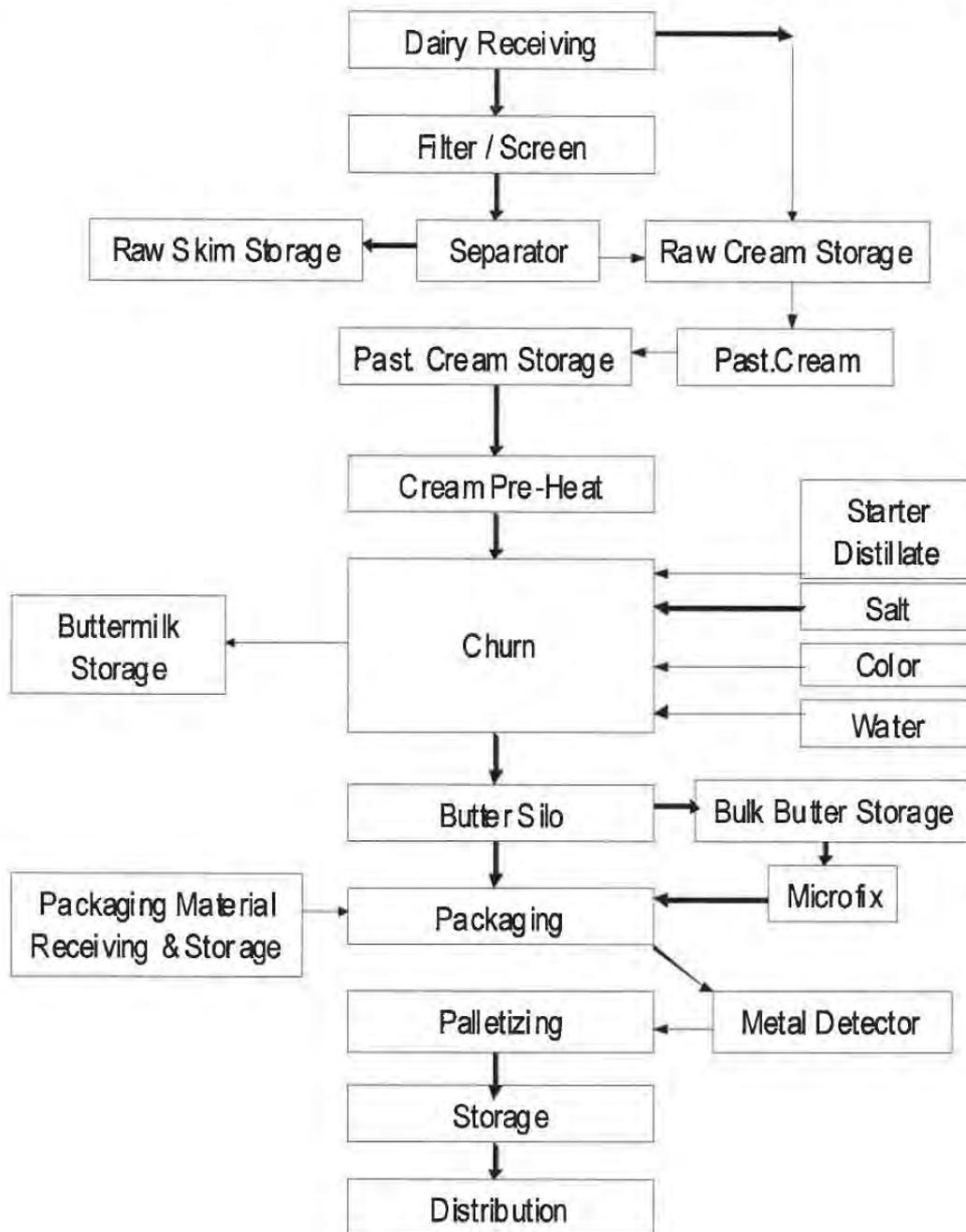
## Pasteurized Milk Processing





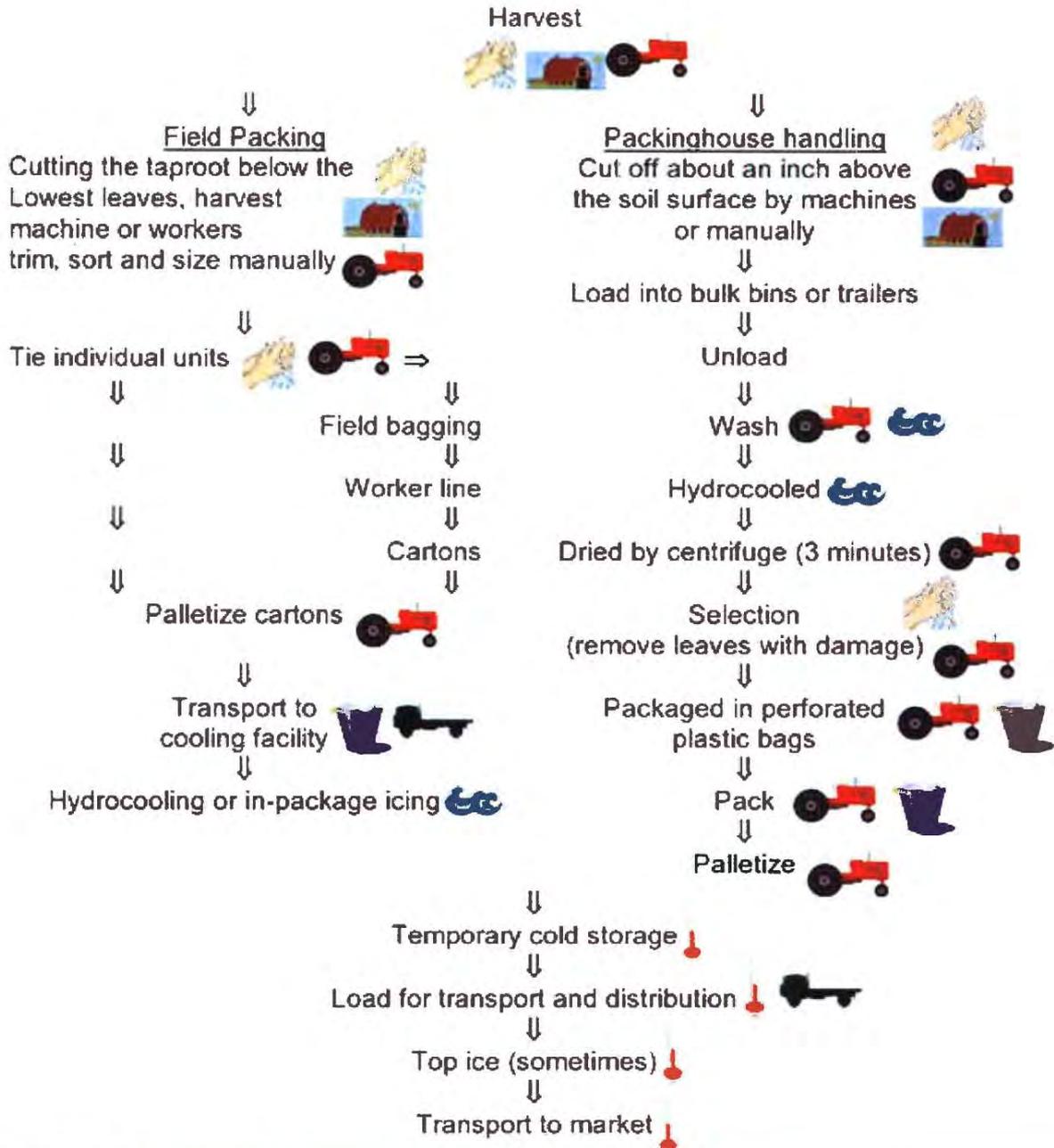


# Butter



Chapter 10: HACCP FOR PRODUCE

Harvest and Post-Harvest Process for Leafy Vegetables



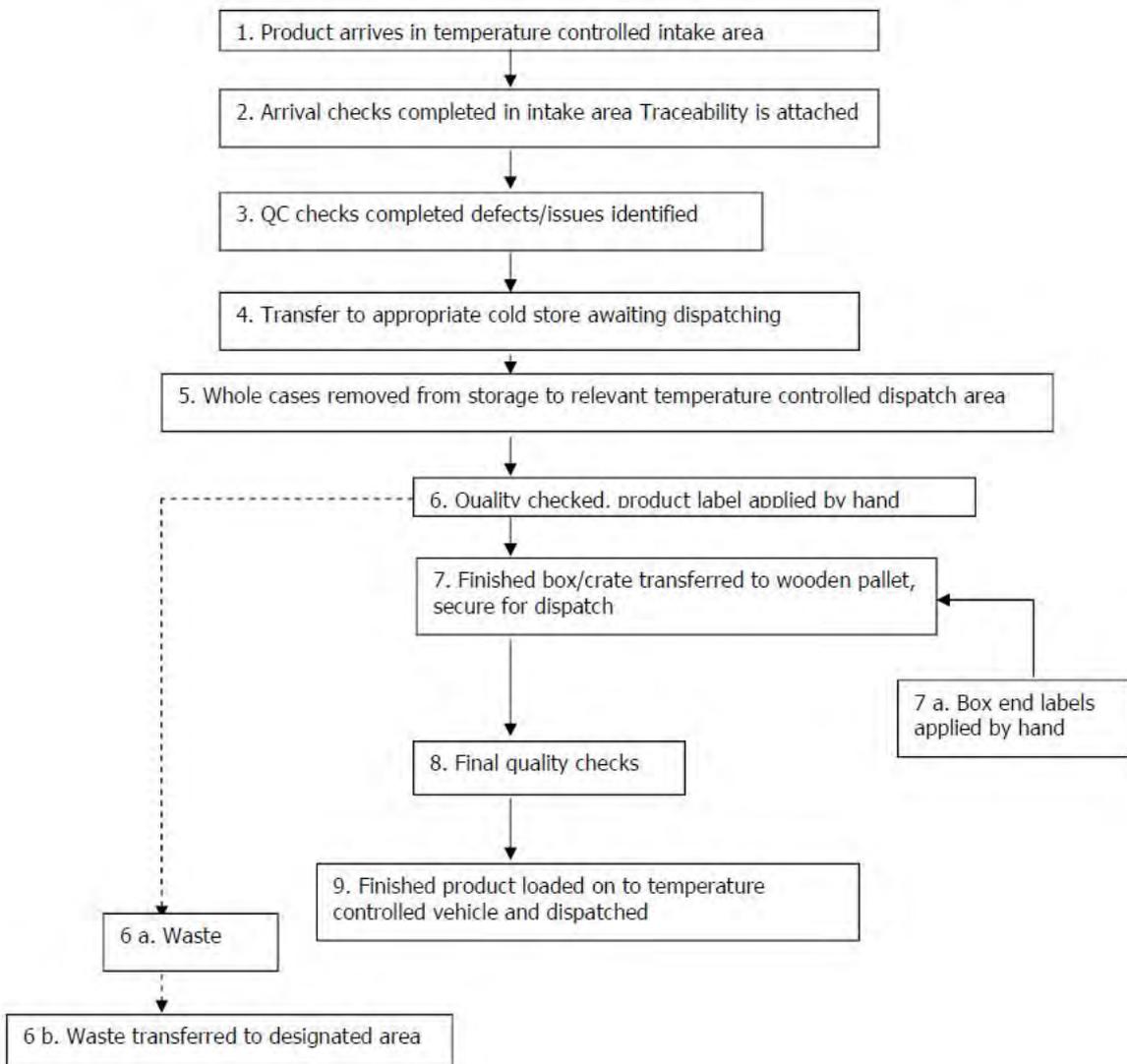
Hazard Control Point



<i>HACCPEuropa.com</i>	<b>HACCP Plan</b>  <b><i>Wholesale Fruits and Vegetables</i></b>	Issued:
		Issued by:
		Reviewed:
		Next review:
		Page 12 of 24

**Flow Diagram**

*Product sold as whole loose cases or products pre-packed/labelled at source of origin*



VALIDATED BY:

POSITION:

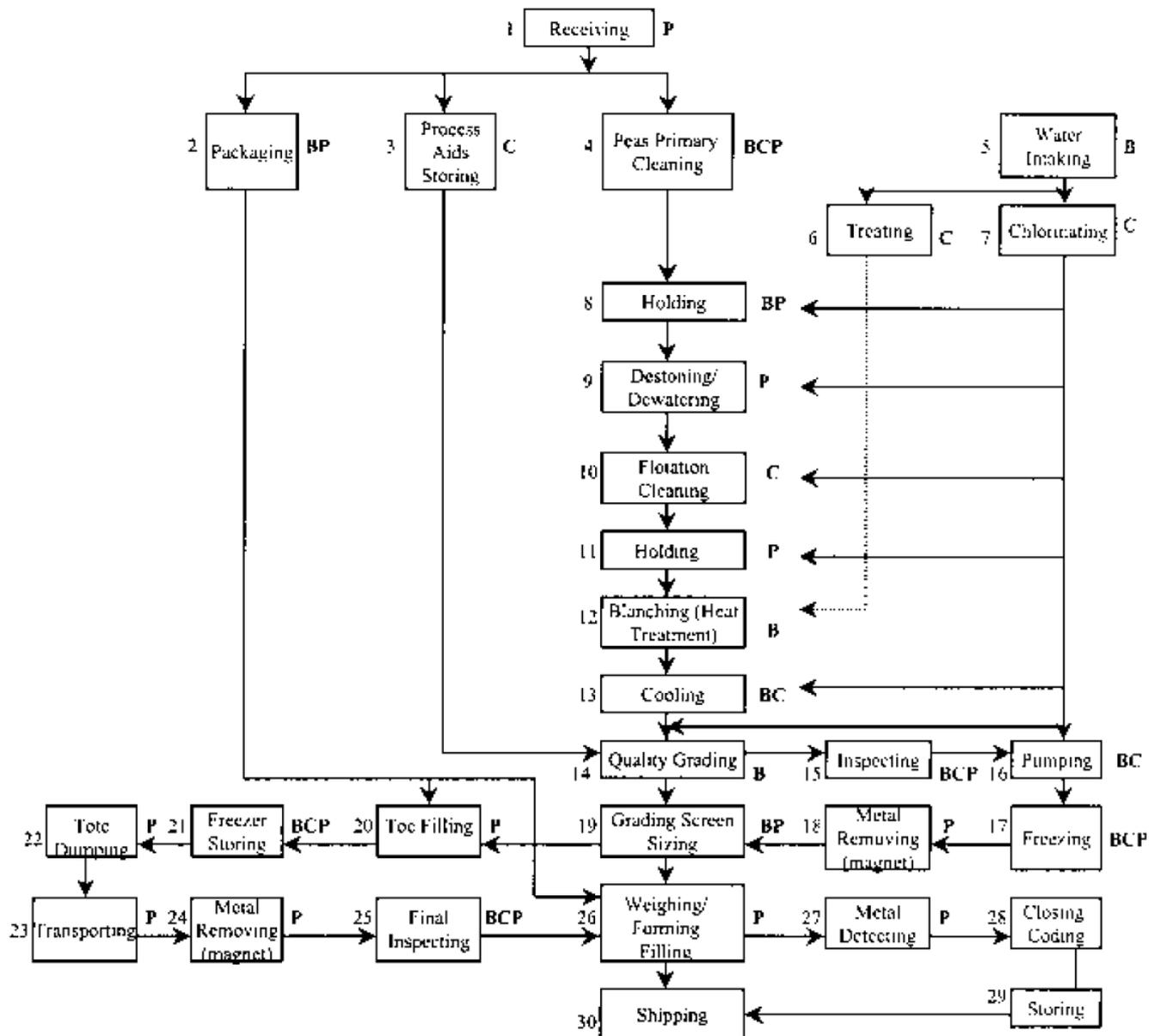
DATE:

VALIDATED BY:

POSITION:

DATE:

### Flow Diagram for Frozen Vegetables



Chapter 11: HACCP REVIEW AND U.S. SYSTEMS



## Food Safety

### Prevention of hazards in foods

- Physical
- Biological
- Chemical
  - Allergens



## Responsibility for food safety

- Producer/grower
- Manufacturer
- Distributor
- Transporter
- Retailer
- Consumer



## Industry Responses

- Consumer education
- HACCP and HACCP based Food safety programs for all sectors



## HACCP - Answers 3 questions

- |                  |   |
|------------------|---|
| <b>H</b> azard   | • <b>WHAT</b> hazards can enter the product?            |
| <b>A</b> nalysis | • <b>Where</b> do these hazards occur?                  |
| <b>C</b> ritical | • <b>How</b> can we control or eliminate these hazards? |
| <b>C</b> ontrol  |   |
| <b>P</b> oint    |   |



## HACCP

- Science based
- Step wise process:
  - Identifies hazards
  - Installs preventative measures to eliminate or reduce hazards in foods
- Proactive rather than reactive
- Risk based



## HACCP

- Does not rely on end product testing
  - hazards not be evenly distributed and can be missed in sampling
  - need to test large quantities
  - product would need to be destroyed or reworked



## HACCP

- Starts from the beginning of the process
  - Receiving of ingredients, packaging
- through process steps
- to final product and shipping



## Pillsbury

***“come as close to 100% assurance as possible that food products would not be contaminated with pathogens.”***

***“needed control over raw materials, environment and people as early in the system as possible....”***



## Components

- Pre-requisite program
- Hazard analysis



## Prerequisites

- Foundation to a HACCP program
- Includes Good Manufacturing Practices
- Addresses food safety at all stages from receiving to shipping
  - Including indirect hazards



## Prerequisite program

- Premises
- Transportation and Storage
- Equipment
- Personnel/Training
- Sanitation and Pest Control
- Recall
- Allergen Control
- Supplier Quality Assurance



## Premises

- Outside property and building
- Design, construction & maintenance
- Lighting
- Ventilation
- Waste disposal
- Inedible areas
- Employee & sanitary facilities
- Water/Steam/Ice



## Transportation and Storage

- Food Carriers
- Temperature Controls
- Receiving and Storage
  - Incoming ingredients and packaging
  - Non-Food Chemicals
- Finished Product Storage



## Equipment

- Design and installation
- Maintenance and Calibration



## Personnel

- Trained for their job
- Understand food safety



## Sanitation and Pest Control

- Sanitation
  - Equipment and Utensils
  - Floors
  - Locker rooms
  - Lunch rooms
  - Washrooms
- Pest control



## Recall

- Product identification
- Locating product
- Returning product



## Allergen control

- Identification of Allergens
- Control of allergens
  - Special handling
  - Segregate
  - Special sanitation procedures
  - Rework
  - Proper labelling



## Supplier Quality Assurance

- Vendor approval process
- Product specifications
- Inspect incoming materials



**Now on to the  
HACCP plan ....**



## Sequence of 12 Steps

1. Assemble HACCP team
2. Describe product
3. Identity intended use
4. Construct process flow and plant schematic
5. On site verification of flow and schematic
6. List hazards associated with each process step  
(principle #1)



## Sequence of 12 steps

7. Apply HACCP decision tree to determine CCP's  
(Principle #2)
8. Establish critical limits (Principle #3)
9. Establish monitoring procedures (Principle #4)
10. Establish deviation procedures (Principle #5)
11. Establish verification procedures (Principle #6)
12. Establish record keeping/documentation for  
principles 1 - 6 (Principle #7)



## Product Description

- **Product Name(s)**
- **Important Product Characteristics**
- **How it is to be used**
- **Packaging**
- **Shelf Life**
- **Where it will be sold**
- **Labelling Instructions**
- **Special Distribution Control**
- **Specific Ingredients**



## Define the processing steps



## Construct Plant Schematic

Place Your Establishment's Plant Schematic Here



## Determine hazards

- Look at each input- ingredients
- Determine possible hazards
- How are they controlled?



## CCPs

- **Critical control points**
- **Place where you can prevent, remove or reduce a hazard**
- **if there is not step in the process that can eliminate or reduce the hazards- use labelling, cooking instructions to inform how control can be achieved**



## Our CCPS

- **Metal detector**
  - **Metal is a hazard in our facility**
  - **Not fully controlled by any prerequisite program**
  - **Metal detectors specifically designed identify product containing metal**
  - **That product can be removed**
  - **No other step will remove the metal**



## CCPs

### What is your role?

- **Monitor**
  - Look, smell, measure
- **Record**
- **Corrective actions**
- **Verify**
  - Monitor people doing activity
  - Take corrective actions when necessary
  - Complete records properly



## Practical application



## On the job.....

- Watch for hazards and remove any that you find
- If you are involved in CCP monitoring:
  - Perform your checks as required:
    - according to procedure
    - on time



## Food Defense





### Federal Activities Pertaining to Agriculture

- The **National Strategy for Homeland Security** agriculture identified as a critical infrastructure
- **PATRIOT ACT** defines the critical infrastructure as systems or assets whether physical or virtual that are so vital that incapacity or destruction of them would have a debilitating impact on the security, economic security, or public health of the Nation.
- **Homeland Security Presidential Directive/HSPD-9** establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies.



## Bioterrorism Preparedness Act



- Expand FDA authority of manufacturing and import
- Tightened control of Biological Agents and toxins
- Expanded Ag security activities at USDA
- Criminal penalties for activities against animals and violation of the select agent rules



## Homeland Security Act - 2002



- Transferred Ag border inspections from APHIS to DHS (2,680 inspectors)
- Possession of Plum Island from USDA to DHS





**USDA** *United States Department of  
Agriculture*

- In the event of an Agricultural Emergency the USDA would take the lead in protecting agriculture the environment and our food supply.
  - Animal and Plant Health Inspection Service - APHIS
  - Veterinary Services - VS
  - Foreign Animal Disease Diagnosticians - FADD
  - Food Safety and Inspection Service - FSIS
  - Agricultural Research Service - ARS
  - Cooperative State Research Education and Extension Service - CSREES



*The Department of Health And  
Human Services*

- HHS is the principal agency for protecting the health of all Americans
  - The Centers for Disease Control and Prevention (CDC)
  - Food and Drug Administration (FDA)
  - Center for Veterinary Medicine (CVM)



## ***Why Agriculture is a potential target of Terrorism?***



- Ease of implementation
- Disruption of the nation's food supply and effect on the U.S. economy
- Public fear regarding the safety of their food
- Public fear regarding the government's capacity to protect them against human-directed WMD
- Disruption of the United States' ability to export food products



## ***Bioterrorism***

- The use or threatened use of microorganisms or toxins
- Intended to promote or spread fear upon an individual, group or population.
- Agroterrorism: Act of terror directed against livestock, plants, foods or feeds.



### Office International des Epizooties List A Diseases

- FOOT AND MOUTH DISEASE
- VESICULAR STOMATITIS
- SWINE VESICULAR DISEASE
- RINDERPEST
- PESTE DES PETIS CONTAGIOUS BOVINE PLEUROPNEUMONIA
- LUMPY SKIN DISEASE
- RIFT VALLEY FEVER
- BLUETONGUE
- SHEEP POX AND GOAT POX
- AFRICAN HORSE SICKNESS
- AFRICAN SWINE FEVER
- CLASSICAL SWINE FEVER
- HIGHLY PATHOGENIC AVIAN INFLUENZA
- NEWCASTLE DISEASE
- BSE

Transmissible diseases that have the potential for very serious and rapid spread, irrespective of national borders



### Foodborne Pathogens as Bloweapons?

- *Bacillus anthracis*
- *Escherichia coli* O157:H7
- *Campylobacter jejuni*
- *Listeria monocytogenes*
- *Clostridium botulinum*
- *Salmonella spp.*
- *Clostridium perfringens*
- *Staphylococcus aureus*

## Zoonotic?



**Potential to affect both man and other Animals**



## Food Defense

Wisconsin is famous for its production of fine Cheddar cheese, comprising more than 50% of the total cheese production of the state.



**What is going to happen if someone adds Ricin to a bulk milk tank on the farm? How will this effect Wisconsin's dairy industry?**



## Vulnerability

### Assessments (Carver Plus Shock)

- Offensive targeting prioritization tool that has been adapted for use in the food sector.
- It allows you to think like an attacker by identifying the most attractive targets for attack.



## CARVER

- **Criticality** - measure of public health and economic impacts of an attack
- **Accessibility** – ability to physically access and egress from target
- **Recuperability** – ability of system to recover from an attack
- **Vulnerability** – ease of accomplishing attack
- **Effect** – amount of direct loss from an attack as measured by loss in production
- **Recognizability** – ease of identifying target



## CARVER evaluates a seventh attribute!

The combined health, economic, and psychological impacts of an attack, or the **SHOCK** attributes of a target.



### Using a scale from one to ten for each of the seven CARVER + Shock attributes

Criticality Criteria	Scale
Loss of over 10,000 lives or loss of more than \$100 billion.	9 – 10
Loss of life is between 1,000 – 10,000 or loss of between \$10 billion and \$100 billion.	7 – 8
Loss of life between 100 and 1000 or loss of between \$1 and \$10 billion.	5 – 6
Loss of life less than 100 or loss of between \$100 million and \$1 billion.	3 – 4
No loss of life or loss of less than \$100 million.	1 – 2



## Example of using a CARVER + Shock Analysis for Wisconsin Cheddar Cheese

### • Farm to Fork Analysis



WISCONSIN CHEESE.  
PRIDE. OUR SECRET INGREDIENT.®



### Steps Farm to Grocery



## Where do you start?



- Determine what part of the entire system will you evaluate.

- Farm to fork or
- Just the steps directly under you control e.g. cheese manufacture.

- Define your scenario.

- Type of terrorist (internal or external)
- Agent of concern (biological or chemical)



## What does a CARVER + Shock Analysis do for us?

- Determine vulnerabilities - Identify steps in the process with the highest scores
- Consider potential mitigations strategies



## Mitigation Strategies might include:

### FIFE SECURITY AGENCY



NOT MUCH GETS BY HIM!

- Increased physical security such as improved lighting, locks and fences.
- Improved employee training, limited access, and screening.
- Process technology changes such as increased cook temperatures.
- Increased testing of incoming materials



## Higher-risk Foods Share Several Common Vulnerability Factors

- Large batch size,
  - large number of servings
- Short shelf-life
  - rapid turnaround at retail and rapid consumption
- Uniform mixing
  - maximize the number of people exposed
- Accessibility of a critical node
  - a process or activity in the farm-to-table chain during which the agent could be added, undetected, in effective quantities



**Are you prepared?  
Do you have?**

- **Recall and Traceability Program** - Will it work in the case of an intentional act?
- **Self Inspection Program** – How often and does it evaluate all processes, equipment and shifts?



**Is your Facility prepared?  
Do you have?**

- **Customer Audit Policy** – Are you following this policy with every audit?
- **Regulatory Inspection Program** - Do you verify the inspectors identify?



## Is your Facility prepared? Do you have?



- **Guard Services Program- Are you monitoring and directing their activities?**
- **Outside Contractor Policy – Are they aware of your policies? What are they allowed access to? [maintenance, uniform, sanitation etc]**
- **Chemical Control Program – Are your chemicals securely stored and inventoried?**



## Is your Facility prepared? Do you have?



- **Visitor Entry Policy – Unauthorized visitors can be a security risk.... How do you control them?**
- **Employee Locker Inspection Policy – Do you know what's in your companies lockers?**
- **Facility Water Control Program – Do you know if your water is secure?**



## Is your Facility prepared? Do you have?



- Access Control Program – Do you know where all your keys are?
- Uniform Policy – Where have your employees been?
- Tour Group Policy - Do you still allow groups to visit your facility?
- Human Resource Program – Are any of your employees disgruntled?

## Summary

- ***Food safety*** addresses the accidental contamination of food. ***Food defense*** deals with the deliberate contamination of food with the intent of causing harm or disruption.
- Food producers must prevent or eliminate the deliberate contamination of food.
- Effective prevention starts by first understanding the vulnerabilities associated with food production.

# Questions?



## FOOD SAFETY MODERNIZATION ACT(FSMA)



January 2011

The FSMA is the first major amendment in almost 75 years to the food safety regulations of the Food Drug and Cosmetic Act (FD&C)





- The FSMA governs food products regulated by the FDA; it does not apply to meat, poultry or egg products regulated by the USDA. The new law grants additional power to, and also places additional requirements on, the FDA



## FSMA Basics

- Mandatory Recalls Authority
- Inspections
- Administrative Detentions
- Facility Registration
- Suspension of Registration
- Imported Products
- Import Certification
- Performance Standards
- Develop and Implement HACCP plans



## Mandatory Recalls Authority

- FDA now has the authority to force a food recall.
  - Class 1 recall – reasonable probability the food is adulterated or misbranded and its use “will causes serious adverse health consequences or death to humans or animals”



## Inspections

- FDA must inspect high-risk food processing facilities at least once every three years.
- Low-risk facilities must be inspected at least once every five years.



## Administrative Detentions:

- FDA has the authority to detain food product if it has “reason to believe” that a product is adulterated or misbranded and may cause harm to humans or animals.



## Facility Registration

- Food companies must register with the FDA biennially, between October 1 and December 31 of every even-numbered year. (in addition to the Terrorism Act of 2002)
- Companies must include an assurance that FDA will be permitted to inspect the facilities.



## Suspension of Registration

- FDA may now suspend facility operations if it believes there is a reasonable probability that food from the facility could cause harm to humans or animals.



## Imported Products

- Food importers must perform risk based foreign supplier verification activities to verify that the food imported is not adulterated.
- **Effective January 2013.**

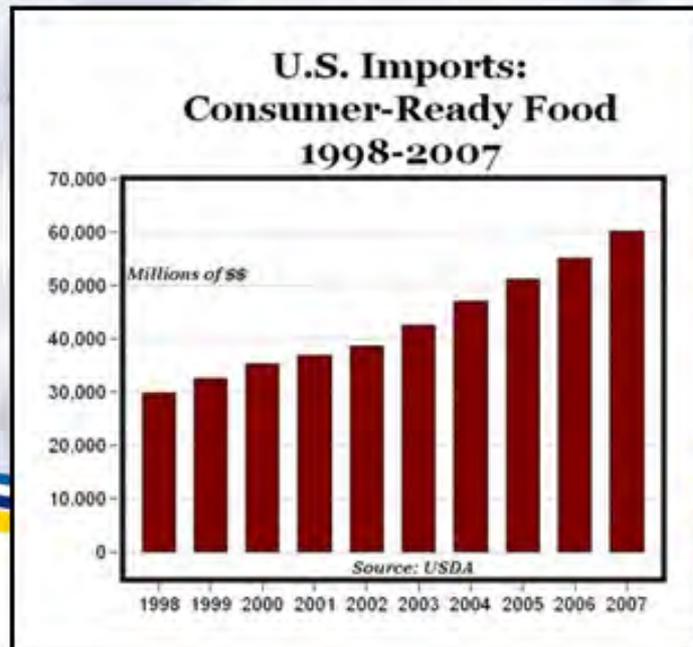


## Import Certification

- FDA may require importers to provide safety certification from an accredited third-party auditor as a condition of granting admission.



## Importance of Imported Food



## Performance Standards

- FDA in conjunction with USDA must evaluate relevant health data every two years to determine the most significant foodborne contaminants and then issue guidance documents or regulations setting contaminant-specific performance standards.
- **Effective date undetermined, implementation requires FDA rulemaking.**



## Additional Performance Standards

- Food companies must engage a Federal laboratory or other accredited laboratory to perform analyses of food products and submit the results directly to the FDA.
- **Effective January 2013.**



## Develop and Implement HACCP plans

- Companies executing good HACCP controls should see strong inspection results and avoid detentions, suspensions and recalls.
- Companies will be required to monitor the effectiveness of their preventive controls, verify accuracy and undergo a regular re-analysis of their plans.



## The written HACCP plan must include

Table 1 The principles of HACCP (modified from Codex, 1993)

Principle	Subject	Action
1	Hazard analysis	Construct a flow chart of the process stages. Identify and list all potential hazards
2	Identification of critical control points (CCPs)	Identify CCPs using a decision tree. Specify the systems of control
3	Establishing critical limits	Target values and critical limits must be set for each CCP
4	Monitoring	Continual or regular registering at each CCP to verify maintenance of control
5	Correction	Establish protocols for: (i) when CCPs are moving towards loss of control; and (ii) when CCPs are out of control
6	Verification	Establish systems to confirm the correct functioning of HACCP
7	Documentation	Establish documentation for all of the procedures and records necessary for the implementation and operation of the above procedures

Source: Kirby (1994)



## Recordkeeping

- Maintain records for not less than 2 years
  - records documenting the monitoring of the preventive controls,
  - instances of nonconformance material to food safety
  - the results of testing and other means of verification
  - corrective actions
  - and the efficacy of preventive controls and corrective actions.

• **HACCP protocols in place by June 2012.**

• **Unless a very small company**



## Traceability Door is Open?



- Although the new law doesn't establish new traceability requirements for food ingredients it directs FDA to collaborate with food manufactures to develop mechanisms to rapidly identify recipients of food that may have been contaminated.
  - Paving the way for future traceability requirements



## Questions

