TOTAL QUALITY ASSURANCE

and

HAZARD ANALYSIS CRITICAL CONTROL POINT

MANUAL for the CATFISH PROCESSING INDUSTRY

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FOREWORD

This manual is designed to guide catfish processors in the efficient operation of their firms and in the sanitary production of catfish. Preparing and implementing an operational plan that complies with state and federal food regulations is the first and best step toward the production of wholesome, high quality product free from disease-causing microorganisms.

Since no two processing facilities are identical, it is impossible to provide a manual to satisfy the specific requirements of all firm operations. This manual has been developed to provide a basis for developing a Total Quality Assurance (TQA) and Hazard Analysis Critical Control Point (HACCP) system.

HACCP is not a stand alone quality assurance system It is a food safety assurance plan specific to a product or process The current industry approach should be to develop a HACCP plan for each product as the food safety element in a food manufacturer' s TQA system.

The authors realize that it may be difficult for some firms to develop a personal plan without some initial technical assistance Please do not hesitate to contact us or representatives of your Cooperative Extension Service or Sea Grant Marine Advisory Program if you have any questions or comments concerning this manual or if you require assistance in modifying the information to meet your firm' s needs.

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This manual was published in a ring notebook format to facilitate the adding, modifying, or deleting of information as an individual firm' s needs arise and when FDA' s mandatory quality assurance program based on the HACCP concept is finalized. The authors updates which can be easily added to the manual will be made available to those who have received manuals.

The authors hope that this manual is useful to your processing firm. It is obvious that no one publication can be written that applies to all catfish processing plants with the numerous products produced. The authors appreciate any suggestions you may have toward improving this publication.

Anyone wishing to order this manual may do so by contacting:

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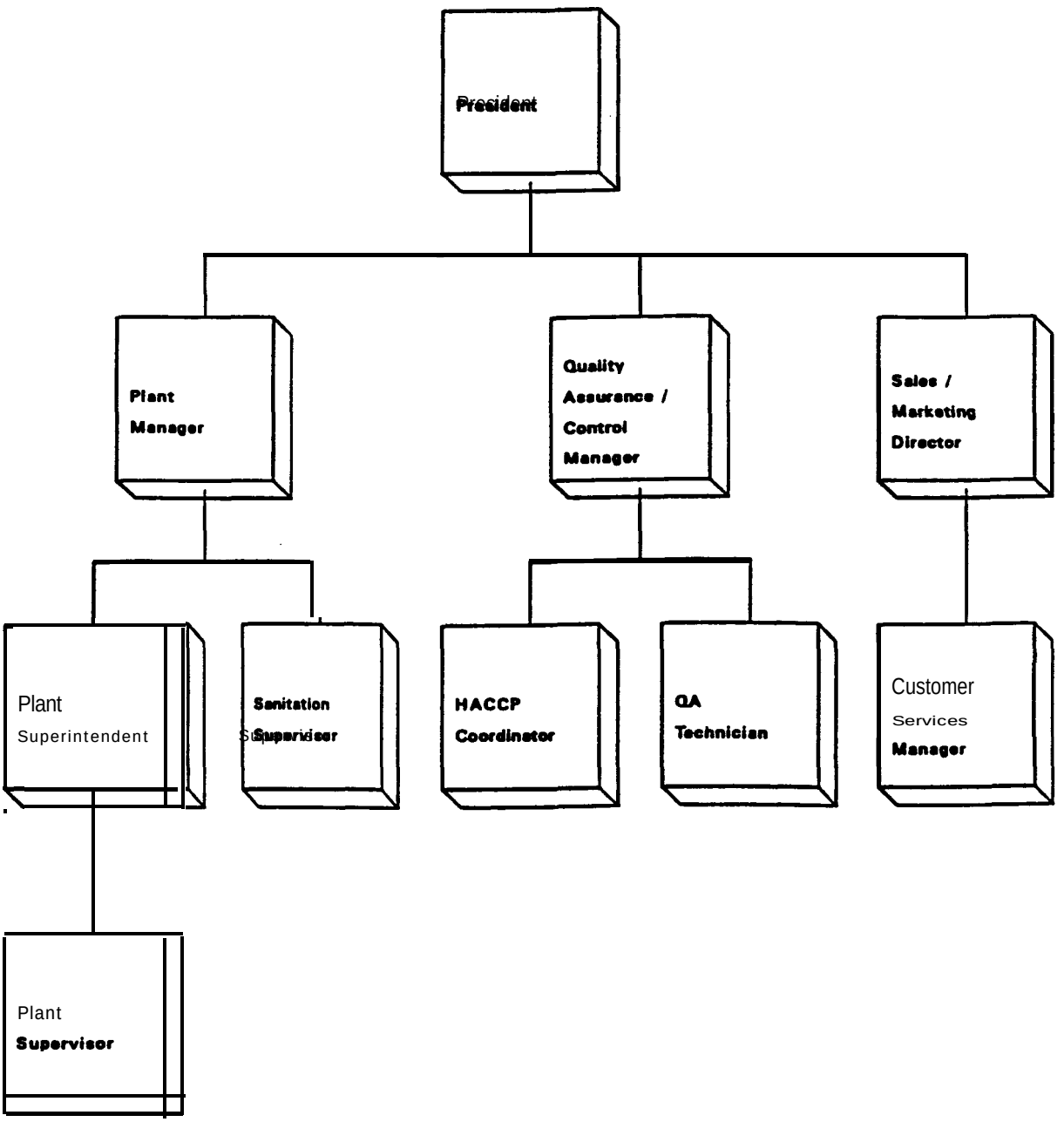
EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

ORGANIZATIONAL CHART



EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

ORGANIZATIONAL CHART NARRATIVE

PRESIDENT- Makes business and economic decisions for present and future operations. Reviews HACCP Plan with Plant Manager, QA/QC Manager, Sales/Marketing Director, and HACCP Coordinator.

SALES/MARKETING DIRECTOR - Reports to the President. Directs all aspects of Sales and Marketing of the Company. Reviews HACCP Plan with President, Plant Manager, QA/QC Manager and HACCP Coordinator.

CUSTOMER SERVICES MANAGER- Reports to the Sales/Marketing Director. Directs the activities of sales orders and needs as related to production. Responsible for receiving, routing, and reviewing customer complaints with QA/QC Manager.

PLANT MANAGER - Reports to President. Responsible for day-to-day operations of facility. Responsible for directing production and any new processes or procedures for the facility. Reviews HACCP Plan with the President, Sales/Marketing Director, QA/QC Manager, and HACCP Coordinator. Ensures compliance with HACCP Plan.

PLANT SUPERINTENDENT - Reports to Plant Manager. Responsible for line supervisors and sanitation supervisor. Ensures compliance with HACCP plan.

PRODUCTION SUPERVISOR · Reports to Plant Manager/Plant Superintendent. Oversees unit processing operations. Responsible for overseeing all personnel in production and storage areas.

QUALITY ASSURANCE/CONTROL MANAGER - Reports to President or Director of Operations. Responsible for all QA/QC personnel, quality of product, labels, labeling law compliance. Responsible for handling customer complaints and initiating recalls. Responsible for implementation and verification of HACCP plan. Responsible for recordkeeping and adherence to QA procedures. Responsible for HACCP training. Reviews HACCP Plan with President, Plant Manager, Sales/Marketing Director, and HACCP Coordinator.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

SANITATION SUPERVISOR - Reports to Plant Manager. Oversees the daily cleaning and sanitation of the plant.

HACCP COORDINATOR - Reports to Quality Assurance/Control Manager. Designated individual responsible for developing and implementing HACCP plan to comply with federal and state regulations. Reviews HACCP Plan with the President, Plant Manager, Sales/Marketing Director, and QA/QC Manager.

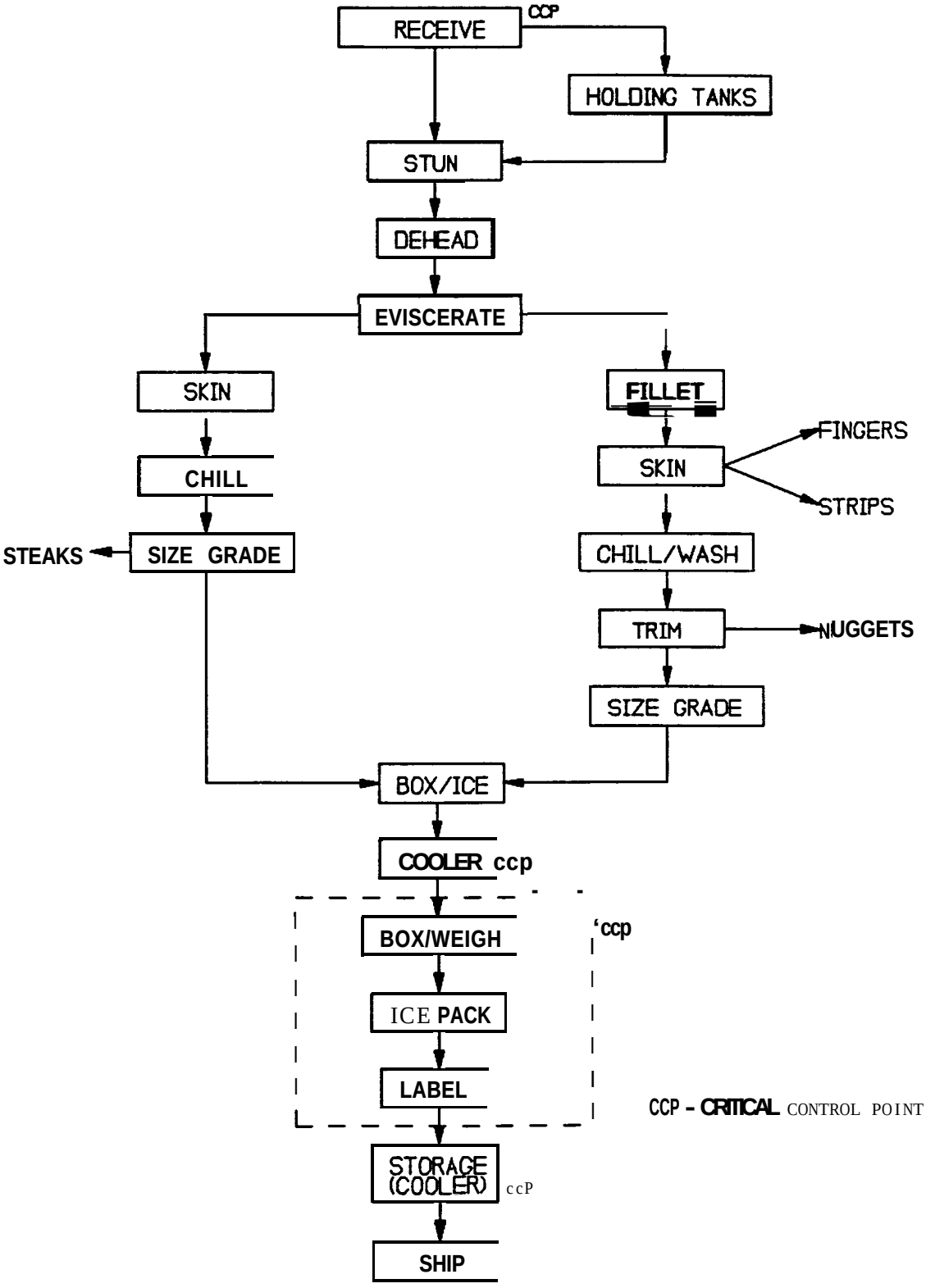
HACCP TEAM - Company personnel responsible for assisting in developing HACCP plan and conducting periodic reviews\evaluations and HACCP plan validations.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

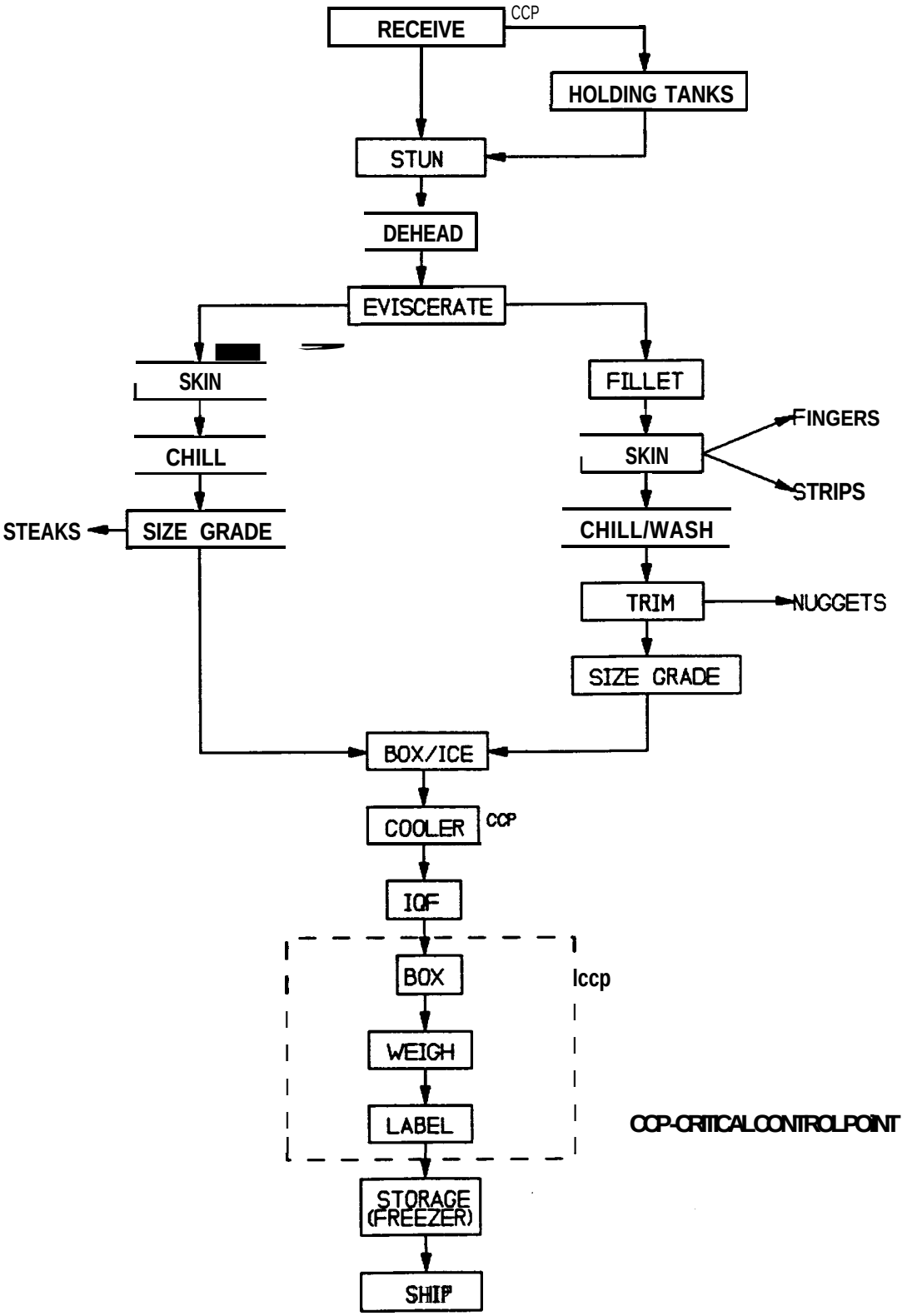
PRODUCT DESCRIPTION

WHOLE FISH	(1) Deheaded, eviscerated, skinned with or without fins removed; (2) Round and gutted - eviscerated only;
WHOLE FILLET	Slices of practically boneless fish flesh, which are removed from the carcass by cuts made parallel to the entire length of the backbone. Skinless.
SHANK FILLET	Fillet with belly flap removed. Also called trimmed fillet.
NUGGET	Belly flap portion, boneless, with or without stomach lining (peritoneal membrane) removed and weighing not less than 3/4 ounce
STRIPS	Boneless, skinless fillets cut into strips weighing not less than 3/4 ounce
FINGERS	Boneless, skinless fillets cut into pieces larger than strips
STEAKS	Axial, cross-sectional cuts of definned dressed fish weighing not less than 1 l/2 ounces
BREADED	Whole fish, fillets, nuggets, strips, with or without phosphates, predusted, battered, breaded, IQF
FLAVORED	Fillets, nuggets, strips, tumbled, with or without phosphates, with flavorings added
PHOSPHATED	Whole fish, fillets, nuggets, strips injected or tumbled with phosphate solution
FORMED	Heat-set product made from minced and\or pieces of raw fish
MINCED	Meat from deboned frames, trimmings, and other parts, with or without cryoprotectants, and frozen
FROZEN	Any form of catfish product frozen with or without the addition of phosphate and/or flavoring

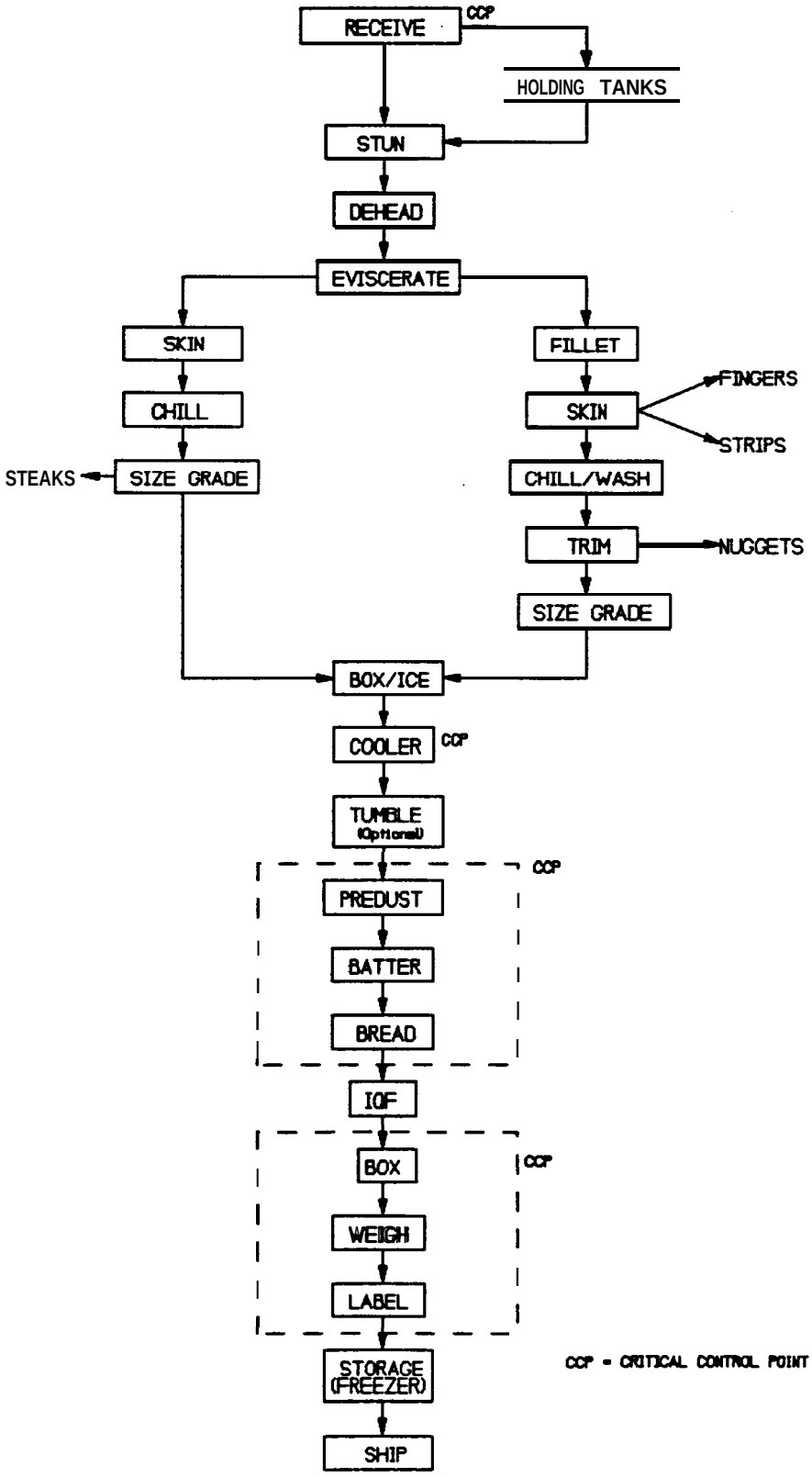
CATFISH PROCESSING OPERATION FLOWCHART
ICE PACK PRODUCT



CATFISH PROCESSING OPERATION FLOWCHART
IQF PRODUCT



CATFISH PROCESSING OPERATION FLOWCHART
BREADED IQF PRODUCT



EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PROCESS STEPS

UNIT OPERATION	DESCRIPTION
1. Receiving Live Catfish	Live fish are transported from the pond to the receiving station in live haul trucks. Fish are held in holding tanks or passed directly to the processing line.
2. Stunning	Fish are exposed to a low voltage electric current for a few seconds.
3. Deheading	Fish are deheaded using an electric band saw or mechanical deheader.
4. Slitting/Eviscerating	Deheaded fish are conveyed to the evisceration station where the operators using a sharp knife slit the fish and use a vacuum extractor to remove the viscera, or the fish are mechanically slit and eviscerated.
5. a.Skinning	Skin is removed from whole fish with a mechanical skinner using manual labor. Skin from fillets is mechanically removed after the fillets are cut.
b.Filleting	Filleting may be accomplished using either manual or mechanical procedures.
6. Chilling	Whole dressed fish and/or fillets are placed into a chilled water tank in order to reduce the fish temperature. Normally the water temperature in the chiller is kept below 40°F.

7. Trimming-Nuggets	Fillets are trimmed, residual bones are removed, and the belly flap is removed. Belly flaps then become nuggets.
8. Size Grading (Whole fish/fillets)	Whole fish and fillets are electronically size graded for the purpose of further processing and/or commercialization.
9. Boxing (Holding in tubs, optional)	Whole fish, fillets, nuggets, strips, fingers are packed in tubs and covered with ice. Thereafter, the product may be held in coolers until ready for further processing.
10. Tumbling (optional)	Fillets are placed in a tumbler with flavoring, phosphates, etc.
11. Predust, Batter and Breading	Fillets, nuggets, strips, fingers go through a process of Predusting: The fillets are covered with a dry mixture which absorbs surface moisture and improve adhesion of the batter to the fillets. Battering: Fillets are coated with a liquid mixture of water, starch, flour and seasoning. Breading: Fillets are covered with a dry mixture of flour, starch and seasoning.
12. Freezing Product	Product is individually quick froze (IQF) and held in the freezer until shipped.
13. Packing	Product is placed in individual or master cartons, weighed, and labeled.
14. shipping	Product is loaded in refrigerated trucks for distribution.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

HAZARD ANALYSIS

PROCESS STEP	HAZARD	PREVENTIVE MEASURE
1. Receiving Live Fish	Biological Contamination Economic Fraud Chemical Contamination	Company purchasing specifications Employee training Catfish Quality Assurance Program
2. Stunning	No hazard identified	
3. Deheading	No hazard identified	
4. Eviscerating	No hazard identified	
5. Skinning	No hazard identified	
6. Filleting	No hazard identified	
7. Chilling	No hazard identified	
8. Trimming	No hazard identified	
9. Size grading	No hazard identified	
10. Battering/Breading	Biological Contamination Economic Fraud	Control batter temperature Check breading percent
11. Freezing	No hazard identified	
12. Weigh/Pack/Label	Economic Fraud Physical Contamination	Employee training; Coded product; Scale calibration Effective metal detectors
13. Cooler Storage	Biological Contamination	Temperature checks; Employee training
14. shipping	No hazard identified	
15. Receiving Non-Fish Materials	Biological & Physical Contamination	Company purchasing specifications; Employee training

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

CRITICAL CONTROL POINTS

PROCESSING STEP

RECEIVING LIVE FISH

HAZARD(S): ***An assumption has been made that the supplier of fish has implemented the Catfish Quality Assurance Program. If the supplier is not committed to this program, then the Hazards will be different.***

1. Diseased or decomposed fish
2. Improper species

CONTROL POINT

Receiving station

CRITICAL LIMIT(S):

1. No diseased or decomposed fish will be processed.

2. Only proper species will be used for processing.

PREVENTIVE MEASURE(S):

1. Company purchasing specifications. Employee training to recognize diseased or decomposed fish.

2. Company purchasing specifications. Employee training to recognize fish species.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

MONITORING PROCEDURE(S):

1. Upon entry into processing plant, live fish sorters will remove diseased or decomposed fish from the processing line. These fish are weighed and recorded on the Daily Live Fish Receiving Report These fish are then destroyed.

2. Upon entry into processing plant, live fish sorters will remove any improper fish species from the processing line. These fish are weighed and recorded on the Daily Live Fish Receiving Report. These fish are then destroyed.

CORRECTIVE ACTION(S):

1. If any diseased or decomposed fish are not culled at the sorter, the QA technician will reject the tub or box containing the diseased or decomposed product. After the tub or box has been reworked and culled product removed, an organoleptic evaluation of the reworked product will be performed. These fish will be weighed, recorded, and destroyed.

2. If any improper species fish are not culled at the sorter, the QA technician will reject the tub or box containing the improper species. After the tub or box has been reworked and the improper species removed, weighed, recorded, reworked product will go back into production.

RECORD(S):

1. Daily Live Fish Receiving Report

2. Daily Live Fish Receiving Report

INDIVIDUAL RESPONSIBLE: Kill Area Supervisor

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PROCESSING STEP

BATTERING\BREADING

HAZARD(S):

1. Microbial growth/temperature
2. Excessive breading of product

CONTROL POINT

Battering\breading

CRITICAL LIMIT(S):

1. Batter temperature should not exceed 50°F for more than 30 minutes where batter is changed every 4 hours and should not exceed 40°F for more than 30 minutes where batter is changed every 8 hours.

2. Batter and breading should not exceed 50% of fish weight.

PREVENTIVE MEASURE(S):

1. Batter temperature should be held below 50°F if batter is changed every 4 hours or 40°F if batter is changed every 8 hours.

2. Percent breading will be checked every hour to insure that batter/breading does not exceed 50% of fish weight.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

MONITORING PROCEDURE(S):

1. Record batter temperature and time of use on Batter Temperature and Use Report

2. Three samples of each product style (fillets, nuggets) will be checked for percent batter/breading periodically during each hour of each product's production by the QA technician. Results will be recorded on Percent Batter/Breading Report.

CORRECTIVE ACTION(S):

1. When time and/or temperature limits have been exceeded, batter will be disposed.

2. Lots or portions of lots that exceed the critical limit should be repacked (after unbreading or rebreading) and relabeled. The breading equipment should be adjusted.

RECORD(S):

1. Batter Temperature and Use Report

2. Percent Batter/Breading Report

INDIVIDUAL RESPONSIBLE: Batter/breading Supervisor

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PROCESSING STEP

WEIGH\PACK\LABEL

HAZARD(S):

1. Improper net weights
2. Metal contamination
3. Incorrect product labeling

CONTROL POINT

Packing\Weighing area

CRITICAL LIMIT(S):

1. The average of sample net weights will meet or exceed stated net weight.
2. No product containing detectable metal will be sold.
3. Product must bear correct label.

PREVENTIVE MEASURE(S):

1. Employees will be trained to properly use the scales. Scale calibration.
2. Metal detection equipment will be installed at a point on the line after product is boxed.
3. Employees will be trained to identify correct product labels.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

MONITORING PROCEDURE(S)

1. Samples of each product style and type pack will be checked for net weights by the QA technician during each hour of each product's production according to a predetermined sampling plan.

2. All product will be checked for the presence of detectable metal.

3. Samples of each product style and type pack will be checked for proper labels by the QA technician during each hour of each product's production according to a predetermined sampling plan.

CORRECTIVE ACTION(S):

1. If the sampled net weight of a particular package exceeds the established standard for a particular product style, three additional samples of the same product will be evaluated. If the average sampled net weight is found to be violative, all packages of the product produced since the last acceptable sample will be reweighed. All noncompliance samples will be repackaged to conform with the standard.

2. If the metal detector indicates a detective sample, the product will be withdrawn from production by the QA technician. The product will be examined and the product will be placed in production for rework. A metal detection report will be completed for each shift.

3. If an incorrect label is found on any sample of product, three additional samples of the same product will be evaluated. If any of the samples are found to be violative, all packages of the product produced since the last acceptable sample will be reevaluated. All non-compliance samples will be relabeled.

RECORD(S)

1. Net weight records. Calibration reports.
2. Metal detection reports and calibration reports
3. Label records

INDIVIDUAL RESPONSIBLE: Packing Supervisor

EXAMPLE-FOR ILLUSTRATIVE PURPOSES ONLY

PROCESSING STEP

COOLER STORAGE

HAZARD(S):

1. Decomposition/Temperature of Product

CONTROL POINT

Cooler

CRITICAL LIMIT(S):

1. Temperature of fresh product should be below 45°F within 12 hours. Decomposed product will not be used.

PREVENTIVE MEASURE(S) :

1. All product placed in the cooler will be coded with the date and time of entry. Employees will be trained on visual examination of product and proper icing procedures.

MONITORING PROCEDURE(S):

1. Product will be sampled and visually and organoleptically checked once per shift to ensure proper temperature and absence of decomposition according to a predetermined sampling plan. Time and temperature will be recorded on the Cooler Storage Log.

CORRECTIVE ACTION(S):

1. Product will be checked for decomposition. If decomposition is detected, the product will be discarded. If decomposition is not detected, the product will be reiced and reevaluated once per shift. Disposition of the product will be recorded on the Cooler Storage Log

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

RECORD(S):

1. **Cooler Storage Log**

INDIVIDUAL RESPONSIBLE: Refrigerated Storage Manager

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PROCESSING STEP

NON-FISH MATERIALS RECEIVING AND STORAGE

HAZARD(S):

1. Contamination of ingredients and/or packaging materials

CONTROL POINT

Receiving station

CRITICAL LIMIT(S):

1. Only food grade ingredients and packaging materials will be used. Any contaminated ingredient or packaging material will not be used.

PREVENTIVE MEASURE(S):

1. Company purchasing specifications. Employee training.

MONITORING PROCEDURE(S):

1. Visually inspect label on ingredients and packaging to ensure compliance with specifications and record on Materials Receiving and Storage Sheet.The QA technician will monitor storage practices of ingredients and packaging materials on a daily basis.

CORRECTIVE ACTION(S):

1. If any contaminated ingredients or packaging materials are received, they will be removed from process flow and destroyed or returned to vendor. The QA technician will record product name, amount, cause of contamination, and corrective action.

EXAMPLE-FOR ILLUSTRATIVE PURPOSES ONLY

RECORD(S):

1. Materials Receiving and Storage Sheet

INDIVIDUAL RESPONSIBLE: Receiving Clerk/Manager

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

RECORDKEEPING PROCEDURES

All records pertaining to the HACCP plan will be kept in the Quality Assurance Manager's office. All records will be kept together according to the production date. A copy of all NUOCAs (Notice of Unusual Occurrence and Corrective Action) will be kept in a separate file.

VERIFICATION PROCEDURES

All records will be collected, reviewed, and initialed daily by a QC technician before filing. When any problem or unusual occurrence is noted, the QC technician will inform the QA manager who will also initial the record and take appropriate corrective action.

The appropriate members of the HACCP team will meet once a month to verify the HACCP plan and to evaluate its effectiveness. Records of the meeting will be kept.

The entire HACCP team will meet quarterly/semi-annually to evaluate the effectiveness of the HACCP plan and to ensure compliance with the HACCP plan. Records of the meeting will be kept.

If any **product and/or process changes are** proposed, the HACCP team will meet and evaluate the new product/process and its hazards to determine if any changes need to be made in the HACCP plan. The team will also meet to review the HACCP plan if a critical control point is excessively exceeded.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

STANDARD OPERATING PROCEDURES

1. All incoming ingredients and packaging materials are inspected upon receipt and information recorded on Materials Receiving and Storage Sheet.

2. All incoming ingredients and packaging materials are labeled with date of receipt, stored properly, and rotated into production on a first in - first out basis.

3. Sanitary zones should be established to prevent cross-contamination of product caused by personnel movement and product flow. Brushes and other utensils should be color coded indicating their area of use. This system will prevent the transfer or introduction of pathogenic and spoilage microorganisms into the processing area.

4. All scales used in production are checked with standard weights by both maintenance and QA personnel. QA personnel will calibrate scales daily before start up of each shift and after lunch. Maintenance will perform scale check two times per week. If, at any time, scales are found to be working improperly, they are taken out of production until repaired. Once a year the scales will be checked by either the state weights and measures control agency or an independent contractor. Scale Calibration/Monitoring form will be used to record any activity of improperly weighing scales.

5. All size grading equipment is calibrated daily before start-up of each shift and after lunch by the QA personnel using standard weights. All product being size graded is monitored by QA personnel and line supervisors. Any malfunctions are recorded on Scale Calibration/Monitoring form.

6. All temperature indicating and recording devices used in production will be checked and calibrated before start up at the beginning of each week by QA personnel. Results will be recorded on the Thermometer Calibration form.

7. All metal detectors are checked on a daily basis prior to start-up by maintenance and randomly throughout the production day by QA personnel and line supervisors. If the detector is found to be not functioning properly, it is removed from the production line until repaired Results of these checks are recorded on the Metal Detector Calibration Sheet.

8. Operating limits are set at levels lower than the critical limits to ensure that critical limits are not exceeded. Therefore, corrective actions will be less likely to be taken.

9. All sampling plans will be designed statistically using approved statistical methods to ensure adequacy of sampling.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

CLEANING AND SANITATION

The proper selection of cleaners and sanitizers, their concentrations, and the method of application depends on several factors including:

- Nature of the soil
- Degree of cleaning and sanitation to be achieved
- Type of cleaning and sanitizing equipment used
- Type of surface being cleaned - food contact and non-food contact

An important criterion is the specific kind of material used to fabricate equipment and to construct the facility. Improper cleaners and sanitizers can cause permanent damage to equipment and plant structures. Firms should obtain professional advice from a reputable dealer before purchasing any chemicals.

A firm should develop a plan to ensure proper disposal of all chemicals left over at the end of a cleaning and/or sanitation operation.

A firm should implement a hazard communication program for personnel applying cleaners and sanitizers. Limited and/or long-term skin contact or improper use of sanitizers can result in employee injury. All MSDS (Materials Safety Data Sheets) should be displayed in the chemical storage area.

NOTE: Rinse all non-stainless steel equipment with fresh water l/2 hour after sanitizing.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Sanitation Standard Operating Procedures

All compounds used in cleaning and sanitizing will conform to either EPA requirements or can be found in the USDA's List of Proprietary Substances and Nonfood Compounds and will be used in accordance with manufacturers instructions.

All chemicals used in the facility will be kept locked in the chemical storage area located outside the production area.

Sanitation Procedures for Specific Areas

(Procedures will be carried out daily unless noted otherwise.)

Facility

1. Construction and design of the building will be suitable in size and design for appropriate maintenance and sanitary operations for processing.
2. Grounds surrounding the building are kept such that contamination of food is prevented.
3. Buildings, equipment, and other physical facilities of the plant are maintained in a sanitary manner and are sufficiently kept to prevent food from becoming adulterated.
4. Ventilation in the building is such that contamination from odors and vapors is minimized.

Fish Receiving Area

Daily

1. Remove all dead and diseased fish to offal area as they accumulate. A dye may be used on the fish to prevent salvage.
2. Thoroughly check all conveyor equipment for scraps of fish and other soils and remove.
3. Rinse all equipment with water (less than 140°F). Ensure that all mud and debris is removed from the area.
4. Thoroughly clean all fish equipment such as shovels, forks, conveyors, tubs and stunners using an approved cleaner. Care should be taken not to contaminate active holding tanks with detergent solution.
5. Rinse all equipment using cold water. At this time, care should be taken to remove any excess soil. Store all hand equipment in a sanitary area.

6. Sanitize all equipment using an approved sanitizer at the appropriate concentration.

Weekly

1. Drain holding tanks and wash using an approved cleaning solution. Also apply the acid cleaning solution to equipment such as tubs, shovels, forks, conveyors, and other equipment which show mineral build-up. The use of acid is necessary to remove gradual mineral build-up that occurs in this area. The degree and frequency of such build-up will determine the frequency of such procedures.
2. Rinse thoroughly with water.
3. Sanitize using an approved sanitizer at the appropriate concentration.

Eviscerating Area

1. Prepare area for cleaning and rinse thoroughly to remove all loose soils.
2. Wash equipment using an approved cleaner.
3. Thoroughly rinse all equipment with water (less than 140°F) to remove soil and detergent.
4. Sanitize all equipment prior to start-up using an approved sanitizer at the appropriate concentration.

Band Saws

1. Remove all loosened soil by pre-rinsing.
2. Remove blade from saw for thorough cleaning.
3. Wash blade in pail of an approved cleaning solution.
4. Rinse thoroughly and allow to dry.
5. Leave saw disassembled and open for inspection.
6. Prior to use, sanitize saw. After assembling, resanitize using an approved sanitizer at the appropriate concentration.

Skinners

1. Rinse all loosened soil from skinner.
2. Carefully remove all pieces of skin and product from the skinner using the high pressure rinse technique or manual technique.
3. Thoroughly wash this equipment with an approved cleaner.

4. Rinse thoroughly with water (less than 140°F) and inspect for any residual soils.
5. Prior to use, sanitize with an approved sanitizer at the appropriate concentration.
6. Due to possible mineral build-up on this piece of equipment, it may be necessary to use a heavy duty acid weekly to remove any build-up of this nature. This is used in place of the detergent whenever needed.

Chillers

1. Drain water from tank.
2. Wash with an approved cleaner.
3. Thoroughly rinse all equipment with water (less than 140°F) to remove any adhering soil and detergent.
4. Sanitize all equipment prior to start-up using an approved sanitizer at the appropriate concentration.

Batter/Breaders

1. Thoroughly rinse all batter and breading materials from the equipment.
2. Disassemble pump and remove all hoses and fittings prior to cleaning.
3. Wash all removed equipment in a pail or tank and all surfaces of equipment with an approved cleaner.
4. Rinse thoroughly with water (less than 140°F). Leave equipment disassembled until next use.
5. Prior to use, sanitize all equipment with an approved sanitizer at the appropriate concentration. Assemble equipment and resanitize.

Packing

1. Thoroughly clean all product contact surfaces, such as scales and ice shovels, with a general purpose detergent.
2. Rinse all equipment thoroughly with water (less than 140°F) to remove any loosened soil.
3. Thoroughly rinse all equipment with an approved cleaner.
4. Prior to use, sanitize all equipment with an approved sanitizer at the appropriate concentration.
5. Store ice shovels in a sanitary area or in a sanitizing solution.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Processing Area

1. Hose down the walls and floors in the processing area to remove any loose debris.
2. Spray walls and floors with an approved cleaner, scrub using plastic bristle brushes and pads, and allow to sit for 15 minutes.
3. Rinse with water.
4. Reclean with an approved cleaner until all areas are effectively cleaned. Rinse again.
5. Sanitize equipment before production starts. Sanitizing walls and floors before production starts may be optional.
6. All water used for manufacturing purposes is potable, as defined by EPA (Environmental Protection Agency).

Refrigerated Storage Areas

Daily

1. Sweep every night after the end of production.

Weekly or as needed

1. Empty and clean using an approved cleaner.
2. Rinse with water (less than 140°F).
3. Sanitize with an approved sanitizer at the appropriate concentration.

Spiral Freezer

1. Clean daily depending on volume and use.
2. Clean weekly if temperature is maintained at 0°F or below.

Freezer Storage

1. sweep daily.
2. Remove excess ice as needed.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Ice Room

Monthly

1. Empty and rinse with water (less than 140°F).
2. Rinse with an approved cleaner.
3. Rinse with water (less than 140°F).
4. Sanitize with an approved sanitizer at the appropriate concentration.

Offal Area

1. All offal should be removed from the processing plant when containers are full and at the end of the production day.
2. Thoroughly rinse all equipment using water (less than 140°F).
3. Rinse with an approved cleaner.
4. Rinse with water (less than 140°F).
5. Sanitize with an approved sanitizer at the appropriate concentration.
6. If a vacuum system is used, the solution should be pulled through the system from all inlets. This solution should flow directly into the offal tank.

Dry Storage Area (Ingredients and Packaging Materials)

1. sweep daily.
2. Empty and clean with an approved cleaner as needed.

Knives, Cutting Boards, Totes, Utensils, Brushes

After every shift or as needed

1. Remove all loosened soil by pre-rinsing.
2. Clean with an approved cleaner.
3. Rinse thoroughly with water (less than 140°F).
4. Sanitize by soaking in an approved sanitizing solution.

EXAMPLE-FOR ILLUSTRATIVE PURPOSES ONLY

Employees

1. Each new employee will read the employee sanitation guidelines.
2. Employees will receive appropriate training in proper food handling techniques and food-protection principles and will be informed of dangers associated with poor personal hygiene and insanitary practices.
3. Locate non-hand operated sinks with soap dispensers and premixed sanitizing solutions adjacent to the production lines.
4. Employees wash and then sanitize their hands/gloves:

    a) at the beginning of the day when they go to their work stations,
    b) after each break,
    c) each time they return to their work stations
    d) each time they have contaminated their hands.

5. Hand dips will be changed frequently.
6. Hair restraints (hair nets, beard covers) must be worn by anyone entering the production and refrigerated areas.
7. Clean outer garments must be worn by all employees.
8. No eating, chewing gum, or use of any tobacco in the production or refrigerated storage areas.
9. Employees shall not be allowed to wear any decorative or loose jewelry.
10. Pens and other instruments should not be kept in shirt pockets.
11. An employee infected with a communicable disease or physical condition (boil, infected wound, acute respiratory infection) that can be transmitted by food shall not work in any capacity in which there is a likelihood of product becoming contaminated. Employee will notify their supervisor of this situation.

Restrooms

1. Adequate, accessible, and maintained in a clean and sanitary manner.
2. Clean daily and adequately supply with water, paper towels, soap, toilet paper, etc., for the next day.
3. Check supplies throughout the day.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Inspection

1. Pre-operational sanitation inspection will be performed every morning by a QC technician to verify that all equipment and areas have been sufficiently cleaned and sanitized.
2. Reclean and resanitize, before production begins, any equipment and areas that have not been properly cleaned and sanitized.
3. Perform microbiological counts weekly or as needed on equipment surfaces to verify effectiveness of the cleaning and sanitizing procedures of the facility. QC technician will be responsible for sanitation checks. Results will be recorded on **Daily Sanitation Log**.
4. Results of QC checks will be used to guide the sanitation crew on areas for improvement.
5. Examine the entire plant during production time to monitor for personnel hygiene and areas of concern.
6. Correct and record any insanitary conditions on the Daily Sanitation Log.
7. On-going monitoring will be conducted by the QC manager to ensure sanitary compliance and personal hygiene (hand washing, hand dipping, etc.).

Pest Control

1. Keep exterior areas free from litter, used boxes, high grasses.
2. Implement and maintain regular routine pest extermination and prevention procedures and measures.

Maintenance

1. The QC manager will conduct periodic sanitation inspection focusing on general facility conditions. This is a preventive measure to identify problems before they occur or to initiate remedial action.
2. Ensure areas are maintained properly and equipment is kept in good working condition and work areas are free of unnecessary clutter. Monitor daily.
3. Daily sanitation checks by QC technician prior to production start-up.
4. Production will not begin until the Daily Sanitation Report has been completed and signed by appropriate personnel.
5. Whenever maintenance is performed on equipment during processing operations or after final sanitation has occurred, a sanitizing rinse should be applied to prevent contamination of product.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PRODUCT RECALL PLAN

From time to time a catfish processor may need to remove one of its products from the market. The vast majority of recalls are voluntary. Whether the problem is minor or life-threatening, good advance planning is the key to resolving it thoroughly and quickly. This section of the manual is intended to help a company create a product recall plan or help it evaluate and improve a recall plan that is already in existence.

DEFINITIONS

For precise legal definitions, consult an attorney on FDA guidelines. The FDA's guidelines, policies, and procedures for recalls can be found in Title 21 of the Code of Federal Regulations Part 7. Generally speaking, terms are interpreted as follows:

Correction

A correction means a firm is modifying, adjusting, relabeling, destroying or inspecting **a** product, without removing it to another location, so that the firm will not be in violation.

Recall

A recall means a firm, on its own initiative or at the request of a government agency, is removing or correcting some aspect of a marketed product which would be found to be in violation and against which action would otherwise be taken. Recall does not include a market withdrawal or a stock recovery.

Market Withdrawal

A market withdrawal means a firm is removing or correcting a distributed product where there is no FDA violation or a minor violation against which FDA would not act. This includes normal stock rotation and, in the absence of manufacturing or distribution problems, response to actual or alleged tampering with individual units.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Stock Recovery

A stock recovery means a firm is removing or correcting a product that is unmarketed and\or has not left the direct control of the firm.

Recall Strategy

A recall strategy means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

Recall Classification

A recall classification is a numerical designation (I, II, or III) assigned by the FDA to a particular product recall to indicate the severity of the health hazard presented by the product being recalled.

- Class I indicates reasonable probability that the violative product will cause serious adverse health consequences or death.
- Class II indicates a violative product may cause temporary or medically reversible adverse health consequences, but serious consequences are remote.
- Class III indicates a violative product is not likely to cause adverse health consequences.

Depth of Recall

Depth of recall are levels used to indicate how far into the distribution chain the recall will extend, depending on the product's degree of hazard and extent of distribution.

- Consumer or user level may vary with the product and includes any intermediate wholesale or retail level; may include the individual consumer.
- Retail level is the recall level immediately before the consumer level and includes any intermediate levels.
- Wholesale level includes all distribution levels between the manufacturer and the retailer.

OBJECTIVES

A recall has three basic objectives:

1. Locate the recalled product already in the marketplace.
2. Remove the product from the marketplace.
3. Provide accurate, up-to-date information throughout the recall.

Failure to conduct a recall when products are, or could be considered to be, illegal, unsafe or a threat to public health can have serious consequences. The more serious the problem, the more swift and effective the recall must be.

FDA CONSIDERATIONS

A good recall plan must include an understanding of the FDA's requirements. The FDA has the responsibility for insuring that food products which present a real or potential threat to public health are removed from the marketplace and reconditioned or destroyed. FDA is always concerned that recalls of such products are done in a timely and complete manner. While the firm is morally and legally responsible for its product, it is FDA's privilege and duty to evaluate whether that responsibility is being met. Although it does not have statutory authority to compel a recall, FDA can request one and can back up its request with the real threat of enforcement action (seizure). Once FDA is involved in monitoring a recall, you can be certain that, to some extent, FDA will call the shots and will not accept a poorly done, last-minute plan of action. For this reason, a recall plan should be drafted thoroughly and in advance, with the help of an attorney, and legal advice should be sought before considering any recall.

STATE REGULATIONS

State regulations vary concerning product recalls. Some states have recall powers while other states have limited authority. Each processor should be aware of their state's regulations and include a copy of those regulations in this section.

INVESTIGATING PRODUCT PROBLEMS

Recalls are initiated as a result of consumer or customer complaints. It is essential that every legitimate consumer and\or customer complaint be investigated thoroughly and documented. Sometimes a product problem is identified before the product leaves the processor; it should be investigated and documented the same way. Any investigation should be as objective as possible and every effort must be made to assess a complaint fairly and not cover up a problem. The company must keep an accurate record of what was reported, when, and by whom, as well as how the company acted in response. If a product problem is determined to be one that could threaten public health, recall action must be taken right away, with consideration given to involving FDA in the process.

FIRM-INITIATED RECALL

A firm may decide on its own will and under any circumstances to remove or correct a product in distribution. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate FDA district office. Such removal or correction will be considered a recall only if FDA regards the product as involving a violation that is subject to legal action (seizure). The firm will then be asked to provide FDA the following information:

1. Identity of the product involved.
2. Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
3. Evaluation of the risk associated with the deficiency or possible deficiency.
4. Total amount of such products produced and\or the timespan of the production.
5. Total amount of such products estimated to be in distribution channels.
6. Distribution information including the number of direct accounts and, where necessary, the identity of the direct accounts.
7. A copy of the firm's recall communication if any has been issued, or a proposed communication if none has been issued.
8. Proposed strategy for conducting the recall.
9. Name and telephone number of the firm official who should be contacted concerning the recall.

General Recall Procedures

Important steps to initiating a recall include the following:

- Have a well-thought-out, written recall plan in place that can be activated immediately; speed will be critical if management determines recall to be necessary.
- Have a well-trained recall team in place, from management down, prepared to organize, analyze, document, and disseminate critical information about a product problem.
- Management, depending on the nature and extent of a product problem, should make and document a decision for either immediate recall, market withdrawal, stock recovery, or the need for additional information.
- Once a decision has been made to institute a recall, the recall must be initiated immediately, and those involved must be given appropriate written notice.
- If management believes the product problem endangers public health, a further decision must be made about informing **FDA** or other relevant governmental authorities.
- If a determination is made to notify **FDA**, follow **FDA** procedures and requests regarding the recall; be prepared to present a recall plan for **FDA's** review and, if well done, agreement.
- The recall team must be fully informed of their responsibilities, which will depend on the depth of the recall, determined by the nature of the product problem and, in some instances, by its **FDA** classification or state requirements.
- Determine the distribution of the product and identify the code numbers to be recalled.
- Decide as soon as possible what will be done with the recalled product, whether it is to be destroyed, reconditioned as food for human beings, as food for animals, or for another use. Destruction plans can require contact with Environmental Protection Agency personnel at the state or federal level, depending on the nature of the product problem.
- Issue warning to the public when, as, and if ncessary.

- Prepare weekly status reports documenting the recall and use them to prepare status reports for FDA or for the appropriate state agency.

  Monitor the recall closely and assess whether it is being carried out quickly and effectively, take remedial steps as necessary, and document all effectiveness checks and remedies.

- Stay in contact with customers and consumers, as necessary.

- Stay in contact with **FDA** and/or state agencies, as necessary.

- Decide in advance what constitutes completed recall; notify all involved.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Code Dating

A production date code will be printed on all finished product packages and/or cases. This code can identify the production date, shift or hour of production and/or lot or batch number, and production facility. Each company may devise its own variation of coding. It is very important that a meaningful coding of products be established and a recordkeeping system be adopted so that individual lots of product can be traced from your processing facility to the end user. The code date should be used on all quality control records, production reports, and shipping forms.

Example: Julian Date Code

2315A - 231 represents the day of the year;
5 represents the year 1995
A represents hour period of production

Example: Gregorian Date Code

January 30, 1995A or 1/30/95A
Date is self-explanatory.
A represents hour period of production

All product produced is recorded on a Daily Production Log, identifying the product produced, total number of cases produced, and case size. This information is linked to invoices of shipped product, bill of lading, and inventories.

If a legitimate customer complaint is received or if the company has found a problem, a recall can be initiated more easily with the use of the above described coding systems. If a recall is necessary, product can be identified, accounted for in inventory and put on hold, and tracked to the customer until all product is accounted for and located. Arrangements should then be made to get product returned to the processing facility.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

CONSUMER COMPLAINT FILE

All consumer complaints are directed through a designated person who is qualified to receive the particulars of the complaint. This person fills out a complaint form and immediately notifies the Quality Assurance/Control Manager. The Quality Assurance/Control Manager completes the Customer Complaint form and investigates the cause of the complaint with the assistance of the plant manager. If the complaint is legitimate, corrective action is taken by the plant manager. If any action is taken because of a complaint, it is recorded on the Customer Complaint form. The Quality Assurance/Control Manager will handle the disposition of the product. Sales/Marketing will authorize settlements and notify the customer.

All of the Customer Complaint forms from the designated person receiving the complaint are kept on file in the Quality Assurance/Control Manager's office.

Taking a Complaint

When the customer lodges a complaint, the firm must keep in mind a list of do's and don'ts. The principal assignment of the designated person receiving the complaint is to obtain as much factual information surrounding the complaint as possible, while the knowledge of the complaint is fresh in the mind of the customer and before positions have hardened.

Regardless of the circumstances relating to the complaint, the designated person taking the complaint should scrupulously pay attention to the following warnings:

- Do not admit fault.
- Do not promise any settlement or performance.
- Do not promise to furnish analytical results on samples received.
- Do not mention any insurance coverage.

Filing a Report

Speed is especially critical when a government agency is already involved, when the possibility exists that a product recall may be necessary, or if the complaint relates to product

liability. By taking quick action the manufacturer often can limit its losses and at the same time protect the interests of its customers. Complaints of a less serious vein do not call for such a rapid response; however, the decision as to what constitutes a serious complaint should be made by QA, not by field personnel.

Copies of the completed complaint form are sent to everyone involved with the complaint as well as to other individuals or departments that may have an interest. Thus, any liability would be circulated to the Law/Legal Department.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

CONSUMER COMPLAINT FORM

Date _____ Time _____

Individual Receiving Complaint _____

Individual Investigating Complaint _____

Customer/Consumer's Name _____

Address _____

_____

_____

City _____

State _____ Zip _____

Phone ( ) _____

Fax ( ) _____

Complaint _____

_____

_____

_____

_____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Identification of Product _____

Product _____

Product Code Date _____

Container Type and Size _____

Quantity _____

Has a Sample Been Obtained? Yes_____ No_____

Are Other Containers Available? Yes_____ No_____

Was a Doctor or Hospital Involved? **Yes**_____ **No**_____

Name _____

Address _____

_____

Phone ( )_____

Investigation: By _____ Date _____

_____

_____

EXAMPLE-FOR ILLUSTRATIVE PURPOSES ONLY

Corrective Action Taken: By _____ Date_____

Nature of Corrective Action:_____

Disposition: By _____Date_____

Allowed _____
Disallowed _____
Undetermined _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

EMPLOYEE EDUCATION PROGRAMS

Formal employee education programs are important to the efficient operation of a food processing facility. Properly developed programs ensure products of high quality and wholesomeness and a safe, hazard-free working environment.

The following four educational programs should be presented each year:

- Annual employee training program
- Plant sanitation and cleaning training program
- Hazard communication training program
- Work place safety training program

Additional educational programs should be developed and presented whenever a particular need is identified.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Annual Employee Training Program

Each year all employees should be required to attend a meeting to review good manufacturing practices, sanitation practices, and employee responsibilities. Attendance at the meeting should be recorded. Any employee who misses the meeting must be given an appropriate opportunity to learn what was covered at the meeting.

At the annual meeting a policy manual for the firm will be distributed to all employees. Each employee must sign a statement pledging that they will abide by all the rules and regulations contained in the manual as well as the U.S. Food and Drug Administration (FDA) regulations as set forth in the Good Manufacturing Practices. If employees do not adhere to established rules, they should be warned and then reminded of the importance of good manufacturing practices, and that repeated offenses could ultimately lead to dismissal.

Program content

Goals and Objectives

- Employee questions and concerns
- Distribution of firm's employee manual

Sanitation

- Plant cleaning and sanitation
- Employee hygiene
- FDA's Good Manufacturing Practices
- Dress Code

Safety

- Material Safety Data sheets
- Safety hazards in the work environment
- Reporting of injuries and safety hazards
- Employee evacuation in case of fire or other disaster
- Establishment of an employee safety committee

Pathogens

- Sources of product contamination (including cross contamination)
- Employee responsibilities for pathogen control and elimination
- Microorganisms of public health significance and their control

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Economic fraud

- Fill of packages
- Proper packages/labeling
- Proper use of weigh scales

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Plant Sanitation and Cleaning Training Program

All employees responsible for cleaning and sanitizing are required to attend to review and discuss proper cleaning and sanitizing procedures. Attendance at this meeting should be recorded.

Program Content

Firm' Sanitation Program

- Review firm's cleaning and sanitation manual
- Proper chemical storage, mixing, and disposal
- Proper use of cleaning equipment, brushes, and pads
- Proper sanitation of brushes and pads
- Safety equipment and its proper use
- Proper cleaning procedures
- Evaluation of cleaning and sanitation effectiveness

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Hazard Communication Training Program

All employees exposed to cleaning and sanitizing compounds are required to attend a meeting on hazard communication. Attendance should be recorded.

Program Content

Cleaning and Sanitizing Compounds

- **Safe mixing procedures**
- **Required personal protective clothing**
- **Application procedures**
- **Disposal of excess chemicals**
- **First aid procedures**

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Work Place Safety Training Program

All employees exposed to cleaning and sanitizing compounds or equipment are required to attend a meeting on work place safety. Attendance should be recorded.

Program Content

Processing Equipment

- Safe equipment operating procedures
- Proper equipment cleaning
- Protective equipment
- Lock out\tag out plan
- Proper and safe equipment maintenance

Cleaning Equipment

- Safe equipment operating procedures
- Proper equipment cleaning
- Proper and safe equipment maintenance
- Proper disposal of chemicals

General Safety Issues

- Proper clothing and personal safety devices
- Emergency exits
- Fire equipment and its use
- Accident reporting and first aid

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Miscellaneous Programs to be Decided on Identified Needs

Other employee education programs will be held as needed. Each additional program's topics and contents will be selected to meet new or changed requirements. Such programs may include continuing education programs offered by trade and professional organizations, health regulatory agencies, and educational institutions.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PEST CONTROL AND MANAGEMENT

Controlling insect and rodent pests is an important part of maintaining the sanitation and quality control standards necessary in catfish processing. Each establishment has its own particular quality control standards and a program to achieve them. An effective pest control program involves the participation of management and pest control personnel. The Plant Manager or Quality Assurance/Control Manager must work closely with the pest control personnel.

The most capable and dependable employees should be assigned to handle pest control. However, their training and experience in pest control may be limited.

Management and Pest Control Personnel

A good pest management or pest control program in catfish processing is based on a coordinated effort between the processing plant management and the pest control personnel. The pest control personnel usually can accomplish little without full involvement and cooperation of management in an overall sanitation effort. Both must understand that controlling pests requires a complete sanitation program, accounting for all facets of the operation from raw material to shipping and distribution.

Management and pest control personnel should survey the facility and discuss the operating and cleaning schedules, physical conditions inside and outside the facility, employee and operating practices, and storage of pest control chemicals and equipment. Before a pest control program can be developed and carried out, both management and pest control personnel must understand each other's responsibilities and role in pest control.

EXAMPLE -FOR ILLUSTRATIVE PURPOSES ONLY

Pest Control and Management Program

Control of pests associated with catfish processing operations should be based on both chemical and non-chemical control methods. Insects and rodents are becoming resistant to commonly used pesticides; therefore, future pest control programs must integrate chemical and non-chemical (sanitation, traps, preventive measures) methods into an ongoing program, under the direction of trained and properly equipped personnel.

A good pest management program must be continuous and designed to keep pest populations low. It is virtually impossible to eliminate or eradicate most pests from an environment favorable for them. Pest control must be on-going and continuously improved.

The concept of pest management involves dealing with pest populations that are interacting with the total plant environment. Pest management requires the integration of sanitation, prevention, exclusion, mechanical control methods, and chemical pesticides into a program with a goal of significantly reducing (and possibly eliminating) a pest population.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

In 1970 Congress passed the Occupational Safety and Health Act to assure as safe and healthful working conditions as possible for every working person in the Nation and to preserve our human resources. The act made the Secretary of Labor responsible for the collection, compilation, and analysis of statistics of work-related injuries and illnesses. The Bureau of Labor Statistics administers this recordkeeping and reporting system. Under this Act, the Occupational Safety and Health Administration (OSHA) was created within the Department of Labor to:

- Encourage employers and employees to reduce workplace hazards and to implement new or improve existing safety and health programs;
- Provide for research in occupational safety and health to develop innovative ways of dealing with occupational safety and health problems;
- Establish "separate but dependent responsibilities and rights" for employers and employees for the achievement of better safety and health conditions;
- Maintain a reporting and recordkeeping system to monitor job-related injuries and illnesses;
- Establish training programs to increase the number and competence of occupational safety and health personnel;
- Develop mandatory job safety and health standards and enforce them effectively; and
- Provide for the development, analysis, evaluation, and approval of state occupational safety and health programs.

OSHA continually reviews and redefines specific standards and practices, but its basic purposes remain constant.

OSHA's regulations are collected and published in Title 29 of the Code of Federal Regulations, Part 1900-1999. For information on OSHA publications and other informational materials, contact the OSHA Publications Office, 200 Constitution Avenue, NW, Room N-3101, Washington, DC 20210, or phone (202) 523-9667 **or** contact your regional OSHA office (see page 13-7 of this section).

Occupational injuries and illnesses must be recorded. Employers of 11 or more employees must maintain records of occupational injuries or illnesses as they occur. Employers with 10 or less employees are exempt from keeping such records unless the Bureau of Labor Statistics has selected them to participate in the Annual Survey of Occupational Injuries and Illnesses. Some

states operate the iiow nOSHA-approved **job** safety and health plans. State plans must have a standard that is identical to, or at least as effective as, the federal plan. Employers located in states with a state-approved plan are required to keep the same records as employers in other **States.**

Employers are responsible for keepmg their employees informed about OSHA and the various safety and health matters with which they are involved. Employers are required to post certain materials at a prominent location in the workplace.

OSHA is authorized under the Act to conduct workplace inspections. Every establishment covered by the Act is subject to inspection by OSHA compliance safety and health officers. States with their own occupational safety and health programs conduct inspections using qualified compliance safety and health officers.

Employer Responsibilities and Rights

Responsibilities

The Occupational Safety and Health Act of 1970 provides the employers with certain responsibilities and rights. Employer responsibilities and rights in states with their own programs are generally the same as the federal OSHA states.

As an employer, you must:

- Meet your general duty responsibility to provide a workplace free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees, and comply with standards, rules, and regulations issued under the Act.
- Be familiar with mandatory OSHA standards and make copies available to employees for review upon request.
- Inform all employees about OSHA.
- Examine workplace conditions to make sure they conform to applicable standards.
- Minimize or reduce hazards.
- Make sure employees have and use safe tools and equipment and that such equipment is properly maintained.
- Use color codes, posters, labels, or signs when needed to warn employees of potential hazards.

- Establish or update operating procedures and communicate them so that employees follow safety and health requirements.

- Provide medical examinations when required by OSHA standards.

- Provide training required by OSHA standards for hazard communication, lead, etc.

- Report to the nearest OSHA office within 48 hours any fatal accident or one that results in the hospitalization of five or more employees.

- Keep OSHA-required records of work-related injuries and illnesses, and post a copy of the totals from the last page of OSHA No. 200 during the entire month of February each year (for employers with 11 or more employees).

- Post, at a prominent location within the workplace, the OSHA poster (OSHA 2203) informing employees of their rights and responsibilities.

- Provide employees, former employees, and their representatives access to the Log and Summary of Occupational Injuries and Illnesses (OSHA No. 200) at a reasonable time and in a reasonable manner.

- Provide access to employee medical records and exposure records to employees or their authorized representatives.

- Cooperate with the OSHA compliance officer by furnishing names of authorized employee representatives who may be asked to accompany the compliance officer during an inspection. (If none, the compliance officer will consult with a reasonable number of employees concerning safety and health in the workplace.)
- Not discriminate against employees who properly exercise their rights under the Act.

- Post OSHA citations at or near the worksite involved. Each citation, or copy thereof, must remain posted until the violation has been abated, or for three working days, whichever is longer.

- Abate cited violations within the prescribed period.

Rights

As an employer, you have the right to:

- Seek advice and off-site consultation as needed by writing, calling or visiting the nearest OSHA office. (OSHA will not inspect merely because an employer requests assistance.)
- Be active in your industry association's involvement in job safety and health.
- Request and receive proper identification of the OSHA compliance officer prior to inspection.
- Be advised by the compliance officer of the reason for an inspection.
- Have an opening and closing conference with the compliance officer.
- Accompany the compliance officer on the inspection.
- File a Notice of Contest with the OSHA area director within 15 working days of receipt of a notice of citation and proposed penalty.
- Apply to OSHA for a temporary variance from a standard if unable to comply because of the unavailability of materials, equipment or personnel needed to make necessary changes within the required time.
- Apply to OSHA for a permanent variance from a standard if you can furnish proof that your facilities or method of operation provide employee protection at least as effective as that required by the standard.
- Take an active role in developing safety and health standards through participation in OSHA Standards Advisory Committees, through nationally recognized standards-setting organizations, and through evidence and views presented in writing or at hearings.
- Be assured of the confidentiality of any trade secrets observed by an OSHA compliance officer during an inspection.
- Submit a written request to NIOSH for information on whether any substance in your workplace has potentially toxic effects in the concentrations being used.

Employee Responsibilities and Rights

Although OSHA does not cite employees for violations of their responsibilities, each employee "shall comply with all occupational safety and health standards and all rules, regulations, and orders issued under the Act" that are applicable. Employee responsibilities and rights in states with their own occupational safety and health programs are generally the same as for employees in federal OSHA states.

Responsibilities

As an employee, you should:

- Read the OSHA poster at the job-site.
- Comply with all applicable OSHA standards.
- Follow all employer safety and health rules and regulations, and wear or use prescribed protective equipment while engaged in work.
- Report hazardous conditions to the supervisor.
- Report any job-related injury or illness to the employer, and seek treatment promptly.
- Cooperate with the OSHA compliance officer conducting an inspection if he or she inquires about safety and health conditions in your workplace.
- Exercise your rights under the Act in a responsible manner.

Rights & Protection for Using Rights

As an employee, you have the right to:

- Seek safety and health on the job without fear of punishment.
- Complain to an employer, union, OSHA or any other government agency about job safety and health hazards.
- File safety or health grievances.
- participate on a workplace safety and health committee or in union activities concerning job safety and health.

- participate in OSHA inspections, conferences, hearings, or other OSHA-related activities.

If an employee is exercising any of these or other OSHA rights, the employer can not discriminate against that employee in any way. If an employee believes that he\she has been punished for exercising safety and health rights, a complaint must be filed within 30 days to the nearest OSHA office. If a state agency has an OSHA-approved state program, employees may file their complaint with either federal OSHA or the state agency under its laws.

U.S. Department of Labor
Occupational Safety and Health Administration
Regional Offices

Region I
(CT,*,MA,ME,NH,RI,VT*)
133 Portland Street
1st Floor
Boston, MA 02114
Telephone: (617) 565-7164

Region II
(NJ,NY,*PR,*VI*)
201 Varick Street
Room 670
New York, NY 10014
Telephone: (212) 337-2378

Region III
(DC,DE,MD,*PA,VA,*WV)
Gateway Building, Suite 2100
3535 Market Street
Philadelphia, PA 19104
Telephone: (215) 596-1211

Region IV
(AL,FL,GA,KY,*MS,NC,*SC,*TN*)
137 5 Peachtree Street, N.E.
Suite 587
Atlanta, GA 30367
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(IL,IN,*MI,,*MN,*OH,WI)
230 South Dearborn Street
Room 3244
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Telephone: (312) 353-2200

Region VI
(AR,LA,NM,*OK,TX)
525 Griffin Street
Room 602
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Region VII
(IA,*KS,MO,NE)
911 Walnut Street, Room 406
Kansas City, MO 64106
Telephone: (816) 426-5861

Region VIII
(CO,MT,ND,SD,UT,*WY*)
Federal Building, Room 1576
1961 Stout Street
Denver, CO 80294
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71 Stevenson Street
Room 415
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Telephone: (415) 744-6670

Region X
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*These states and territories operate their own OSHA-approved job safety and health plans (Connecticut and New York plans cover public employees only). States with approved plans must have a standard that is identical to, or at least as effective as, the federal standard.

REFERENCES USED IN THIS SECTION ARE AVAILABLE FROM YOUR STATE OR REGIONAL OFFICE.

OSHA Publication No. 2056, All About OSHA.

OSHA Publication No. 2254, Training Requirements in OSHA Standards and Training Guidelines.

Materials SAFETY DATA SHEETS (MSDS)

Material Safety Data Sheets (MSDS) provide information on product stability, storage conditions, disposal of unused material, spill handling, industrial hygiene, and general precautions for safe use. Data on toxicology are provided from the perspective of occupational safety and health.

In 1983, the Occupational Safety and Health Administration (OSHA) promulgated final regulations for hazard communication. The regulations provided that MSDS were to be the primary means for transmitting safety information. Chemical manufacturers and importers are obligated to send a MSDS with each initial shipment of a product. In order to ensure that a required MSDS is available at every workplace, it is incumbent on the employer who purchases a material to request any missing data sheets.

The contents of a MSDS are specified in the regulations as follows:

1. The identity used on the label.
2. Physical and chemical characteristics of the hazardous chemicals.
3. The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity.
4. The health hazards.
5. The primary route(s) of entry into the body.
6. The OSHA permissible exposure limit, ACGIH (American Conference of Governmental Industrial Hygienists) Threshold Limit Value and any other exposure limit.
7. Whether the hazardous chemical is listed in the National Toxicology Program (NTP) ***Annual Report on Carcinogens.***
8. Any generally applicable precautions for safe handling and use.
9. Any generally applicable control measures.
10. Emergency and first aid procedures.
11. The date of preparation of the MSDS or the last change to it.

12. The name, address, and telephone number of the chemical manufacturer, importer, employer, or other responsible party preparing or distributing the MSDS.

Important Points About MSDS

When chemicals are ordered, the purchase order shall specify that chemicals are not to be shipped without corresponding **MSDS.**

When MSDSs arrive, they will be reviewed for completeness by a designated person. Should any MSDSs be incomplete, a letter will be sent immediately to the manufacturer requesting the additional information.

A complete file of MSDSs for all hazardous chemicals to which employees are exposed should be kept in a labeled binder at designated locations.

MSDSs for hazardous chemicals used by departments should be kept in labeled binders in the office of that department. MSDSs should be available for employees at all times.

MSDSs should be reviewed and updated annually by a designated person.

PART 110-Federal Government Rules and Regulations for Good Manufacturing Practices

Subpart A - General Provisions

Subpart B - Buildings and Facilities

Subpart C - Equipment

Subpart D - [Reserved]

Subpart E - Production and Process Controls

Subpart F - [Reserved]

Subpart G - Defect Action Levels

Authority: Secs. 402,701,704, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

Source 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A - General Provisions

S 110.3 Definitions

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- ***Acid foods or acidified foods*** means foods that have an equilibrium pH of 4.6 or below.
- "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- ***Batter*** means a semi-fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- ***Blanching,*** except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- ***Critical control*** point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- ***Food*** means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- ***Food-contact surfaces*** are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
- ***Lot*** means the food produced during a period of time indicated by a specific code.
- ***Microorganisms*** means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA uses the adjective "microbial" instead of using an adjectival phrase containing the word "microorganism."
- ***Pest*** refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies and larvae.
- ***Plant*** means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- ***Quality control operation*** means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- ***Rework*** means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

- *Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w) An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.
- *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- *Shall* is used to state mandatory requirements,
- *Should* is used to sate recommended or advisory procedures or identify recommended equipment.
- *Water activity (a_w)* is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

s 110.5 Current good manufacturing practice

- The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).
- Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

s 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

- *Disease control*. Any person who by medical examination or supervisory observations, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.
- *Cleanliness*. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

1. Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
2. Maintaining adequate personal cleanliness.
3. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
4. Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
5. Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
6. Wearing, where appropriate, in an effective manner, hair nets, head-bands, caps, beard covers, or other effective hair restraints.
7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
8. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
9. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

- Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

- Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

s 110.19 Exclusions.

- The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.
- FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B - Buildings and Facilities

S 110.20 Plant and grounds

- *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:
  1. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
  2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
  3. Adequately draining areas that may contribute to contamination of food by seepage, foot-borne filth, or providing a breeding place for pests.
  4. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

  If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that maybe a source of food contamination.
- *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:
  1. Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
  2. Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination maybe reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

3. Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

   (i) Using protective coverings
   (ii) Controlling areas over and around the vessels to eliminate harborages for pests
   (iii) Checking on a regular basis for pests and pest information
   (iv) Skimming the fermentation vessels, as necessary

4. Be constructed in such a manner that floors, walks, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
5. Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, sky-lights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
6. Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
7. Provide, where necessary, adequate screening or other protection against pests.

S 110.35 Sanitary operations

- General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

- *Substances used in cleaning and sanitizing; storage of toxic materials.*
  1. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;
(ii) Those necessary for use in laboratory testing procedures;
(iii) Those necessary for plant and equipment maintenance and operation; and
(iv) Those necessary for use in the plant's operations.

2. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

- ***Pest control.*** No animals or pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs in unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials.
- *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.
  1. Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.
  2. In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
  3. Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.
  4. Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
  5. Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.
- ***Storage and handling of cleaned portable equipment and utensils.*** Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

S 110.37 Sanitary facilities and controls

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

- ***Water supply.*** The water supply shall be sufficient for the operations intended and shall be

derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

- *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:
  1. Carry sufficient quantities of water to required locations throughout the plant.
  2. Properly convey sewage and liquid disposable waste from the plant.
  3. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
  4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
  5. Provide that there is not back-flow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.
- ***Sewage disposal.*** Sewage disposal shall be made into an adequate sewage system or disposed of through other adequate means.
- ***Toilet facilities.*** Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
  1. Maintaining the facilities in a sanitary condition.
  2. Keeping the facilities in good repair at all times.
  3. Providing self-closing doors.
  4. Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).
- ***Hand-washing facilities.*** Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
  1. Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
  2. Effective hand-cleaning and sanitizing preparations.
  3. Sanitary towel service or suitable drying devices.
  4. Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

5. Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
6. Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

- ***Rubbish and offal disposal.*** Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C - Equipment

S 110.40 Equipment and utensils.

- All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

- Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

- Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

- Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

- Each freezer and cold storage compartment used. to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

- Instruments and controls used for measuring, regulating, or recording temperature, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

- Compressed air or their gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D - [Reserved]

Subpart E - Production and Process Controls

S 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected or, if permissible, treated or processed to eliminate the contamination.

- ***Raw materials and other ingredients.***
  1. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination of deterioration of food.
  2. Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
  3. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.
  4. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means,

including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

5. Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.
6. Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.
7. Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

- ***Manufacturing operations***.

1. Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
2. All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.
3. Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

   (i) Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved.
   (ii) Maintaining frozen foods in a frozen state.
   (iii) Maintaining hot foods at 140°F (60°C) or above.
   (iv) Heat-treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

4. Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH, or controlling a_w. that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.
5. Work-in-process shall be handled in a manner that protects against contamination.
6. Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving,

loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

7. Equipment, containers, and utensils used to convey, hold, or store raw food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

8. Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

9. Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

10. Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting, and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

11. Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to tilling, water used shall be safe and of adequate sanitary quality.

12. Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

    (i) Using ingredients free of contamination.
    (ii) Employing adequate heat processes where applicable.
    (iii) Using adequate time and temperature controls.
    (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
    (v) Cooling to an adequate temperature during manufacturing.
    (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

13. Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in S 130.3(d) of this chapter.
(iv) Providing physical protection from contamination, particularly airborne contamination.
(v) using sanitary handling procedures.

14. Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a_w of food.
(ii) Controlling the soluble solids-water ratio in finished food.
(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

15. Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.
(ii) Controlling the amount of acid or acidified food added to low-acid food.

16. When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
17. Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

s 110.93 Warehousing and distribution

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G - Defect Action Levels

S 110.110 Natural or unavoidable defects in food for human use that present no health hazard

- Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health The Food and Drug Administration established maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
- Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
- Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect levels of the final food.
- A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C. St. SW., Washington, DC 20204.

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

DAILY SANITATION CHECK SHEET

Employee Practices: adequate hair covering; no jewelry; no nail polish; no items in front shirt pockets; no food or beverages in processing area; hand washing thoroughly at least every two hours. Yes No
Action to correct: _____

Outside grounds free of litter, manicured, free of dust. Yes No
Items to be maintained: _____

Dry Storage Area clean and orderly. Yes No
Action to correct: _____

Ice machine clean, functioning, adequate supply. Yes No
Action to correct: _____

Equipment: Tables, Floors, Knives, Plastic Tubs (Totes), Scales, Deheader, Filleting Machines, Eviscerators, Saws, Skinning Machine, etc. cleaned and sanitized. Yes No
Items to be recleaned: _____

All perishable food items returned to refrigerator. Yes No
Items left out: _____
Disposition: _____

Refrigerators orderly, clean, and functioning. Yes No
Action to correct: _____

Freezer(s) orderly, clean and functioning. Yes No
Action to Correct: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

Chemicals stored properly. Yes No
Action to correct: _____

Pests, insects under control. Yes No
Action to correct: _____

Rest rooms cleaned, supplied with soap, toilet tissue, and paper towels. Yes No
Action to correct: _____

Dining Areas clean and orderly. Yes No
Action to correct: _____

Locker Rooms orderly and clean. Yes No
Action to correct: _____

Other areas (specify): _____
Action to correct: _____

Inspected by: _____ Date: _____ Time: _____

Reviewed by: _____ Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

METAL DETECTOR CALIBRATION SHEET

DATE/TIME	METAL DETECTOR #1	METAL DETECTOR #2	INSPECTED BY

Reviewed by:_____

Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

SCALE CALIBRATION / MONITORING FORM

DATE/ TIME	SCALES (RECEIVING)	SIZE GRADERS #1	#2	#3	SCALES (PACKING)	QC SCALES (SIZE GRADING)	QC SCALES (PACKING)	INSP. BY

Action taken: _____

_____

_____

Reviewed by: _____ Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

THERMOMETER CALIBRATION FORM

(Check weekly to Plus or Minus 0.5 °F)

DATE	TIME	READING- ICE WATER	REJECT / ACCEPT	OPERATOR INITIALS

Reviewed by: _____

Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

DAILY LIVE FISH RECEIVING REPORT

Receiving Date: _____

FARMER	POND NO.	FARM WT.	PLANT WT.	DEAD DECOMP.	DISEASED	IMPROPER SPECIES	TRASH	NET WT.	OPR. INIT.

Reviewed by: _____ Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PERCENT BATTER/BREADING REPORT

DATE / TIME	PRODUCT	WEIGHT BEFORE WASH	WEIGHT AFTER WASH	PERCENT BATTER/ BREAD	INSPECT. BY

Reviewed by:_____

Date:_____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

BATTER TEMPERATURE AND USE REPORT

DATE / TIME	BATCH #	BATTER TEMPERATURE	INSPECTED BY

Reviewed by: _____

Date: _____

EXAMPLE- FOR ILLUSTRATIVE PURPOSES ONLY

WEIGH/PACK/LABEL REPORT

DATE / TIME	PRODUCT	PACKAGE SIZE	NET WEIGHT	LABEL OK	INSPECT. BY

Was metal detected during shift? Yes No

If so, time: _____

Product Description: _____

Disposition: _____

_____

Reviewed by: _____ Date: _____

EXAMPLE-FOR ILLUSTRATIVE PURPOSES ONLY

COOLER STORAGE LOG

DATE / TIME	PRODUCT	PRODUCT TEMPERATURE	COOLER/FREEZER TEMPERATURE	INSPECTED BY

Disposition of product: _____

_____

_____

Reviewed by: _____

Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

DAILY PRODUCTION LOG

DATE	PRODUCT	CASE SIZE	CODE DATE	TOTAL CASES PRODUCED

Comments: _____

_____

_____

Reviewed by: _____

Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

MATERIALS RECEIVING AND STORAGE SHEET

Receiving Date: _____

PRODUCT	SUPPLIER	MFG. CODE	CONDITION	INSPECT BY

Reviewed by: _____ Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

PEST CONTROL FORM

DATE	AREA	PROBLEM	ACTION TAKEN	CHEMICALS USED	OPERATOR INITIALS

Reviewed by:_____

Date:_____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

NOTICE OF UNUSUAL OCCURRENCE AND CORRECTIVE ACTION

(Not covered by other forms)

Date _____ **Time** _____

Operation or processing step _____

_____

_____

_____

Description of the problem _____

_____

_____

Corrective Action _____

_____

_____

Name _____ **Date:** _____

Reviewed by: _____

Date: _____

EXAMPLE - FOR ILLUSTRATIVE PURPOSES ONLY

SANITIZER HAND DIP CHECKS FORM

(Check Every Two Hours)

DATE/ TIME	HAND DIP #1	HAND DIP #2	HAND DIP #3	HAND DIP #4	OPERATOR INITIALS

Reviewed by:_____

Date:_____

DEVELOPING A HACCP PLAN

HACCP PLAN OVERVIEW

The principles of HACCP as generally recognized for seafood processing operations by the National Fisheries Institute, the National Marine Fisheries Service and the U.S. Food and Drug Administration are contained in the Seafood Industry Hazard Analysis Critical Control Point (HACCP) Training Manual (NFI, 1991). Although not officially adopted to date, this manual provides a valuable discussion of the concepts and implementation of HACCP. The excerpts which follow are provided as an aid to managers and employees who are contemplating the development of HACCP programs. Contact NFI, Sea Grant institutions, or an appropriate regulatory agency regarding more complete training programs and materials.

1. What Does HACCP Do?

HACCP provides a more focused approach to the control of hazards in food than is achievable by traditional inspection and quality control programs. It does **not** require continuous inspection. Rather, HACCP is a combination of industry self-inspection and government monitoring. HACCP can be boiled down to the following: the program is based on the identification and control of potential hazards versus the end use of the product. The ability to identify and to control potential hazards is absolutely fundamental to the successful implementation of HACCP. Once the potential hazards are identified, HACCP allows you to focus efforts to control the hazards at specific critical points in the process. Furthermore, since the hazards are identified with regard to the end use of the product, more control and monitoring will be necessary for products such as cooked products, which do not require additional cooking, than for fresh fish which in all probability will be cooked.

Simply then, what do you do under HACCP as a catfish processor? You study and critique your plant procedures from the receipt of raw materials through shipment of the final product. You determine which processing steps are critical elements in controlling hazards and you assess overall sanitation. Then you write your own HACCP plan identifying the steps to be monitored and the records to be kept that will indicate compliance with your plan. This is not as difficult as it may sound; there are documents and aids already developed that will assist you. The remainder of this chapter, as well as the other chapters in this training manual, are designed to assist you in identifying the potential hazards in your specific processing plant and in developing effective control and monitoring procedures.

2. HACCP

The HACCP procedure was developed by the National Advisory Committee for Microbiological Criteria for Foods, an independent panel of food safety experts convened by the National Academy of Sciences (NAS) at the request of federal food inspection agencies. To understand and implement an effective HACCP program, you as a catfish processor must follow the steps in Table 1.

	Table 1. Implementation of a HACCP Program
Step	Process
1.	Prepare a process flow chart. Assess the hazards associated with each operational step: growing, harvesting, using raw materials and ingredients, processing, manufacturing, distribution, marketing, preparation, and consumption of the food.
2.	Identify the critical control points (CCPs) where the identified hazards can be controlled.
3.	Set the critical limits that must be met at each CCP.
4.	Define monitoring procedures to ensure critical limits are met.
5.	Define corrective actions to be taken when the monitoring procedures identify a deviation.
6.	Devise record-keeping systems that document the effectiveness of the HACCP plan.
7.	Establish verification procedures to ensure that the HACCP system is working correctly. Verification measures may include biological, physical, chemical, and sensory methods. Where they are needed, establish limiting criteria.

Initially, the process may seem unnecessary and perhaps difficult, but it is absolutely essential. The reason for this perceived difficulty is that you will be asked to evaluate closely your production processes. You are familiar with these processes. Consequently, it can be difficult to step back and view them with a critical eye. It may be helpful to imagine yourself as an outsider viewing the process for the first time and asking questions, especially **"why'** and **"what** if" questions.

HOW TO DEVELOP A HACCP PLAN

1. INTRODUCTION

In this section, we are going to describe how you, as a member of the catfish industry, can develop your own HACCP plan. This plan will not only be appropriate for your own catfish processing operation, but it will also meet the requirements of the federal agency that will eventually be responsible for administering a seafood inspection program based on the HACCP system. You will see that the procedures for developing a HACCP plan are quite straightforward, involving only seven basic steps, all of which can be accomplished by you and your staff. Before we get to these seven steps, however, let's first define some terms so that you have a clear understanding of what we are talking about.

As you know, "HACCP" stands for "Hazard Analysis Critical Control Point." What does this really mean?

Hazard

Hazard, as used here, simply means a chance for, or the risk of, an unacceptable biological, chemical, physical, or economic property in a food product that could cause consumer distress or illness.

Hazard Analysis

Hazard analysis means the process of identifying biological, chemical, physical, or economic-fraud risks relative to a food product or manufacturing process which takes into consideration the intended end use of the food product. The key word here is end-use; it means that the conditions or situations that should be considered hazardous are those that present a risk only with respect to the ultimate use of the product. For example, the presence of certain pathogens in raw materials would not necessarily be considered hazardous if the pathogens are destroyed during processing. Such is the case with fully cooked products and those intended to be fully cooked by the consumer before being eaten. On the other hand, the presence of glass in a product would obviously be considered a hazard whether it was eventually cooked or not.

Critical Control Point

A critical control point is an area or item of equipment in the processing facility where specific operational steps in a manufacturing process take place, and where the loss of control of such steps would automatically result in an unacceptable safety, hygiene, or economic-fraud risk.

Food Safety

Food safety risks are those that could cause harm to a consumer's health or physical well-being. Safety issues are usually addressed through biological, chemical, or physical criteria, and are distinct from issues relating to food hygiene or economic fraud.

Food Hygiene

Food hygiene refers to those characteristics of a product or process relating to wholesomeness or facility sanitation.

Economic Fraud

Economic fraud refers to those illegal or misleading actions which defraud purchasers. Such actions include, among other things, species substitution, short weight and overglazing. Also included is the excessive use of so-called approved chemicals in processing and the misuse of chemicals, such as sodium tripolyphosphate, originally intended to minimize drip loss, for the express purpose of adding weight to the final product.

HACCP System

A Hazard Analysis Critical Control Point system is a non-traditional inspectional approach to controlling hazards in foods. It is a two-part process done on a commodity-by-commodity basis. The first part deals with defining the consumer hazards within a specific food commodity relative to the intended use of the product. The second part deals with: 1) flow charting each operational step of a food-manufacturing process and defining the hazards associated with each step; 2) assessing the relative importance of the hazards and identifying the critical control points of the manufacturing process; 3) determining the appropriate preventive measures to be employed; 4) determining the monitoring procedures, either by observation or by measurement, that are needed to ensure that hazards are being controlled; 5) establishing the critical limits that must be met at each Critical Control Point and the corrective actions to be taken to return deviations to acceptable limits; 6) developing the records necessary for monitoring that will ensure hazards are being controlled; and 7) establishing verification procedures to assure an effective HACCP plan.

The HACCP Plan

A HACCP plan is a planning document and its related records which, under a HACCP-based inspection system, would be required to be on file at each processing facility. The planning document and related records are established by the facility in conjunction with the regulatory agency prior to the facility's admission to a HACCP seafood surveillance program. Such a plan includes: 1) documentation of critical control points, 2) action taken when critical deviations occur, 3) disposition of product subjected to "critical" deviations, 4) clear designation of the records to be made available for government inspections, and 5) provisions for record maintenance.

2. DEVELOPMENT OF A HACCP PLAN

Although a fully-developed plan would likely include much general information that you already possess, such as organizational charts and responsibilities, company directives concerning product manufacture, process specifications, etc., the components that are essential to a HACCP plan can be developed by you and your staff by following the seven basic steps below:

1 - Prepare process flow charts and assess potential hazards
2 - Identify critical control points
3 - Set critical limits that must be met at each CCP
4 - Define monitoring procedures
5 - Define corrective actions
6 - Devise record keeping systems
7 - Establish verification procedures

2.1 STEP 1 - Prepare Process Flow Charts and Assess Potential Hazards

The first step in starting a HACCP program is to prepare a detailed process flow chart for your major processing operation (or charts for each distinct processing operation) from which you will analyze your operations.

2.1.1 Development of the Flow Chart

The chart should list the sequence of specific operational steps (control points) in the manufacturing process of your food product where microbiological, chemical, physical, and/or economic factors can be controlled (see sample on the following page). In addition to developing such flow charts, standard operating procedures (SOPs) should be written and followed by your firm. The SOPS relate to the operations that must be accomplished at each process step in terms of both the product processing methods and sanitation controls.

Each chart should begin with the “receiving” of fresh and/or frozen raw materials and end with the “shipping” of your product to the wholesale or retail trade.

Chapter 3 contains a general process flow chart for processed catfish. It identifies specific processing steps or control points where hazards can be monitored and controlled. Of these control points, various steps are identified as “critical control points.” How to determine such critical control points is discussed in “Step 2” of this section.

2.1.2 Assess Potential Hazards At Each Step

Following development of your process flow chart(s), you are ready to begin the identification and assessment of hazards that could occur at each processing step (control point). Using your process flow chart as a guide, at each step in the processing operation, ask yourself the following question:

- What can go wrong at this step in terms of product safety, wholesomeness, and economic fraud?

The following are examples of hazards that could arise at individual processing steps for various catfish products. You may determine that one or more of these hazards could occur at any single step in the processing of your product.

Microbiological/Chemical

- Fuel oil
- Pathogens
- Cross-contamination
- Contaminated dip
- Contaminated ice
- Decomposition
- Time/temperature abuse
- Chemical contamination
- Additive abuse

Physical

- Filth
- Insect/rodent contamination
- Metal fragments
- Bones
- Other foreign materials
- Parasites
- Freezer burn
- Dehydration
- Damaged packaging
- Damaged product
- Improper sealing of package

Economic

- Excess moisture
- Excess glaze
- Short weights
- Mislabeling
- Misgrading
- Masking country of origin
- Incorrect product in package
- Wrong proportions of additives, ingredients

2.2 STEP 2 - Identify Critical Control Points

You must now determine the relative importance of the hazards involved in the processing of each of your products. It is here that the "Critical Control Point Analysis" phase of the HACCP system takes place. Evaluate each hazard in each processing step by answering the question: "Does the critical control of this hazard occur here or at another step?" That is, if there should be a failure to control this hazard at this specific step in the manufacturing operation, would it automatically result in an unacceptable safety, hygienic, or economic risk in terms of the end use of the product? For all steps where the answer to this question is "yes," such steps should be considered "critical control points."

A simple method of deciding whether a control point is critical is to follow the Critical Control Point Decision Tree found on Page 17-21 of this section.

2.3 STEP 3 - Set Critical Limits That Must be Met At Each CCP

The third step in setting up your HACCP plan is to establish the limits which must be met at each "critical control point." A critical limit is defined as one or more prescribed tolerances that must be met to ensure that the plan effectively controls a hazard or risk. There may be more than one limit for a critical control point. If any one of those limits is out of tolerance, the process will be out of control, and a potential hazard or risk can exist.

Examples of criteria frequently used for limits are temperature, time, moisture level, amounts of preservatives, additives and ingredients and net weight. Many types of limit information may be needed for control of a critical control point.

2.4 STEP 4 - Define Monitoring Procedures

Your next step is to determine the appropriate "monitoring procedures" to be used with the various preventive measures. Such procedures should be primarily observations or physical measurements that can be readily carried out in terms of realistic time delays and costs. Examples of such monitoring procedures include the following:

- Sampling and inspection of fresh and frozen raw materials
- Checks and documentation of temperatures of raw materials
- Checks and documentation of temperatures of product
- Checks and documentation of temperatures of coolers/freezers
- Checks of temperature and humidity in dry storage rooms
- Checks of inventory control
- Checks of amounts of additives used for each batch/lot
- Monitoring adequacy and potability of water supply
- Product sampling for bacterial analysis
- Periodic checks of net weights
- Checks of labels used
- Checks of production schedules
- Periodic checks of process control specification
- Visual inspections of product and equipment
- Checks of equipment maintenance
- Supervisory check points throughout the processing operation

2.5 STEP 5 - Define Corrective Actions and Preventive Measures to Control Hazards

The fifth step in setting up your HACCP plan is to determine, for each processing step, the appropriate corrective actions to be taken when prescribed limits are exceeded, and the preventive measures to control the potential hazards you identified earlier.

Listed below are examples of some common corrective actions and preventive measures that all catfish processors might consider in developing a plan:

- Rejecting unsatisfactory raw and finished product
- Physically separating raw and finished product in storage
- Using approved, potable water supply
- Ensuring proper time/temperature control
- Using only approved chemicals
- Using adequate screens to keep out insects/pests
- Ensuring proper removal of extraneous materials
- Ensuring proper maintenance and sanitation of equipment
- Ensuring proper calibration of scales
- Using visual and organoleptic inspection of product
- Ensuring proper packaging/labeling of product
- Ensuring proper rotation of product in storage (FIFO)
- Using standard operating procedures for plant
- Using training programs for employees
- Ensuring good personal hygiene of employees
- Employing good housekeeping practices
- Using trucks capable of maintaining proper temperatures
- Ensuring proper loading of trucks
- Developing a product recall system
- Requiring individual accountability from supervisors

2.6 STEP 6 - Devise a Record Keeping System

In addition to the "monitoring procedures" and "corrective actions" that you have already identified for each processing step, the HACCP system requires that your plan include one additional safeguard, particularly for those processing steps you determined to be "critical control points." That safeguard is the inclusion of a suitable record-keeping system in your HACCP plan.

The key to a successful application of the HACCP inspection system is the ability of plant management, quality control personnel, and regulatory authorities to perform routine and meaningful examinations of the process controls used, the level of plant sanitation, and the product itself throughout the entire processing operation. Most of these examinations are, in turn, dependent on the examination of the records maintained by your plant in these areas. Such records provide several vital functions: 1) they document that the critical limits set for a critical

control point have been met by recording the results of monitoring activities; 2) if critical limits were exceeded, they document what control action was taken and the disposition of the product; and 3) they offer product traceability from start to finish.

It is recognized that a plant, in the course of doing business, must keep records of many types and kinds of information. However, HACCP regulatory authorities will need only those records that verify monitoring results, pinpoint problems, and provide product traceability. They will have **no** need for any information that is legitimately of a proprietary nature!

Records can be of different types. In most cases, they need not be complex. In fact, the simpler the better, as long as they provide the necessary information. Examples of some of the primary records of these types are:

- Invoices of receipt of raw products
- Raw product origin records
- Incoming product inspection reports
- Product purchasing and processing specifications
- Quality control and assurance reports
- Scale calibration records
- Additives use logs
- Time/temperature records
- Unit and package weight records
- Shipping records, etc.
- Logs of NUOCAs (Notices of Unusual Occurrences and Corrective Actions taken)

The NUOCAs come into existence only when deficiencies are found during the established monitoring process. They provide valuable supplementary information to your other routinely-used processing records, particularly those required for critical control points. They serve to record what you found to be wrong, unusual, or unacceptable from a potential safety, quality, or economic hazard standpoint during the course of a particular processing step...and what action(s) you or your plant personnel took to correct it. NUOCAs may be separate forms of your own design which record such basic information as:

- Date and time of occurrence
- Processing step involved
- Problem identified
- Corrective action taken
- Other comments

Or, NUOCAs may simply be your inclusion of the above information onto another type of record you may be using, such as one of those indicated above. For example, the receipt of a decomposed product by the Receiving Department and its consequent return to the shipper could be noted on your copy of the receiving invoice. That invoice would now serve as your NUOCA.

2.7 STEP 7 - Establish Verification Procedures

The seventh and final step is to establish adequate verification procedures to assure that your HACCP plan is in fact being complied with and that it is effective. Both the producer and the regulatory agency have a role in verifying HACCP plan compliance. Verification confirms that all hazards were identified in the HACCP plan when it was developed. Verification activities include: establishment of appropriate verification inspection schedules; review of the HACCP plan; review of records kept for critical control points; review of process deviations and product dispositions; visual inspections of operations to observe if critical control points are under control; random sampling and analysis of products; and a written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken.

These seven steps for the development of a HACCP plans are straightforward, rational, and reasonably easy to accomplish. There are, however, two other important aspects of a mandatory HACCP system that need to be addressed in your plan. They are: Registration and Certification of Plants and a Product Recall System.

3. REGISTRATION AND CERTIFICATION OF PLANTS

A mandatory seafood surveillance program will likely require that all plants processing finished products for export or domestic trade be registered (for identification purposes only) and then certified in terms of plant process and sanitation controls. Sanitation (plant hygiene) will likely be assessed through use of an appropriate Plant Sanitation Compliance Checklist. The example on the following pages was developed for the manufacturers of raw fish products.

Such plant sanitation compliance checklists are comprehensive forms intended for intermittent use in determining the general sanitation compliance of a plant. They are not intended for use on a daily basis and, in fact, cannot be used to determine if a plant will produce a safe and wholesome product during any day's run. Note that the sanitation compliance checklist incorporates minor, major, serious, and critical deficiency scores, defined as follows:

Minor defect
One not in accordance with the requirements, but is not major, serious, or critical in terms of deterioration of product quality.

Major defect
One which inhibits general sanitation; the deterioration of product quality, however, is not serious or critical.

Serious defect
One which prevents proper plant sanitation; may result in tainted, decomposed or unwholesome product, but is not considered critical.

Critical defect
One which results in unwholesome product; presents health and safety threats; is not in accordance with Good Manufacturing Practices (GMP).

You should determine the maximum number of minor, major, or serious items acceptable for your plant at any one time. However, at no time should your plant operate with a critical deficiency.

Table 2. Sample Plant Sanitation Compliance Check List

For Catfish Processing Plants

Premises	Minor	Major	Ser	Crit*	Check If OK
1. Litter, waste, or improperly stored equipment	X				
2. Excessively dusty roads, parking lots	X				
3. Inadequate drainage	X				
4. Controls not in place to discourage pests such as flies and rodents		X			
BUILDING CONSTRUCTION 5. Design, materials or construction inhibits sanitation		X			
6. Ceilings over exposed product not free of peeling paint			X		
7. Exterior openings, where practical, not equipped with screens, etc., to prevent entrance of pests, etc.		X			
8. Air curtains, strip doors, and screen doors, if installed, are not effective		X			
9. Processing area opens directly (without barriers) into living quarters, garage, or heavy maintenance shop		X			

Premises	Minor	Major	Ser	Crit*	Check If OK
LIGHTING					
10. Lighting is inadequate	X				
11. Lights in product packaging or ingredient storage areas not safety type and unshielded			X		
VENTILATION					
12. Accumulation of condensates over exposed product, packaging material or ingredients		X			
13. Mold is present in processing or storage area	X				
WATER SUPPLY					
14a. Inadequate supply of cold or hot water		X			
b. Water not accessible		X			
15. Water subject to contamination, e.g., siphoning, cross-connection				X	
16. Fresh water not potable				X	
17. Water not approved by appropriate authorities for food processing				X	

Premises		Minor	Major	Ser	Crit*	Check If OK
ICE						
18.	Not made from potable water				X	
19.	Not made from an approved water supply				X	
20.	Not manufactured, handled or used in a sanitary manner			X		
21.	Transferred and re-used on other raw materials	X				
DISPOSAL OF WASTES						
22.	Liquid waste not disposed of in a sanitary and timely manner		X			
23.	Dry waste not collected in suitable containers conveniently located throughout the plant or disposed of in a sanitary and timely manner	X				
24.	Product waste not collected or disposed of in a sanitary manner		X			
25.	Absence of functional washing facilities, tissue, soap, hot water, hand drying facilities, or signs directing employees to wash hands			X		
26.	Insufficient number of toilets as defined by USDA requirements	X				

Premises		Minor	Major	Ser	Crit*	Check If OK
CONSTRUCTION AND REPAIR OF EQUIPMENT, CONTAINERS AND UTENSILS						
27.	Product contact surfaces of all equipment, containers, and utensils not constructed from suitable, impervious, non-toxic corrosion-resistant material, with the exclusion of the re-use of wooden boxes holding round or gutted fish until appropriate research is concluded			**X**		
28.	Design, construction, or location of equipment, containers, and utensils is such that it demonstrably contributes to contamination and cannot be cleaned nor effectively sanitized, with the exclusion of the re-use of wooden boxes holding round or gutted fish until appropriate research is concluded				X	
29.	Equipment, containers, or utensils not in good repair	X				
30.	No demonstrated monitoring program to remove used or abused containers, utensils, and equipment	X				

Premises	Minor	Major	Ser	Crit*	Check If OK
CLEANING AND SANITIZING					
31. Equipmcnt, utensils and containers not cleaned and sanitized before use			X		
32. Cleaning methods do not preclude product contamination			X		
33. Rooms and areas used for receiving, processing, and storing raw materials and finished product not maintained in a clean and sanitary manner		X			
34. Absence of effective in-plant sanitation program			X		
35. Sanitation control of finished product not sufficient to protect the product from contamination			X		
36. Absence of accessible washing and/or hand-dipping stations		X			
INSECTS, BIRDS, ANIMALS					
37. Birds and animals not excluded from the plant			X		
38. Insect & rodent control measures not effective			X		
CHEMICALS					
39. Insecticides or rodenticides not used as prescribed by EPA or USDA		X			

Premises	Minor	Major	Ser	Crit*	Check If OK
40. Chemicals not employed by approved methods or handled and stored in an unsafe manner		X			
41. Chemicals, toxins, sanitizer, food additives not properly labeled or stored		X			
42. Unapproved chemicals and sanitizer used			X		
FROZEN, REFRIGERATED, DRY STORAGE FACILITIES					
43. Shelves, cabinets, dunnage, and/or other methods not used where necessary to inhibit contamination	X				
44. Storing methods do not minimize deterioration	X				
45. Storage facilities not clean, not sanitary, or not in good repair:					
a. Product packaging and ingredient storage		X			
b. Other storage		X			
46. Plant management does not have in effect measures to restrict people with known disease (i.e., cuts, boils, influenza, etc.) from contaminating product		X			

Premises		Minor	Major	Ser	Crit*	Check If OK
47.	Personnel Cleanliness- Personnel specified not maintaining a high degree of personal cleanliness and conforming to hygienic practices while on duty (e.g., lack of clean outer garments, hairnets, wearing jewelry (other than unadorned wedding bands), chewing gum, drinking coffee, using tobacco, eating at their work station, storage of personal belongings at work station)	X				
48.	Personnel Practices- Personnel not taking necessary precautions to minimize contamination of foods with microorganisms or foreign substances (e.g., gloves not in sanitary and good condition, touching face, hair, picking product off the floor, not washing hands)		X			
49.	Training of personnel in food hygiene is inadequate	X				
50.	Appropriate supervisors (e.g., production, line, quality control, etc.) not held accountable for the cleanliness compliance of their employees		X			

4. PRODUCT RECALL SYSTEM

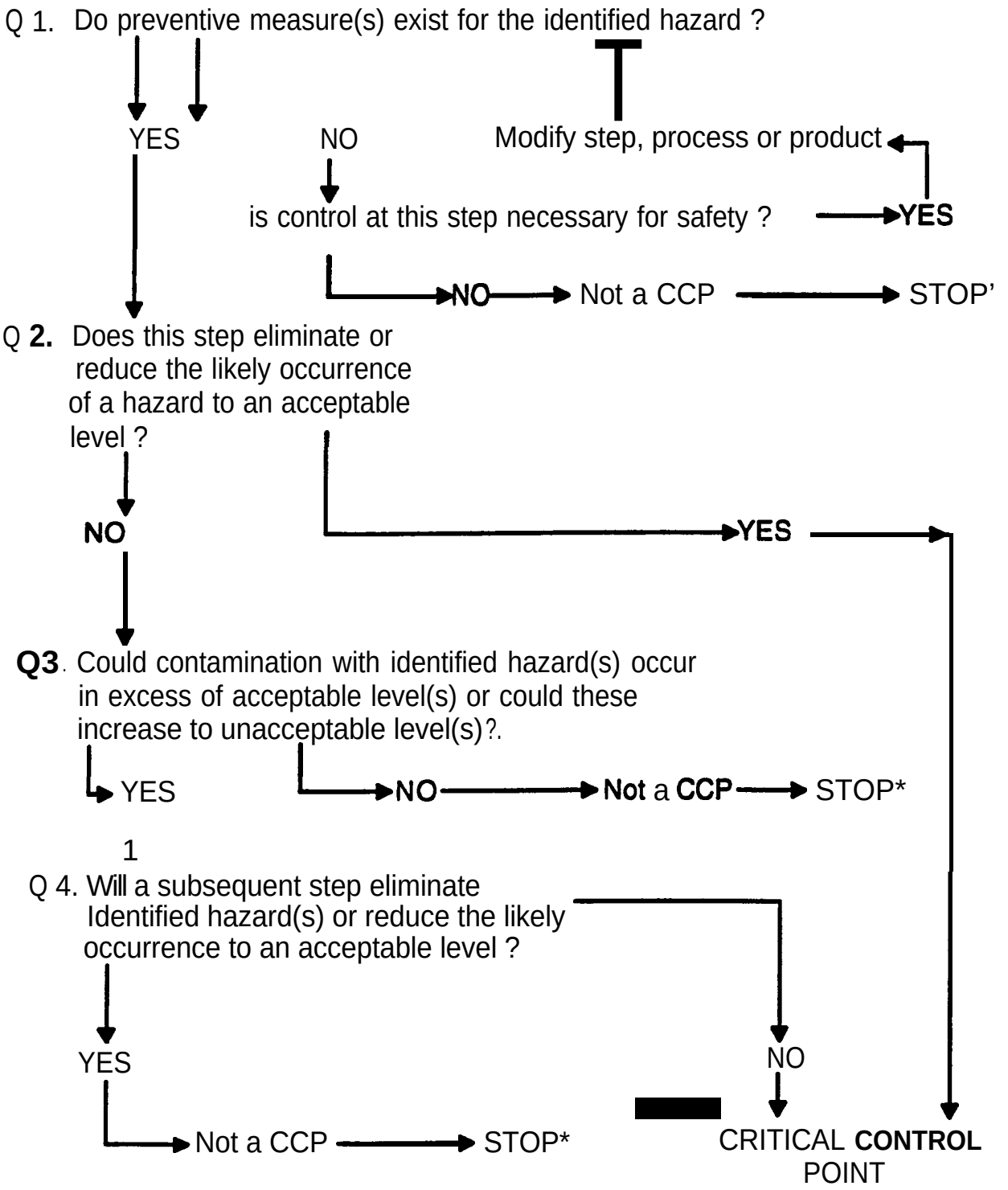
And finally, your HACCP plan will be required to include a suitable product recall system. Recall is an effective method of removing or correcting consumer products that are in violation of laws concerned with the safe manufacture of food products in the United States and with their distribution to either domestic or foreign markets. Recall is a voluntary action whereby manufacturers and distributors carry out their responsibility to protect the public from products that present a risk of injury or gross deception or are otherwise defective.

The current Food and Drug Administration's (FDA) enforcement policy on product recall is provided in Section 21 of the Code of Federal Regulations (CFR). It is likely that this policy would remain essentially unchanged under any future mandatory seafood surveillance program, regardless of the federal agency chosen to implement it.

In brief, a recall procedure starts with an evaluation by FDA scientists of the health hazard presented by a product being recalled or considered for recall. Next, a recall strategy is developed by FDA (and by the recalling firm for a firm-initiated recall) to suit the circumstances of the recall. A recall may be either an FDA-requested recall or a firm-initiated recall. In either case, it must address: 1) the level in the distribution chain to which the recall is to extend; 2) a public warning that the product being recalled presents a serious hazard to health; and 3) checks to verify that all appropriate consignees have received notification of the recall and have, in turn, taken appropriate action.

FDA suggests a firm take advance precautions against the disruptions of a recall. They are: 1) prepare and maintain a current written contingency plan for initiating a recall in accordance with the recommended CFR; 2) use sufficient coding of regulated products to make possible positive lot identification; and 3) maintain product distribution records to aid in locating the products that are being recalled.

Critical Control Point Decision Tree



. **PROCEED TO NEXT STEP** IN THE DESCRIBED PROCESS