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Survey Instruments for a Cost Study of HACCP in the Seafood Industry

by
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SURVEY INSTRUMENTS FOR A COST STUDY OF HACCP IN THE SEAFOOD INDUSTRY

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Abstract: The Hazard Analysis and Critical Control Points (HACCP) approach to assuring food safety was first mandated in the United States in 1995 for the seafood industry, with full implementation to take place by December, 1997. The survey instruments included in this Working Paper were developed as part of a cost analysis of the adoption of HACCP in the Seafood Industry. The purpose of the survey was to quantify the change in costs that average seafood companies experienced during the first year of HACCP adoption.

Survey Instruments for a Cost Study of HACCP in the Seafood Industry

Governments across the world are increasingly mandating the use of Hazard Analysis and Critical Control Points (HACCP) approaches to assuring food safety. In the United States, HACCP was first mandated in 1995 for the seafood industry, with full implementation to take place by December 1997. Since that time, HACCP has been mandated for the meat and poultry industries by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture and it is expected that FDA will eventually apply HACCP to all other food products.

The adoption of HACCP as a regulatory approach in the United States was based on an estimation of the program's benefits and costs. However, accurately estimating benefits and costs prior to implementation is difficult. As implementation occurs, better estimates should be possible based on actual experience.

The survey instruments included in this Working Paper were developed as part of a cost analysis of the adoption of HACCP in the Seafood Industry. The purpose of the survey was to quantify the change in costs that average seafood companies experienced during the first year of HACCP adoption. All costs were considered (sunk, on-going, etc.). Given the length and complexity of the information gathered, the survey was designed to be administered by personal interview. The survey instruments were developed specifically for the breaded fish industry. If used for other food products, some modifications would be required: (1) a model of the production process for the specific food product should be developed; (2) HACCP, and if applicable SSOP, plans specific to the food product should be developed; and (3) the section of the Discussion Guide that is specific to the CCPs should be modified to reflect those relevant to the food product.

These survey instruments draw on the previous work of the Research Triangle Institute (RTI) (Martin et al. 1993). Here we share the instruments with other researchers who are developing cost analyses of HACCP adoption. The Working Paper has three parts:

Part 1: Model of production practices in the breaded fish industry, the industry subsector analyzed in the study. This model is necessary for designing survey instruments that are specific enough to be used in interviewing breaded fish processing companies.

Part 2: HACCP Plan and Sanitation Standard Operating Procedures (SSOP): The HACCP survey instrument was based on the FDA's Fish and Fishery Products Hazard Control Guides. The survey is specific to the hazards presented by the product. It also is complex because HACCP is flexible, with each producer choosing its own method of complying with the regulation. For this reason, the theoretical HACCP plan has to be much longer and more detailed than plans often are in practice (e.g., 12 CCPs instead of the industry average of 5). The HACCP plan survey instrument enumerates all potential CCPs and suggests some controls, frequency, and corrective actions. For each CCP, it also asks whether the control was done before introducing HACCP or

was introduced because of HACCP implementation. In the latter case, it asks for any differences in the control procedure before and after HACCP implementation.

The SSOP survey instrument specifies some basic inspection procedures which a seafood company may implement in order to control its sanitation. For each procedure it also asks whether the control was done before introducing HACCP or was introduced because of HACCP implementation. In the latter case, it asks for any differences in the control procedure before and after HACCP implementation. The main references used in developing this instrument were the Current Good Manufacturing Practices (GMP) regulations and the RTI discussion guide (Martin et al. 1993).

Part 3: Seafood Processors Discussion Guide: This discussion guide asks for information on several issues including when and why the company implemented HACCP; the plant's production, size, sales, costs, number of employees, etc.; the design and development costs for the HACCP plan; the plant's process, CCPs, and sanitation procedures; the changes introduced due to HACCP implementation; and the estimated costs. For example, an additional 30 minutes of control for a Quality Assurance Manager might cost a company:

Time	30 min/day
Wages	$25/hr
Total Cost	(0.5 hrs/day) * ($25 /hr) = $12.50 /day

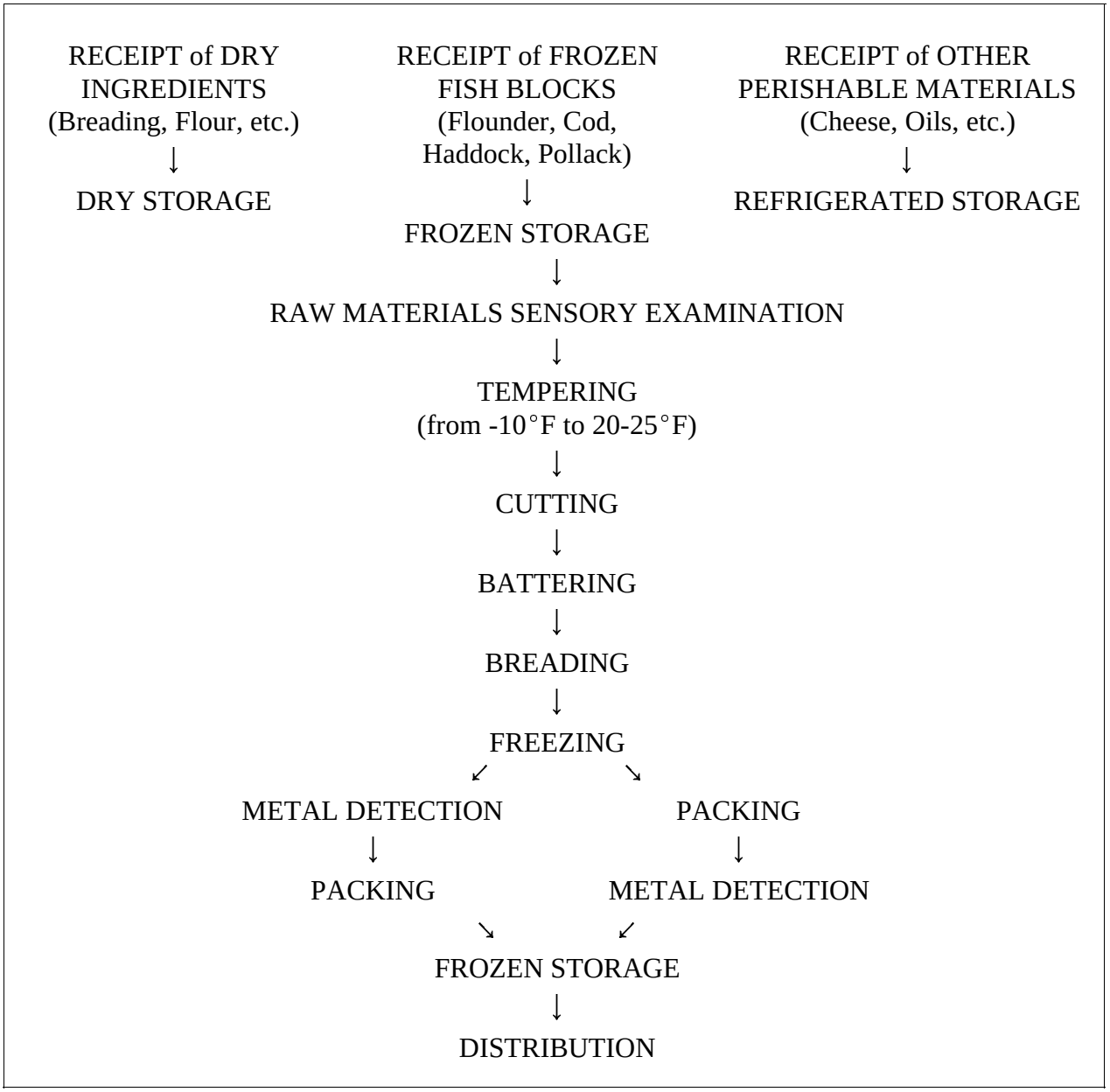
Finally, the interviewed person was asked to express his or her opinions about the regulation, its effectiveness, and its fairness.

References

Martin, S. A., B. J. Bowland, B. Calingaert, N. Dean, and D. Ward. Economic Analysis of HACCP Procedures for the Seafood Industry, Final Report, Volume I. Research Triangle Institute. November 1993.

Part 1

Model of Production Practices in the Breaded Fish Industry



Part 2

HACCP and SSOP Plans

Part A: Instructions

In the following pages you will find a list of *suggested* control procedures, broken down by CCP. Near each of them you will find two columns: a BEFORE one and a NOW one. They apply to the situation *before* the introduction of the HACCP regulation on fishery products and *after* it. For each control procedure, you should:

a. Mark the first box if you were applying (completely or just partially) the control procedure *before* the introduction of the regulation.

b. If you checked the first box, you should then write in the BEFORE space any comment about the way you performed the control procedure. Do not write anything if you performed the control procedure exactly in the way and at the frequency suggested in the text.

c. You should mark the second box if you are *now* applying (completely or just partially) the control procedure.

d. If you checked the second box, you should then write in the NOW space any comments about the way you perform the control procedure, in particular any change in the procedure that you had to introduce due to the regulation.

Ex. An example for a facility where, due to the regulation, the inspection of personnel was made more rigorous, is the following:

PREVENTIVE MEASURES	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: Inspection of personnel. Persons with open lesions, including boils, sores, infected wounds, or any abnormal potential source of microbiological contamination should be precluded from contact with food, food contact surfaces, or food packaging materials.	☐	*We spent 10 min/ day for inspection. No record keeping*	☐	*We now spend 20 min/day + record keeping*
CONTROL: Inspection of outer garments worn by personnel. Outer garments should be clean and suitable to the operation.	☐	*No record keeping*	☐	*Same as before + record keeping*

CONTROL: Inspection of gloves worn by personnel. Gloves used for food handling should be intact, impermeable, and clean.	☐	_____ _____ _____ _____	☐	*5 min/day* *+ record keeping* _____ _____
RECORDS: Once per day.	☐	_____ _____	☐	*total time for record keeping: 5 min/day.*

e. You should now quantify the cost (broken down in *monitoring* costs, *record keeping* costs, *materials*, *additional energy*, *equipment*, *corrective actions*, and *others*) of the CHANGES you introduced to be in compliance with the HACCP regulation.

- The cost of *monitoring* and *record keeping* activities can be supplied in labor hours per day, or in $/day, as you prefer.

- The cost of *additional energy and cleaning materials* should be estimated on a daily basis.

- *Equipment costs* may include the cost of new thermometers you had to purchase, new cooling equipment, etc. If you don't know the exact cost, please just provide a description of the equipment; you should also specify its expected years of life.

- *Corrective actions* are the indirect costs that more restrictive rules can cause. For example, if a tougher control of raw materials caused significant increases in rejections, and if this represents a profit loss, it should be written here.

- In the section *other costs*, please keep in mind indirect costs associated with changes in production volume, in processing steps, in transportation practices, etc., as well as indirect benefits such as reduced need for reprocessing, reduced product failures, etc., and comment on them.

- If you don't have the precise value for a particular cost section, it would be very useful if you could specify a confidence interval for it.

Every processing step listed may not apply to your plant. Please consider only those steps that are pertinent.

Part B: HACCP Plan

CCP		Hazards	Control
I	Receipt of Dry Materials	*Filth*	Visual Check
II	Receipt of Raw Materials	*Chemical Contamination*	Certification
		Filth	Visual Check
		Decomposition	Temp. Check
		Species Substitution	Certification
III	Refrigerated Storage	*Decomposition*	Temp. Check
IV	Raw Materials Examination	*Chemical Contamination*	Lab Analysis
		Filth	Visual Check
		Decomposition	Lab Analysis
		Misuse of Food Additives	Lab Analysis
V	Cutting	*Metal Inclusion*	Visual Check
VI	Batter Mix Storage-Recirculation	*Microbiological Growth*	Temp. Check
VII	Breading	*Metal Inclusion*	Visual Check
		Overbreading	Weight Check
VIII	Freezing	*Decomposition*	Temp. Check
		Filth	Visual Check
IX	Packing	*Short Weight*	Weight Check
X	Metal Detection	*Metal Inclusion*	Metal Detection
XI	Finished Product Storage	*Decomposition*	Temp. Check
XII	Finished Product Distribution	*Decomposition*	Temp. Check

I CCP: RECEIPT OF DRY INGREDIENTS

Hazard: Contamination of dry ingredients upon receipt with rodent, bird, or insect filth.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: Check a representative number of containers in each lot to find out if they are contaminated with filth. The search for evidence of animal infestation can be done by:	☐	_____	☐	_____
A. Black light examination for evidence of rodent activity.	☐	_____	☐	_____
B. Visual search for:				
- urine stains,	☐	_____	☐	_____
- gnawed bags,	☐	_____	☐	_____
- live or dead insects or animals,	☐	_____	☐	_____
- bird droppings,	☐	_____	☐	_____
- rodent excreta pellets.	☐	_____	☐	_____
FREQUENCY: A representative number of containers in each lot or batch.	☐	_____	☐	_____
CRITICAL LIMIT: Accept no dry ingredients with evidence of rodent, bird, or insect activity in the lot.	☐	_____	☐	_____
RECORDS: A record for each lot that shows the result of visual and black light examination of the containers.	☐	_____	☐	_____
CORRECTIVE ACTION:				
A. Reject the whole lot.	☐	_____	☐	_____
B. Remove the filth, process the raw material anyway and inspect the final product to be sure that no filth is present in it.	☐	_____	☐	_____

C. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

II CCP: RECEIPT OF RAW MATERIALS (fish)

A. Hazard: Contamination of raw materials upon receipt with pesticides, radioactivity, toxic elements, and industrial chemicals, derived from the harvest area.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: Find out the harvest area location for each lot from the fisher upon receipt.	☐	_____	☐	_____
FREQUENCY: Each lot or batch.	☐	_____	☐	_____
CRITICAL LIMIT: Accept no fish harvested from an area that is closed to fishing by foreign, federal, state or local authorities.	☐	_____	☐	_____
RECORDS: A record for each lot that shows the harvest area for the fish.	☐	_____	☐	_____
CORRECTIVE ACTION: Reject all shipment of raw materials.	☐	_____	☐	_____

II CCP: RECEIPT OF RAW MATERIALS (fish and other perishable materials)

B. Hazard: Contamination of raw materials upon receipt with filth, extraneous materials, and noxious substances.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: General visual examination of each lot of fish for evidence of filth or extraneous material (rodent, bird or insect contamination, trash, non-marine debris, etc.).	☐		☐	
FREQUENCY: Each lot or batch.	☐		☐	
CRITICAL LIMITS: No detectable visible filth or extraneous material that will not be removed during processing.	☐		☐	
RECORDS: A record for each lot that shows the result of visual examination.	☐		☐	
CORRECTIVE ACTION: A. Reject the whole lot.	☐		☐	
B. Remove the filth, process the raw material anyway and inspect the final product to be sure that no filth is present in it.	☐		☐	
C. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐		☐	

II CCP: RECEIPT OF RAW MATERIALS (fish and other perishable materials)

C. Hazard: Decomposition of raw materials.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Check the temperature of the lot at the time it is delivered.	☐	_____	☐	_____
B. Calibrate the thermometer used for checking product temperature.	☐	_____	☐	_____
FREQUENCY:				
A. Temp. check: each lot or batch.	☐	_____	☐	_____
B. Calibration: once a year.	☐	_____	☐	_____
CRITICAL LIMIT:				
A. Frozen fish should be at a temperature of 0°F (-17.8°C) or lower.	☐	_____	☐	_____
B. Other perishable materials should be at a temperature of 40°F (4.4°C) or lower.	☐	_____	☐	_____
C. The thermometer should agree within 1°C (±2°F) with the NBS.	☐	_____	☐	_____
RECORDS:				
A. A record of temperature for each lot or batch of frozen fish or any other perishable material.	☐	_____	☐	_____
B. Annually: thermometer calibration records that specify:				
- date;	☐	_____	☐	_____
- person performing the test;	☐	_____	☐	_____
- standard used;	☐	_____	☐	_____
- method used;	☐	_____	☐	_____
- results.	☐	_____	☐	_____

CORRECTIVE ACTION:

A. Reject each lot or batch that fails to meet the critical limit.	☐	_____	☐	_____
B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

II CCP: RECEIPT OF RAW MATERIALS (fish)

D. Hazard: Species substitution.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: Require a supplier's guarantee or certificate of authenticity.	☐	_____ _____	☐	_____ _____
FREQUENCY: Each lot.	☐	_____	☐	_____
RECORDS: Supplier's guarantee or certificate of authenticity.	☐	_____ _____	☐	_____ _____
CORRECTIVE ACTION: A. Reject incorrectly identified raw material fish.	☐	_____ _____	☐	_____ _____
B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____ _____ _____ _____ _____ _____	☐	_____ _____ _____ _____ _____ _____
VERIFICATION: Periodically (twice a year per supplier) subject raw material to lab examination as a confirmation.	☐	_____ _____ _____	☐	_____ _____ _____

III CCP: REFRIGERATED STORAGE (fish other perishable materials)

Hazard: Decomposition as a result of time temperature abuse.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. All frozen fish should be stored at a temperature < 0°F (-17.8°C).	☐		☐	
B. All perishable non-frozen raw materials should be stored at a temperature < 40°F (4.4°C).	☐		☐	
C. Freezing and refrigeration units should be equipped with:				
- a temperature indicating device (or a maximum indicating thermometer, or a high temperature alarm).	☐		☐	
- a temperature recording device (or a computerized storage of temperature data).	☐		☐	
D. The temperature indicating device should be calibrated at least once a year.	☐		☐	
E. The temperature recording device should be checked for accuracy at the beginning and end of each production day.	☐		☐	
CRITICAL LIMIT:				
A. The temperature should be:				
- < 40°F (4.4°C) for refrigeration	☐		☐	
- < 0°F (-17.8°C) for freezing.	☐		☐	
B. The temperature indicating device should agree within 2°F (1°C) of the standard thermometer.	☐		☐	

C. The temperature recording device should agree with and never be lower than the temperature indicating device. ☐ _____ ☐ _____

RECORDS:

A. Daily recorder thermometer charts, computerized temperature data storage, or temperature log. ☐ _____ ☐ _____

B. Annually: records of calibration for temperature indicating devices that specifies:
- date; ☐ _____ ☐ _____
- person performing the test; ☐ _____ ☐ _____
- standard used; ☐ _____ ☐ _____
- method used; ☐ _____ ☐ _____
- results. ☐ _____ ☐ _____

C. Daily: records of accuracy checks for the temperature recording devices that specifies:
- time and date; ☐ _____ ☐ _____
- person performing the check; ☐ _____ ☐ _____
- results; ☐ _____ ☐ _____
- corrective action taken. ☐ _____ ☐ _____

D. Records of organoleptic examination and/or total time exposure assessment, where critical limit deviation occurs. ☐ _____ ☐ _____

CORRECTIVE ACTION:

A. Where the refrigeration unit temperature has exceeded 40°F (4.4°C), the product should be subjected to sensory evaluation, with its disposition being determined by the results. ☐ _____ ☐ _____

B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified. ☐ _____ ☐ _____

IV CCP: RAW MATERIALS SENSORY EXAMINATION (fish)

A. Hazard: Contamination of raw materials upon receipt with pesticides, radioactivity, toxic elements, and industrial chemicals, derived from the harvest area.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: Periodically monitor the representative samples of fish for chemical contaminants.	☐	_____	☐	_____
FREQUENCY: Three times per supplier per year.	☐	_____	☐	_____
CRITICAL LIMIT: Pesticides and heavy metals.	☐	_____	☐	_____
RECORDS: Records of analytical results from the laboratory.	☐	_____	☐	_____
CORRECTIVE ACTION: A. Destroy all the products that fail to meet the CL.	☐	_____	☐	_____
B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

IV CCP: RAW MATERIALS EXAMINATION (fish)

B. Hazard: Contamination of raw materials upon receipt with filth, extraneous materials, and noxious substances.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
Check representative portions of each lot of fish to find out if they are contaminated with filth. The examination can be done by:	☐	_____	☐	_____
A. Visual examination for evidence of:				
- rodent, bird or insect contamination,	☐	_____	☐	_____
- trash,	☐	_____	☐	_____
- nonmarine debris.	☐	_____	☐	_____
B. Sensory examination for contaminants as fuel and oil (= organoleptic examination for off odors).	☐	_____	☐	_____
FREQUENCY:				
A representative portion of each lot or batch of fish.	☐	_____	☐	_____
CRITICAL LIMITS:				
A. No detectable visible filth or extraneous material that will not be removed during processing.	☐	_____	☐	_____
B. No noxious odors or odors of contamination.	☐	_____	☐	_____
RECORDS:				
A record for each lot that shows the result of visual and sensory examination.	☐	_____	☐	_____
CORRECTIVE ACTION:				
A. Reject the whole lot or the contaminated portion, if it is possible to part it from the rest.	☐	_____	☐	_____

B. Remove the filth, process the raw material anyway and inspect the final product to be sure that no filth is present in it. ☐ _____ ☐ _____

C. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified. ☐ _____ ☐ _____

IV CCP: RAW MATERIALS EXAMINATION (fish)

C. Hazard: Decomposition of raw materials.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Perform an external sensory examination of representative portions of each lot to find out if fish is decomposed.	☐	_____	☐	_____
B. Microbiological analysis of representative samples.	☐	_____	☐	_____
FREQUENCY:				
Representative portions of each lot.	☐	_____	☐	_____
CRITICAL LIMIT:				
A. The lot or batch is considered decomposed when:				
- 5% of the fish in the sample show class 3 decomposition over at least 25% of their areas;	☐	_____	☐	_____
- 20% of the fish in the sample show class 2 decomposition over at least 25% of their areas.	☐	_____	☐	_____
B. Reject if:				
- APC at 35°C > 100,000/g;	☐	_____	☐	_____
- presence of fecal coliforms.	☐	_____	☐	_____
RECORDS:				
A. Record for each lot or batch that shows the results of the sensory evaluation.	☐	_____	☐	_____
B. Records of microbiological analysis.	☐	_____	☐	_____

C. Records of corrective actions.	☐	_____	☐	_____
CORRECTIVE ACTION:				
A. Destroy, recall, or recondition product that fails to meet the CL.	☐	_____	☐	_____
B. Product that is to be reconditioned should be processed in a way that effectively removes the decomposed fish.	☐	_____	☐	_____
C. Representative portions of in process or finished products should then be collected and given a sensory examination to be sure that the CL is met.	☐	_____	☐	_____
D. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

IV CCP: RAW MATERIALS EXAMINATION (fish)

D. Hazard: Misuse of food additives.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: Chemical analysis of representative samples.	☐	_____	☐	_____
FREQUENCY: Representative portions of each lot.	☐	_____	☐	_____
CRITICAL LIMIT: The lot or batch is to be rejected when a lab analysis shows excessive use of tripoly-phosphate.	☐	_____	☐	_____
RECORDS:				
A. Records of lab analysis.	☐	_____	☐	_____
B. Records of corrective actions.	☐	_____	☐	_____
CORRECTIVE ACTION:				
A. Reject product that fails to meet the CL.	☐	_____	☐	_____
B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

V CCP: CUTTING

Hazard: Metal inclusion.

PREVENTIVE MEASURE	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Visually check the automatic filleting equipment for damage or missing parts.	☐	_____	☐	_____
B. The check should be done:				
- daily, before starting operations;	☐	_____	☐	_____
- every four hours;	☐	_____	☐	_____
- daily, at the end of operations;	☐	_____	☐	_____
- whenever there is an equipment malfunction that could increase the likelihood that metal could be introduced in the food.	☐	_____	☐	_____
CRITICAL LIMITS:				
No broken or missing metal parts from the filleting equipment.	☐	_____	☐	_____
RECORDS:				
Records of equipment inspection.	☐	_____	☐	_____
CORRECTIVE ACTIONS:				
A. When the visual check identifies a damage or a missing part in the automatic filleting equipment, the production should be stopped.	☐	_____	☐	_____
B. The product should be either:				
- destroyed,	☐	_____	☐	_____
- run through a metal detector.	☐	_____	☐	_____
C. The equipment should be adjusted or modified to reduce the risk of metal inclusion.	☐	_____	☐	_____

VI CCP: BATTER MIX STORAGE/RECIRCULATION

Hazard: *Staphylococcus aureus* toxin formation in batter mix.

CONTROL MEASURES	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Check the temperature of the batter at least every two hours.	☐	_____	☐	_____
B. The batter storage/recirculation tank should be equipped with:				
- a temperature indicating device (or a maximum indicating thermometer, or a high temperature alarm).	☐	_____	☐	_____
- a temperature recording device or a computerized storage of temperature data.	☐	_____	☐	_____
C. The temperature indicating device should be calibrated at least once a year.	☐	_____	☐	_____
D. The temperature recording device should be checked for accuracy at the beginning and at the end of each production day.	☐	_____	☐	_____
FREQUENCY:				
A. Control temperature of batter: every two hours.	☐	_____	☐	_____
B. Calibration: once a year.	☐	_____	☐	_____
C. Accuracy checks: at the beginning and at the end of each production day.	☐	_____	☐	_____
CRITICAL LIMIT:				
A. Batter mix temperature should not exceed:				

- 55°F (12.8°C) for more than twelve hours, cumulatively; ☐ _____ ☐ _____
- 70°F (21.1°C) for more than four hours, cumulatively. ☐ _____ ☐ _____

B. The temperature indicating device should agree within 2°F (1°C) of the standard thermometer. ☐ _____ ☐ _____

C. The temperature recording device should agree with and never be lower than the temperature indicating device. ☐ _____ ☐ _____

RECORDS:

A. Records that show:
- the time of the day when batter was added to the reservoir; ☐ _____ ☐ _____
- the time of the day when the reservoir was drained; ☐ _____ ☐ _____
- the temperature of the batter, taken at least every two hours, or recorder thermometer charts. ☐ _____ ☐ _____

B. Annually: record of calibration for temperature indicating devices that specifies:
- date; ☐ _____ ☐ _____
- person performing the test; ☐ _____ ☐ _____
- standard used; ☐ _____ ☐ _____
- method used; ☐ _____ ☐ _____
- results. ☐ _____ ☐ _____

C. Daily: records of accuracy checks for the temperature recording devices. ☐ _____ ☐ _____

CORRECTIVE ACTION:

A. Add ice to the batter storage/ recirculation tank. ☐ _____ ☐ _____

B. Adjust or repair the batter mix refrigeration equipment. ☐ _____ ☐ _____

C. The product involved in a CL deviation should be:
- destroyed; ☐ _____ ☐ _____
- set aside for further evaluation by qualified person. ☐ _____ ☐ _____

D. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified. ☐ _____ ☐ _____

VERIFICATION:
Microbiological analysis on representative samples. ☐ _____ ☐ _____

VII CCP: BREADING

A. Hazard: Metal inclusion during breading operation.

CONTROL MEASURES	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
Visually check the wire-mesh belts (used to convey product during breading operation) for damage or missing parts.	☐	_____	☐	_____
FREQUENCY:				
The check should be done:				
- daily, before starting operations;	☐	_____	☐	_____
- every four hours;	☐	_____	☐	_____
- daily, at the end of operations;	☐	_____	☐	_____
- whenever there is an equipment malfunction that could increase the likelihood that metal could be introduced in the food.	☐	_____	☐	_____
CRITICAL LIMITS:				
No broken or missing metal parts (ex. missing links in the metal belt) from the breading equipment.	☐	_____	☐	_____
RECORDS:				
Records of equipment inspection.	☐	_____	☐	_____
CORRECTIVE ACTIONS:				
A. When the visual check identifies a damage or a missing part in the breading equipment, the production should be stopped.	☐	_____	☐	_____
B. The product should be either:				
- destroyed,	☐	_____	☐	_____
- run through a metal detector.	☐	_____	☐	_____

VII CP: BREADING

B. Hazard: Overbreading.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Test the percentage of breading in representative samples of breaded fish.	☐	_____	☐	_____
B. Check the accuracy of scales used in the testing procedure.	☐	_____	☐	_____
FREQUENCY:				
A. A representative amount of breaded fish, from each breading machine, every hour.	☐	_____	☐	_____
B. Accuracy checks: once per day.	☐	_____	☐	_____
CRITICAL LIMIT:				
A. The product should contain at least 50% fish flesh.	☐	_____	☐	_____
B. The scales should be accurate to within one order of magnitude less than the last significant digit of the smallest quantity of product for which they will be used.	☐	_____	☐	_____
RECORDS:				
A. Records of breading percentage checks for each lot.	☐	_____	☐	_____
B. Scales accuracy check records.	☐	_____	☐	_____
CORRECTIVE ACTION:				
A. Lots that do not meet the QC check CL should be repackaged or relabeled.	☐	_____	☐	_____

B. The breading equipment should be replaced.	☐	_____	☐	_____
C. Scales that cannot be adjusted to meet the CL should be replaced.	☐	_____	☐	_____
D. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

VIII CCP: FREEZING

A. Hazard: Decomposition.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Check the temperature of representative samples of finished product.	☐	_____	☐	_____
B. Calibrate the thermometer used for checking product temperature.	☐	_____	☐	_____
FREQUENCY:				
A. Temp. check: representative samples.	☐	_____	☐	_____
B. Calibration: once a year.	☐	_____	☐	_____
CRITICAL LIMIT:				
A. The product should be at a temperature < 25°F (-3.9°C).	☐	_____	☐	_____
B. The thermometer should agree within 1°C (±2°F) with the NBS.	☐	_____	☐	_____
RECORDS:				
A. A record of temperature for each sample.	☐	_____	☐	_____
B. Annually: thermometer calibration records that specify:				
- date;	☐	_____	☐	_____
- person performing the test;	☐	_____	☐	_____
- standard used;	☐	_____	☐	_____
- method used;	☐	_____	☐	_____
- results.	☐	_____	☐	_____
C. Records of organoleptic examination, where critical limit deviation occurs.	☐	_____	☐	_____

CORRECTIVE ACTION:

A. When the product has exceeded 20°F (-3.9°C), it should be subjected to sensory evaluation, with its disposition being determined by the results.	☐	_____	☐	_____
B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

VIII CCP: FREEZING

B. Hazard: Filth.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL: Visual examination of samples of finished product for evidence of filth or extraneous material.	☐	_____ _____ _____	☐	_____ _____ _____
FREQUENCY: Representative samples of finished product.	☐	_____ _____	☐	_____ _____
CRITICAL LIMIT: No detectable visible filth or extraneous material.	☐	_____ _____	☐	_____ _____
RECORDS: Records that show the results of visual examination.	☐	_____ _____	☐	_____ _____
CORRECTIVE ACTION: A. The product involved in a CL deviation should be:				
- destroyed;	☐	_____	☐	_____
- set aside for further evaluation by qualified person.	☐	_____ _____	☐	_____ _____
- reprocessed in a way that no filth is present in it.	☐	_____ _____	☐	_____ _____
B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____ _____ _____ _____ _____ _____	☐	_____ _____ _____ _____ _____ _____

IX CP: PACKING

Hazard: Short weight.

PREVENTIVE MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Check-weigh each mechanically filled finished product package manually or electronically.	☐		☐	
B. Examine a representative sample of each lot for net weight.	☐		☐	
C. Check the accuracy of scales.	☐		☐	
FREQUENCY:				
A. For check-weight: each finished product package.	☐		☐	
B. For examining sample: a representative sample from each lot or batch.	☐		☐	
C. For checking scales: daily.	☐		☐	
CRITICAL LIMIT:				
A. Individual units should be rejected if they do not meet the declared weight. Allow no more than 1% short weight.	☐		☐	
B. The scales should be accurate to within one order of magnitude less than the last significant digit of the smallest quantity of product for which they will be used.	☐		☐	
RECORDS:				
A. Weight records for each lot or batch.	☐		☐	

B. Scales accuracy check records.	☐	_____	☐	_____
CORRECTIVE ACTION:				
A. Lots that do not meet the QC check CL should be repackaged or relabeled.	☐	_____ _____ _____	☐	_____ _____ _____
B. Scales that cannot be adjusted to meet the CL should be replaced.	☐	_____ _____	☐	_____ _____
C. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____ _____ _____ _____ _____ _____	☐	_____ _____ _____ _____ _____ _____

X CCP: METAL DETECTION

Hazard: Metal inclusion.

CONTROL MEASURES	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. All the product has to pass through metal detection equipment.	☐		☐	
B. Test the effectiveness of the device at start and end of each production day.	☐		☐	
FREQUENCY:				
A. For subjecting to metal detection: all the products.	☐		☐	
B. For testing effectiveness of the device: at start and end of each production day.	☐		☐	
CRITICAL LIMIT:				
No metal fragments of 0.125" (3 mm) or larger in any dimension.	☐		☐	
RECORDS:				
Records of daily device calibration test results and results after adjustments.	☐		☐	
CORRECTIVE ACTION:				
A. Rework or hold and evaluate any product in which the metal detector has detected metal fragments.	☐		☐	
B. Attempt to locate and correct the source of the fragments found in product.	☐		☐	

C. When the product cannot be passed through a properly functioning metal detector, it must be either:

- destroyed; ☐ _____ ☐ _____
- held until it can be run through a metal detector; ☐ _____ ☐ _____
- held until an inspection of the processing equipment excludes that there are any broken or missing parts. ☐ _____ ☐ _____

D. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified. ☐ _____ ☐ _____

XI CCP: FINISHED PRODUCT STORAGE

Hazard: Pathogen growth and toxin formation as a result of time temperature abuse.

CONTROL MEASURE 1	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Where refrigeration units are used to store perishable finished product, they should be equipped with either:				
- a temperature indicating device (or a maximum indicating thermometer , or a high temperature alarm).	☐	_____	☐	_____
- temperature recording device, or a computerized storage of temperature data.	☐	_____	☐	_____
B. The temperature indicating device should be calibrated at least once a year.	☐	_____	☐	_____
C. The temperature recording device should be checked for accuracy at the beginning and end of each production day.	☐	_____	☐	_____
CRITICAL LIMIT:				
A. The temperature of the refrigeration unit should be maintained at or below 0°F (−17.8°C).	☐	_____	☐	_____
B. The temperature indicating device should agree within 2°F (1°C) of the standard thermometer.	☐	_____	☐	_____
C. The temperature recording device should agree with and never be lower than the temperature indicating device.	☐	_____	☐	_____

RECORDS:

A. Daily recorder thermometer charts, computerized storage of temperature data or temperature log. ☐ _____ ☐ _____

B. Annually: record of calibration for temperature indicating devices that specifies:
- date; ☐ _____ ☐ _____
- person performing the test; ☐ _____ ☐ _____
- standard used; ☐ _____ ☐ _____
- method used; ☐ _____ ☐ _____
- results. ☐ _____ ☐ _____

C. Daily: records of accuracy checks for the temperature recording devices. ☐ _____ ☐ _____

D. Records of organoleptic examination and/or total time exposure assessment, where critical limit deviation occurs. ☐ _____ ☐ _____

CORRECTIVE ACTION:

A. Where the refrigeration unit temperature has exceeded 0°F (−17.8°C), the product should be subjected to sensory evaluation, with its disposition being determined by the results. ☐ _____ ☐ _____

B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified. ☐ _____ ☐ _____

XII CCP: FINISHED PRODUCT DISTRIBUTION

Hazard: Decomposition resulting from time temperature abuse during refrigerated finished product distribution.

CONTROL MEASURES	BEFORE		NOW	
	Used	Practice	Used	Practice
CONTROL:				
A. Control measures may include:				
- a temperature indicating device and temperature recording device;	☐	_____	☐	_____
- a maximum indicating thermometer;	☐	_____	☐	_____
- a high temperature alarm;	☐	_____	☐	_____
- temperature or ice checks during distribution;	☐	_____	☐	_____
- receiving checks for internal and ambient temperature or sufficiency of ice;	☐	_____	☐	_____
- standardized and validated icing procedure.	☐	_____	☐	_____
B. The temperature indicating device should be calibrated at least once a year.	☐	_____	☐	_____
C. The temperature recording device should be checked for accuracy at the beginning and end of each production day.	☐	_____	☐	_____
FREQUENCY:				
Each lot distributed.	☐	_____	☐	_____
CRITICAL LIMIT:				
A. Perishable products should be maintained at or below 0°F (–17.8°C) throughout distribution.	☐	_____	☐	_____
B. The temperature indicating device should agree within 2°F (1°C) of the standard thermometer.	☐	_____	☐	_____

C. The temperature recording device should agree with and never be lower than the temperature indicating device.	☐	_____	☐	_____
RECORDS:				
A. Records sufficient to document conformance to the critical limit.	☐	_____	☐	_____
B. Annually: record of calibration for temperature indicating devices, where applicable, that specify:				
- date;	☐	_____	☐	_____
- person performing the test;	☐	_____	☐	_____
- standard used;	☐	_____	☐	_____
- method used;	☐	_____	☐	_____
- results.	☐	_____	☐	_____
C. Daily: records of accuracy checks for temperature recording devices.	☐	_____	☐	_____
D. Records of organoleptic examination and/or total time exposure assessment, where critical limit deviation occurs.	☐	_____	☐	_____
CORRECTIVE ACTION:				
A. Where exposure at temperature > 25°F (–3.9°C) occurs, the product should be subjected to sensory evaluation, with its disposition being determined by the results.	☐	_____	☐	_____
B. Any critical limit deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified.	☐	_____	☐	_____

Part C: SSOP Plan

A. Hazard: Microbiological contamination and insanitation during processing

	CONTROL MEASURES	BEFORE		NOW	
		Used	Practice	Used	Practice
1.	CONTROL: Inspection of personnel. Persons with open lesions, including boils, sores, infected wounds, or any abnormal potential source of microbiological contamination should be precluded from contact with food, food contact surfaces, or food packaging materials.	☐	_____	☐	_____
	CONTROL: Inspection of outer garments worn by personnel. Outer garments should be clean and suitable to the operation.	☐	_____	☐	_____
	CONTROL: Inspection of gloves worn by personnel. Gloves used for food handling should be intact, impermeable, and clean.	☐	_____	☐	_____
	RECORDS: once per day.	☐	_____	☐	_____
2.	CONTROL: Inspection of all fixtures, ducts, pipes, and other surfaces for drip or condensate. Condensate should not be allowed to build up to fixtures, ducts, or pipes, where it may serve as a potential source of contamination.	☐	_____	☐	_____
	CONTROL: Inspection of all processing and storage areas for vermin infestation or ingress. There should be no evidence of vermin infestation or ingress.	☐	_____	☐	_____

	CONTROL: Inspection of sanitary conditions of ice storage area. Ice storage facilities should be maintained in sanitary condition.	☐	_____	☐	_____
	RECORDS: once per day.	☐	_____	☐	_____
3.	CONTROL: Inspection of all hand washing and toilet facilities. The hand washing and toilet facilities should be maintained in a sanitary condition. Hand cleaning preparations, and sanitary towel service or suitable drying devices should be present.	☐	_____	☐	_____
	RECORDS: at least one per day.	☐	_____	☐	_____
4.	CONTROL: Inspection of storage, handling, and labeling of lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, and other toxic agents. Toxic chemicals should be properly stored, handled, and labeled.	☐	_____	☐	_____
	RECORDS: once per day.	☐	_____	☐	_____
5.	CONTROL: Inspection of hand sanitizing facilities and sanitizer strength.	☐	_____	☐	_____
	CRITICAL LIMITS: Hand sanitizer strength should be maintained 100-200 ppm chlorine or 12.5-25 ppm iodine.	☐	_____	☐	_____
	RECORDS: every four hours.	☐	_____	☐	_____
6.	CONTROL: Inspection of all processing equipment, utensils, and contact surfaces; inspection of sanitizer strength.	☐	_____	☐	_____

CRITICAL LIMITS: All food contact surfaces should be thoroughly washed and sanitized at least every four hours. Sanitizer strength should be maintained 100-200 ppm chlorine, 100-200 ppm quaternary ammonium, or 12.5-25 ppm iodine.	☐	_____	☐	_____
		_____		_____
		_____		_____
		_____		_____
		_____		_____
		_____		_____
		_____		_____
RECORDS: at beginning of the day and after each cleaning and sanitizing, which should be every 4 hours.	☐	_____	☐	_____
		_____		_____
		_____		_____

B. Hazard: Microbiological cross-contamination during processing, and shipment.

	CONTROL MEASURES	BEFORE		NOW	
		Used	Practice	Used	Practice
1.	CONTROL: Utensils and food contact surfaces of equipment that come into contact with raw product, waste, or other insanitary objects should not contact cooked product or ice used on cooked product, without first being adequately cleaned and sanitized.	☐		☐	
	CONTROL: Employees that touch raw product, waste, or other insanitary objects should not touch cooked product, food contact surfaces, food packaging materials, or ice used on cooked product, without first washing and sanitizing their hands.	☐		☐	
	CONTROL: Ice used to cool cooked product must be made from potable water and handled so that it does not become the vehicle that transports pathogens to the product.	☐		☐	
	RECORDS: at start up and at least every four hours.	☐		☐	
2.	CONTROL: Sanitary zones should be established around areas in which cooked product is handled or stored. In such areas, objects and employees that have come in contact with waste, raw product, or other insanitary objects should be excluded.	☐		☐	
	CONTROL: Equipment, employees, and any material that must be brought into the sanitary zone should be in a condition that minimizes the risk of introduction of microorganisms.	☐		☐	

	CONTROL: Air handling systems should be designed to minimize the risk of airborne contamination into such sanitary zones and provide positive air pressure in such zones relative to the surrounding areas.	☐	_____	☐	_____
3.	CORRECTIVE ACTION: Instance of potential cross-contamination should be followed up by prompt employee training.	☐	_____	☐	_____
	CORRECTIVE ACTION: Any deviation should result in a timely assessment by management to determine whether the process or HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and appropriate follow up action.	☐	_____	☐	_____
	CORRECTIVE ACTION: Any specific lot or batch known to have been subjected to cross-contamination should be held for microbiological analysis or reprocessed.	☐	_____	☐	_____

Part 3

SEAFOOD PROCESSORS DISCUSSION GUIDE

Conducted by

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Interview date/time: _____

Plant name: _____

Plant location: _____

Names, titles, and telephone numbers of program employees attending the meeting:

Name	Title	Phone #

CONTENTS

INTRODUCTION

The purpose of this interview is to collect information on the costs associated with the implementation of a HACCP plan, in compliance with the HACCP regulation on fishery products which will become effective in December 1997.

This information will be used to give an overall idea of the costs incurred by the breaded finfish industry to comply with the new FDA requirements. It will also be compared with the predicted costs calculated by FDA in the regulatory impact analysis, to see how effectively costs were forecast.

The answers you provide in this interview will be confidential and will not be reported in a way that would directly identify you or your plant. In addition to this assurance, if there is any information that you consider especially sensitive, please indicate so.

Thank you for your participation.

PART A

GENERAL INFORMATION

This section asks for information on:

The Production

A1. What are the various breaded finfish finished products sold by this facility?

_____

_____

_____

_____

_____

_____

A2. What is the total amount in weight of breaded finfish produced, sold or shipped to other facilities for additional processing? _____ lbs or tons/year

What percentage of the total breaded finfish product is sold to:

%_____ *Wholesale domestic markets*: e.g., restaurants, grocery stores, hotels, distributors;

%_____ *Retail domestic markets*: e.g., products sold over the counter at the plant;

%_____ *Other domestic markets*: specify, e.g., shipped to other facilities for additional processing? _____

%_____ *Export markets*?

A3. Has production been affected by the changes you have had to introduce due to the HACCP regulation or do you expect it to be in the future?

_____

_____

_____

_____

_____

_____

Plant Size

A4. How many squared meters (or squared feet) is this plant? _____

A5. Is this facility part of a multi-facility corporation? If so, how many other facilities are there?

_____

A6. Has the plant size been affected by the HACCP regulation or do you expect it to be in the future (e.g., did you have to make major plant investments in response to the regulation)?

_____
_____
_____
_____

A7. How many hours per day, days per week, weeks per year does this plant operate? If there is a seasonal aspect to your business, please explain, and give start and end months for operation (by product if such differences exist).

_____
_____
_____
_____
_____

Sales

A8. Give an estimate of your annual total sales. $_____

A9. Give an estimate of your annual sales of breaded finfish products. $_____

Were your sales affected by the HACCP regulation or do you expect them to be in the future?

_____
_____
_____
_____

A10. What percentage of the total production of this plant is represented by breaded finfish?

_____ % of the total sales (in $).
_____ % of the total amount (in lb) produced.

Costs

A11. Give an estimate of your annual total costs. $_____

A12. What percentage of these costs is due to breaded finfish? _____ %

A13. Did the HACCP regulation influence your costs?

- □ Increase in costs of _____%
- □ Decrease in costs of _____%
- □ No change

Employees

A14. How many employees are there in this plant?

_____ Full time employees

_____ Half time employees

_____ Seasonal employees, with weeks/year_____

A15. What is your total labor cost? _____

A16. Did the HACCP regulation influence your labor costs? _____

Other

A17. Why did you decide to implement HACCP? _____

When did you start to implement it? _____

When did you complete it? _____

A18. How would you estimate your actual level of compliance with the HACCP regulation?

a. Completed

b. _____ % completed

What changes are still to be done?

_____

_____

_____

How much will they cost?

_____

_____

_____

PART B

DESIGN AND DEVELOPMENT COSTS OF A HACCP PLAN

B1. Who designed the HACCP plan (and the SSOP if included in the HACCP plan) for this facility?

a. An employee, with salary $_____; time spent: _____; total cost: $_____

b. A consultant; total cost $_____

B2. Complete Table 1 if you had any training expenses, due to the HACCP regulation (i.e., if any employee had to receive training for activities such as record keeping, monitoring, quality control, sanitation, etc.).

a. *Type* can be:

FT Full time employee;
HT Half time employee;
S Seasonal employee, with weeks/year_____
O Others, specify _____

b. *Salary* should be expressed on an hourly base.

c. *Training received* can be:

HACCP course;
monitoring;
record keeping;
other.

d. *Association* refers to the association which organizes the course (ex. NMFS, HACCP Alliance, etc.).

e. *Cost of training* will be the actual price of the course.

f. *Productivity Loss* will be (lost hours) X (salary).

g. *Other Costs* will include the travel and lodging expenses if the training was in another city, and any other expense, apart from the previous categories.

B3. Complete Table 2 if you had to hire new employees to be in compliance with the HACCP regulation.

a. *Type* can be:

FT	Full time employee;
HT	Half time employee;
S	Seasonal employee, with weeks/year_____
O	Others, specify _____

b. *Salary* and *Benefits* should be expressed on an hourly base.

c. *Search Cost* refers to the global cost of hiring a new employee (i.e., newspaper advertising, loss of time for interviews, etc.).

TABLE 1 Training Costs

Empl. Type and Salary	Training Received and Association	Productivity Loss	Cost of Training	Other

Total Training Costs _____

TABLE 2 New Employees

Duty	Type	Hours/Week	Salary	Benefits	Search Cost

Total New Employees Costs _____

PART C

IMPLEMENTATION AND ONGOING COSTS OF HACCP PLAN

C1. Describe the product:

a. Market or Latin name of the fishery component(s) of the product.

_____

b. Fully describe the finished product food.

_____

c. Describe the packaging type.

_____

C2. a. Identify the intended consumer or user of the product.

_____

_____

b. Identify how the product will be used by the end user or consumer.

_____

_____

C3. Develop a flow diagram of the steps involved in the production process.

What production procedures are utilized in this facility?

Please describe in broad terms the process flow of breaded fish at this plant:

- connect the dots (and draw additional arrows if necessary) on the chart to show the process flow of breaded finfish at this plant;
- * denotes a CCP of the process.


RECEIPT of DRY INGREDIENTS* (Breading, Flour, etc.)
DRY STORAGE
RECEIPT of FROZEN FISH BLOCKS* (Flounder, Cod, Haddock, Pollack)
FROZEN STORAGE
RECEIPT of OTHER PERISHABLE MATERIALS* (Cheese, Oils, etc.)
REFRIGERATED STORAGE*
RAW MATERIALS SENSORY EXAMINATION*
TEMPERING (from -10°F to 20-25°F)
CUTTING*
BATTERING*
BREADING*
FREEZING
METAL DETECTION*
PACKING*
PACKING*
METAL DETECTION*
FROZEN STORAGE*
DISTRIBUTION*

C4. Specify the hazards included in your HACCP plan.

CCP		Hazards	Control	Check
I	Receipt of Dry Materials	*Filth*	Visual Check	□
II	Receipt of Raw Materials	*Chemical Contamination*	Certification	□
		Filth	Visual Check	□
		Decomposition	Temp. Check	□
		Species Substitution	Certification	□
III	Refrigerated Storage	*Decomposition*	Temp. Check	□
IV	Raw Materials Examination	*Chemical Contamination*	Lab Analysis	□
		Filth	Visual Check	□
		Decomposition	Lab Analysis	□
		Misuse of Food Additives	Lab Analysis	□
V	Cutting	*Metal Inclusion*	Visual Check	□
VI	Batter Mix Storage-Recirculation	*Microbiological Growth* .	Temp. Check	□
VII	Breading	*Metal Inclusion*	Visual Check	□
		Overbreading	Weight Check	□
VIII	Freezing	*Decomposition*	Temp. Check	□
		Filth	Visual Check	□
IX	Packing	*Short Weight*	Weight Check	□
X	Metal Detection	*Metal Inclusion*	Metal Detection	□
XI	Finished Product Storage	*Decomposition*	Temp. Check	□
XII	Finished Product Distribution . .	*Decomposition*	Temp. Check	□

Total Implementation Costs

C5. Estimate your additional *equipment costs* (e.g. new computers, new thermometers, etc.), anything you had to purchase to be in compliance with the HACCP regulation. You should also specify for each item its expected years of life.

Equipment	Cost	Years of life

C6. Are you now doing any *lab analysis* which you were not doing before? If so, estimate your additional *lab analysis* costs.

What?	How often?	Who does it?	How much does it cost?

C7. Estimate your additional *monitoring costs*: How much time and money do you spend in addition to before on the monitoring process?

What do you monitor?	How long does it take?	Who does it?	How much does it cost?

C8. Estimate your additional *record keeping* costs: How much time and money do you spend in addition to before on the record keeping process?

Records	How long does it take?	Who does it?	How much does it cost?

C9. Estimate your additional *review of CCP records* costs: How much time and money do you spend in addition to before on the *file revision* process?

How often?	How long does it take?	Who does it?	How much does it cost?

C10. Estimate the cost of *revision of the HACCP plan*. How often do you do it?

How often?	Who?	How much does it cost?

C11. Does or did this facility participate in any inspection program (NMFS, USDC) or any other *validation* system? If so:

How much do you or did you pay per year to participate? $_____

_____

Do you plan to discontinue your participation? _____

_____

I **CCP:** **Receipt of Dry Materials**

Hazard: **Filth**

Control procedure: Visual examination of a representative number of containers in each lot for evidence of rodent, bird, or insect activity.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. *Others.* _____

II CCP: Receipt of Raw Materials (frozen fish)

a. Hazard: Chemical Contamination

Control procedure: Control of the harvest area.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How do you find out about closed harvest areas, how often? Is there a cost associated with this information? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

II CCP: Receipt of Raw Materials, Fish and Other Perishable Material

b. Hazard: Filth

Control procedure: General visual examination of each lot for evidence of rodent, bird, or insect activity, trash, nonmarine debris, etc.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

II CCP: Receipt of Raw Materials, Fish and Other Perishable Material

c. Hazard: Decomposition

Control procedure: - check temperature of each lot;
- calibrate thermometer.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

II CP: Receipt of Raw Materials (frozen fish)

d. Hazard: Species Substitution

Control procedure: - require supplier's guarantee or certificate of authenticity;
- lab examination twice a year.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

III CCP: **Refrigerated Storage (fish and other perishable materials)**

Hazard: **Decomposition**

Control procedure:
- check and record temperatures of freezers and refrigerators;
- calibrate temp. indicating devices once a year;
- check accuracy of temp. recording devices every day.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

IV CCP: Raw Materials Sensory Examination (fish)

a. Hazard: Chemical Contamination

Control procedure: Lab analysis of representative samples of fish for pesticides and heavy metals; three times per supplier per year.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs (including the loss of product, if significant). _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

IV CCP: Raw Materials Sensory Examination (fish)

b. Hazard: Filth

Control procedure: Visual and odor examination of a representative portion of fish in each lot for evidence of filth or fuel contamination.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs (including the loss of product, if significant). _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

IV CCP: Raw Materials Sensory Examination (fish)

c. Hazard: Decomposition

Control procedure: - sensory examination of fish for decomposition;
- microbiological analysis.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs (including the loss of product, if significant). _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

IV CCP: Raw Materials Sensory Examination (fish)

d. Hazard: Additives

Control procedure: Chemical analysis of representative samples.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs (including the loss of product, if significant). _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

V CCP: Cutting

Hazard: Metal Inclusion

Control procedure: Visually check the automatic filleting equipment for damage or missing parts.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

VI CCP: **Batter Mix Storage/Recirculation**

Hazard: ***Staphylococcus aureus* toxin formation in batter mix**

Control procedure:
- check the temperature of the batter at least every two hours;
- check time when the batter is changed;
- calibrate temp. indicating devices once a year;
- check accuracy of temp. recording devices every day;
- verification: microbiological analysis on representative samples.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs (including the loss of product, if significant). _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

VII CCP: Breading

a. Hazard: Metal Inclusion

Control procedure: Visually check the wire-mesh belts (used to convey product during breading operation) for damage or missing parts.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

VII CCP: Breading

b. Hazard: Overbreading

Control procedure:
- test the percentage of breading in representative samples of breaded fish;
- check the accuracy of scales used in the testing procedure.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs (including the loss of product, if significant). _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

VIII CCP: Freezing

a. Hazard: Decomposition

Control procedure:
- check the temperature of representative samples of finished product;
- calibrate the thermometer.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs (including the loss of product, if significant). _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

VIII CCP: Freezing

b. Hazard: Filth

Control procedure: Visual examination of samples of finished product for filth.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

IX CP: Packing

Hazard: Short-weight

Control procedure:
- check-weigh each mechanically filled finished product package manually or electronically;
- examine a representative sample of each lot for net weight;
- check the accuracy of scales.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

X **CCP:** **Metal Detection**

Hazard: **Metal Inclusion**

Control procedure:
- all the product has to pass through metal detection;
- test the effectiveness of the device every day.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

XI CCP: Finished Product Storage

Hazard: Microbiological Growth from Time-Temperature Abuse

Control procedure:
- check and record temperatures of storage units;
- calibrate temp. indicating devices once a year;
- check accuracy of temp. recording devices every day.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

XII CCP: **Finished Product Distribution**

Hazard: **Decomposition**

Control procedure:
- check and record temperatures during distribution;
- calibrate temp. indicating devices once a year;
- check accuracy of temp. recording devices every day.

1. Additional *equipment* costs. _____

2. Additional *lab analysis* costs. _____

3. Were you doing this *control* before, in the same way? If not, how did you change your control procedure? _____
How is the speed of the process affected by the changes you had to introduce? _____
Change in *monitoring* costs. _____

4. Change in *record keeping* costs. _____

5. Change in *record reviewing* costs. _____

6. Additional *verification* costs. _____

7. How often does a CL *deviation* occur? Does it occur more or less often than if you didn't have a HACCP plan? _____
How much does it cost to correct a CL deviation? _____
Estimate your annual *corrective actions* costs. _____

8. Others _____

PART D

IMPLEMENTATION COSTS OF ADDITIONAL GMP OR SANITATION CONTROL PROCEDURES

Design

D1. Did you implement a written Sanitation Standard Operating Procedure (SSOP)? _____

If you included it in the HACCP plan, please consider it as part of section B.

If you developed it separately from your HACCP plan, then who designed it:

a. an employee, with salary $_____; time spent: _____; total cost: $_____

b. a consultant; total cost $_____

Implementation

In addition to the development of a SSOP, did you incur any additional sanitation or GMP cost to meet the conditions required by the HACCP regulation? For example, are you now doing some steps in your sanitation control procedures that you were not doing before or were doing differently? If yes, please specify:

D2. Estimate your additional *equipment costs*. You should also specify for each item its expected years of life.

Equipment	Cost	Years of life

D3. Estimate your additional *energy* costs. _____

_____

D4. Estimate your additional *cleaning material* costs. _____

_____

D5. Estimate your additional *monitoring costs*: how much additional time and money do you spend on the monitoring process?

What do you monitor?	How long does it take?	Who does it?	How much does it cost?

D6. Do you keep records? On deviations or on everything? Estimate your additional *record keeping* costs: how much additional time and money do you spend on the record keeping process?

Records	How long does it take?	Who does it?	How much does it cost?

D7. Estimate your additional *review of SSOP records* costs: how much time and money do you spend more than before in the *file revision* process?

How often?	How long does it take?	Who does it?	How much does it cost?

D8. Estimate the cost of *revision of the SSOP plan* (if not included in the HACCP plan). How often do you do it?

How often?	Who does it?	How much does it cost?

D9. Estimate any indirect effect (positive or negative) that this change in sanitation or GMP procedure may have caused in the production:

positive indirect effects (i.e. less frequent rejection of the product, etc.) _____

negative indirect effects (i.e. slower production, etc.) _____

D10. Did you have any additional expenses (i.e. *pest control, maintenance*, etc.) that were not covered in the previous section? If yes, what type and how much did they cost?

Additional procedure	Cost

PART E

ADDITIONAL COSTS AND COMMENTS

E1. Did you have to make any capital investment (e.g., build new plant sections) to be in compliance with the HACCP regulation? If yes, what was it and how much did it cost?

Type of Investment	Total Expenses
_____	$_____
_____	$_____
_____	$_____
_____	$_____
_____	$_____
_____	$_____

E2. Did you have any other source of expenses that was not covered in the previous sections? If yes, what was it and how much did it cost?

Additional Cost	Total Expenses
_____	$_____
_____	$_____
_____	$_____
_____	$_____
_____	$_____
_____	$_____
TOTAL ADDITIONAL COSTS	$_____

E3. COMMENTS

What do you think of the HACCP regulation? _____

What do you think of its effectiveness in fighting foodborne disease? _____

In your opinion, could the same result be achieved at a lower cost for producers? How? _

What do you think of the fairness of this regulation; i.e. will the costs be equally shared between producers and consumers? _____

In your opinion, will this regulation have any effect on the market price of breaded fish? _

In your opinion, will this regulation have any effect on the consumers' demand for breaded fish?

E4. Comments on specific questions

Q#	Comment
____	_____
____	_____
____	_____
____	_____
____	_____