

# **REPORT ON THE HACCP PROGRAM (HAZARD ANALYSIS CRITICAL CONTROL POINT)**

## **PREPARED BY:**

**AIMU Technical Services Committee**

### Introduction:

According to US government statistics, there are an estimated 114,000 incidents of seafood related illnesses each year, resulting in approximately 9,000 deaths. In an attempt to reduce this, the FDA proposed new rules in January of 1994, which after a period of public comment, became effective in October of 1995. The new rules require all seafood processors to implement a Hazard Analysis and Critical Control Point (HACCP) program. The program is designed to be more proactive than the end product sampling method, which is currently used by the FDA and USDA. Similar rules have also been recently released for meat and poultry processors.

HACCP is a food inspection program which was originally developed in the 1960's for the space program. Scientists needed to develop a way to make food safe for astronauts to eat in space. They established that the only way to have 100% assurance that the food was free of bacteria was to test 100% of it, but if you test 100% you have nothing left to eat. What was needed was a system that was the next best thing, and according to various sources in the meat and fish industry, HACCP was their answer.

HACCP programs have existed in the seafood, meat and poultry industry, since the 1970's, but only on a voluntary basis. Soon, this program will become mandatory. Depending on the size of a company, the firm may have up to three years to develop and implement a HACCP program. The larger companies are expected to comply with the regulations in one – two years and smaller companies, (which are defined as companies with annual revenues of less than \$2.5 million) will be given a longer period of time.

This paper is basically devoted to the seafood portion of the program, as it would appear that the meat and poultry program will be more domestic than imported. Either way, it is essentially the same program, with applications for two industries.

### General Information:

Presently, there are approximately 45 seafood processing companies in the HACCP program; however, this is changing. This was a strictly voluntary program, similar to the ISO9000 program used in Europe, and working within Food and Drug Administration (FDA) regulations. However, it is apparently now being made mandatory, with regulations issued December 18, 1995 and becoming effective December 18, 1997. It will be run by the National Marine Fisheries Service (NMFS) and will cover all "processors." This includes domestic processors and foreign processors who export to the U.S., exempting fishing vessels, common carriers and

retail sellers. Here, it should be noted that some large fishing vessels also have processing capabilities. Any processing vessels, with processing capabilities are to be included under the program.

The Food Safety Inspection Service (FSIS) is responsible for the administration of the HACCP program for the meat and poultry industry.

This particular program was founded in July of 1992, with the principles of the HACCP policy, having already been adopted by several countries, including Canada, Iceland, and Thailand.

#### Over View of the HACCP Program:

What is HACCP? HACCP is a tool that provides a systematic approach to the production of safe, wholesome and properly labeled food. Basically, a flow chart is used to illustrate the production process. The flow chart identifies the sites of possible contamination and, hence, the control points and the critical control points. There are seven steps to a HACCP, which are recapped on the attached sheet. An example of what these might look like would be as follows.

- Analyze hazards. Potential hazards associated with a food are identified. The hazard could be biological, such as a microbe; chemical, such as mercury; or physical, such as ground glass or metal.
- Identify critical control points. These are points in a food's production, from its raw state through processing and shipping to consumption by the consumer, at which the potential hazard can be controlled. Examples would be cooking, chilling, handling, cleaning, and storage.
- Establish preventive measures with critical limits for each control point. For a cooked food, this might include setting the minimum cooking temperature and time required to ensure a safe product. The temperature and time then become the critical limits.
- Establish procedures to monitor the control points. These procedures might include determining how and by whom cooking time and temperature should be monitored.
- Establish corrective actions to be taken when monitoring shows that a critical limit has not been met yet. For example, reprocessing or disposing of food if the minimum cooking temperature is not met.
- Establish effective record keeping to document the HACCP system.
- Establish procedures to document that the system is working consistently; such as, time and temperature recording devices to verify that a cooking unit is working properly.

Attached to the report is a process flow chart of a HACCP program, for the fictional, "Floppy Fish Company,"

How Does the Certification Process Work? Each processor must conduct a hazard analysis to determine whether they have food safety hazards, which they must control. Then, they must develop the implement a HACCP program. It should be noted that they must reassess, whenever a significant change occurs.

NMFS policy is to encourage and assist interested parties in the development and implementation of HACCP based inspection systems. In this respect, the NMFS' purpose is to provide guidance for the development of a plan, which will meet the agency's requirements, and to establish procedures for use by inspectors to insure uniformity in the various systems.

The interested companies must submit the plans to NMFS, following the guidelines that have been developed by the agency. The plans must flow chart the entire process, starting from the time of receipt of the product until packaging. The temperatures, handling procedures, etc. must be developed, identifying the critical control points, which are then tested or monitored on a frequency established by the processor. In addition to the seven points of the HACCP process, the submission must also include:

- An organization chart, indicating the personnel responsible for the development, implementation, and maintenance of the HACCP program.
- Description of all fisheries products, which are covered under the HACCP based inspection program.
- A record keeping system for the plan, which must be maintained for at least six months beyond the shelf life of the product in question.
- Verification procedures for the HACCP plan.
- Sanitation standard and operating procedures.
- Consumer complaint procedures.
- Recall procedures.

After plan review and an on site systems audit, validation of the firm's HACCP program is given.

After the initial certification, processing establishments and seafood processing vessels are subject to unannounced, periodic systems audits. The frequency of these audits can vary, depending on the facility's rating. Also, the firms rating can be improved or lowered, depending on the number of consecutive successful audits. An overview of the proposed matrix for inspections and ratings is shown in the following table.

Seafood Processing Establishments:

Facility Rating	Systems Audit Frequency	Percentage of Lots to be Sampled	Qualifying Visits for Next Higher Level
Level I	Every 6 months	02%	N/A
Level II	Every 2 months	02%	3
Level III	Every month	04%	2
Level IV	Every 2 weeks	08%	2
*Level V	Daily	As necessary	N/A

*\*Firms at level V must submit a rehabilitation plan, and certification may be revoked, at the discretion of the NMFS.*

Seafood Processing Vessels:

Facility Rating	Systems Audit Frequency	Percentage of lots to be sampled	Qualifying Visits for Next Higher Level
Level I	Every 8 <sup>th</sup> trip	02%	N/A
Level II	Every 4 <sup>th</sup> trip	02%	2
Level III	Every 2 <sup>nd</sup> trip	04%	2
Level IV	Every trip	08%	2
*Level V	As necessary	As necessary	N/A

*\*Firms at level V must submit a rehabilitation plan, and certification may be revoked, at the discretion of the NMFS.*

In reference to the HACCP program for the meat and poultry, the US Department of Agriculture Food Safety and Inspection Services (FSIS) has issued a final rule, requiring domestic producers to have some type of HACCP program in place, within three years. The primary rationale being that the current inspection program does not target pathogenic micro-organisms, which represent the largest public health threat to consumers from meat and poultry. The current program also does not make those producers legally responsible for taking systematic preventive measure to reduce or eliminate the presence of pathogenic micro-organisms. Their proposal would require all establishments to develop and keep written records of sanitation standard operating procedures and call for the reduction of salmonella in all meat and poultry products by establishing interim targets and daily microbial testing.

HACCP Pros & Cons.:

Pros:

HACCP focuses heavily on problem prevention and problem solving, through proper monitoring and record-keeping by the industry. It is more proactive than reactive, when compared to traditional end product sampling quality control methods.

One of the primary economic benefits of HACCP is that it provides for reduced destructive sampling of the finished product, as compared to the end-product sampling required under traditional inspection systems, including a program run by NMFS called the Integrated Quality Assurance Program (IQAP).

The program will allow participants an opportunity to apply their existing quality control systems more efficiently and will allow for more efficient use of NMFS resources, as inspection frequencies can be varied depending on an individual facility's compliance history. Firms that demonstrate the ability to maintain consistent control will be inspected less frequently, and those that have demonstrated inconsistent quality control will be inspected more often.

The HACCP program is generic enough that it has potentially widespread application, going beyond seafood processors, such as in the retail and food service industry. Also, some companies in the passenger vessel industry are adapting the HACCP concept to apply their storage, handling and preparation of food.

Cons.:

One of the major criticisms of this program is that it focuses on the processing and packaging of seafood, but does not address the storage and handling of the catch aboard fishing vessels, unless the vessel also has a processing capability. The regulations do, however, put the onus on the buyers of seafood to ensure that the fish they are buying at the docks are fresh.

Similarly, the HACCP program does not do anything toward reducing illness from molluscan shellfish, as the program does not provide any additional resources to states for monitoring and classifying shellfish harvesting waters.

There is a serious concern whether the FDA will have a sufficient number of inspectors, who are adequately trained, in order to effectively audit the industry for compliance with the HACCP program.

Firms may perceive that they are on safer ground with the NMFS if they establish minimum acceptable controls that are more easily met, rather than more stringent controls that are beyond the minimum requirements and, thus are harder to meet.

Underwriting Concerns:

An underwriter that is considering providing coverage to a seafood shipper, or importer, should ascertain if the insured has a voluntary HACCP program and, if so, at what level.

Since each company develops its own HACCP program, underwriters should also consider that the settling of unreasonable control limits, within a HACCP program, could cause the product to be refused upon delivery, even if there is not any physical nor microbial damage. This may result in a claim being presented to underwriters.

For example, if the control limits that were set for temperature are unreasonably low, such as – 20F, this could cause problems upon receipt of a container of fish which had a slight fluctuation in temperature, during shipment. Even if the product was sound and sustained no physical nor microbial damage, it could be rejected by the consignee, based on the temperature fluctuation going beyond the control limits. This could be particularly problematic in a market where the product being received is now valued at less than current market prices, or when the market prices have dropped. Further, even if underwriters accept the claim, they would find that subrogation against the carrier would prove most difficult.

Similar problems could also occur with product not prepared under a HACCP program, which is rejected by consignee or the FDA.

## Conclusion:

The primary purpose of these regulations is to ensure that preventive controls are systematically applied in seafood as a matter of routine custom and usage, and in a way that can be verified by company management, as well as by regulatory authorities. In this respect, the success of this program will depend on the ability of the agencies to adequately monitor processors' HACCP programs through inspections. In turn, this will largely depend on the agencies' ability to convince congress to provide adequate funding for personnel and training.

The HACCP program represents a fundamental paradigm shift for the FDA's food inspection program. Supporters claim that it represents the first meaningful change in federal food inspection procedures in 90 years. The objective of this paper is to give underwriters an understanding of this new program, which undoubtedly will be part of our lives for a long time to come.

Attachments:

- Seven Steps of HACCP program
- Flow chart for Floppy Fish Co.

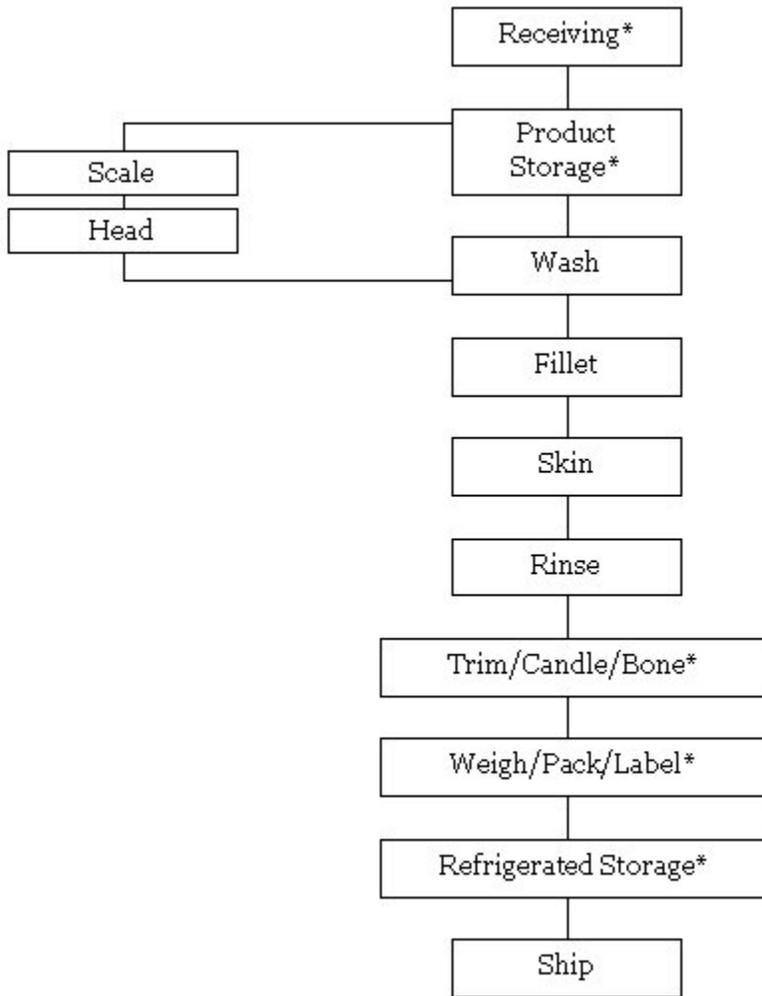
The objective of a HACCP Program is to control three main hazards:

Physical Objects, Chemical Residues, and Microbiological Risks.

Seven steps of HACCP Program:

1. Creation of a flow chart of the production process;
2. Identification of hazards and assessment of severity of these hazards and their risks;
3. Determination of critical control points at which identified hazards can be controlled;
4. Specification of criteria that indicate whether an operation is under control at the particular critical control points;
5. Establishment and implementation of procedures to monitor each critical control point to check that it is under control;
6. Taking whatever corrective action is necessary when monitoring results indicate that a particular critical point is not under control;
7. Verification to ensure the HACCP system is working properly. This verification will also be independently determined, through audits by NMFS, for seafoods, and by the FSIS, meat and poultry.

Floppy Fish Company  
Process Flow Chart



Note: \* denotes critical control points