

**PRINCIPLES OF A QUALITY ASSURANCE SYSTEM
FOR A FISH PROTEIN HYDROLYSATE
PROCESSING OPERATION**

**Prepared for:
Juneau Economic Development Council**

August 2004

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INTRODUCTION

Waste utilization is an important issue for the seafood industry. In some cases, upwards of 40% of the landed fish is discarded. This represents a significant economic impact and is only compounded by the costs and problems associated with waste disposal.

Unused fish by-product includes carcasses, frames, and heads as well as whole fish discarded because they are too dark/mature or damaged. These materials contain valuable protein and oils. While this material could be used as feed stock for a typical fish meal process by separating out the oil and drying the remaining protein, there is a way to enhance the value of the protein. Enzymatic hydrolysis yields a product that has a higher nutritional value because it is more easily digested when used as an agricultural, aquaculture, or human feed ingredient.

Compared to agricultural and aquaculture applications, products sold as human food ingredients have the greatest potential to realize maximal profit margins. For manufacturers of food ingredients commercially distributed in the US, it not only is beneficial, but also required by the US FDA for those manufacturers to examine processes, identify critical steps and establish a formal quality assurance system. Even if protein hydrolysate is not to be used for human consumption, the benefits of a quality assurance system will help attain the desired quality, consistency, and stability necessary to maximize the value of the product. Solid foundational standards from which to build a quality assurance program are found in the principles of Hazard Analysis and Critical Control Point and Defect Action Plans. Following is a description of these plans and how they apply to a fish hydrolysate process.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT & DEFECT ACTION PLAN

Hazard Analysis and Critical Control Point (HACCP), is a program initiated back in the 1960's as a joint effort of The Pillsbury Company and NASA to prevent, rather than react, to hazards in the food supply. Knowing that the astronauts would be millions of miles away from medical care, every precaution had to be taken to prevent any food related illnesses or accidents.

For many years food processors adopted HACCP plans voluntarily. However, as of January 2000, every food processor employing one or more people processing meat, poultry, or seafood is required to be HACCP compliant.

Strictly speaking, HACCP is used to assure food safety. Product quality and integrity issues are addressed through a Defect Action Plan (DAP). The procedure to create a DAP is much the same as the HACCP plan. However, instead of hazards, potential defects regarding wholesomeness and economic integrity are analyzed. While these two plans deal with the process to control product safety and quality, Sanitation Standard Operating Procedures (SSOPs) are created and implemented to establish and maintain control of the processing environment.

All together, the *Hazard Analysis and Critical Control Point* and *Defect Action Plans*, along with *Sanitation Standard Operating Procedures*, make up the overall *Quality Management Plan (QMP)*.

The first step in establishing a HACCP and DAP is to assemble a HACCP team. The team establishes product specifications, flowcharts the process and then develops the plan by following a seven step procedure described in the US federal regulations, Title 21 Section 123:

1. *Hazard and risk assessment*: identify significant hazards that could be introduced into the product. These include:
 - Biological – e.g.: microbial pathogens or spoilage organisms.
 - Physical – e.g.: glass or metal particles.
 - Chemical – e.g.: cleaners or pesticides.
2. *Determine Critical Control Points*: identify the step(s) in the process where these hazards can be controlled.
3. *Establish critical limits*: set acceptable/unacceptable limits at these CCPs.
4. *Monitor*: identify **what, how, when, and who** performs the monitoring. Provides evidence to assess whether a CCP is under control.
5. *Corrective Actions*: determine what to do when the results of monitoring at the CCP indicate a loss of control.
6. *Verify*: check for effectiveness of, and adherence to, the program.
7. *Recordkeeping*: not only documents that the plan is working, but also what was done (corrective action) when critical limits were exceeded.

The same steps are followed to create a DAP, only instead of hazards, product integrity and wholesomeness characteristics are examined. Characteristics include the proper type and quantity of ingredients.

In addition to the HACCP and DAP plans to control product safety and quality, SSOPs are established to describe the procedures, frequency, materials used, and recordkeeping requirements necessary to maintain a sanitary processing environment. Standards for the food processing industry define appropriate cleaners and sanitizers to use and their method of application.

Additional information and guidelines are found in the Code of Federal Regulations:

21 CFR 123 *Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products*

21 CFR 110 *Good Manufacturing Practices in Manufacture, Packing, or Holding Human Food*

and in the publication:

The National Seafood HACCP Alliance, *Sanitation Control Procedures for Processing Fish and Fishery Products*

Applying HACCP & DAP Principles to a Fish Hydrolysate Production Operation

Applying the HACCP and DAP principles to a fish hydrolyzing process, the critical control points are identified and listed in Table 1.

Table 1.

Critical Control Point	Reason for inclusion
1. <i>Fish raw material receiving-inspection.</i>	Enzymatic and bacteriological activity can rapidly decrease the content and quality of the protein and oil.
2. <i>Digestion</i>	Can result in excessive Total Volatile Nitrogen / poor product quality.
3. <i>Cooling & acidification</i>	Insufficient acid concentration could result in growth of pathogenic and spoilage organisms.
4. <i>Storage</i>	Rise in pH could result in growth of pathogenic and spoilage organisms.

The quality or freshness of the raw material limits the quality of protein hydrolysate. Good quality products cannot be made using poor quality raw material. Endogenous enzymes and bacteria can quickly degrade the raw material, significantly impacting the final product quality. The raw material must be continually inspected for signs of deterioration. The raw material must be either fresh or kept refrigerated until processed. Anything less is discarded.

Excessive digestion also results in poor, low nutritional value protein hydrolysate. The relationship between time, temperature, and enzyme concentration must be investigated to establish optimal conditions. Hydrolysis conditions will vary based upon the freshness, composition, quality,

and oil content of the incoming raw materials. A maximum time limit for hydrolysis is established, after which time the batch cannot be used and must be discarded.

While not necessarily a critical control point, the evaporation step is continually monitored using in-line density analyzers and verified by obtaining in-process samples, which are analyzed with laboratory instruments. Based on the findings, digest parameters as well as evaporation conditions are modified accordingly to attain the desired solids content. Analysis results and changes made are routinely recorded on batch records.

Likewise, the addition of an anti-oxidant and a yeast and mold inhibitor is not defined as a CCP but is controlled using standard operating procedures and recorded on batch records.

The last two CCPs involve pH control, which is critical to prevent the growth of pathogenic and spoilage organisms. Before hydrolysate can be packaged or put into storage, the pH must be adjusted below 4, with acid addition and thorough mixing. If volatile acids are used, the temperature of the hydrolysate must be reduced to a level below the flash point of the acid prior to acid addition. If this is not achieved, the acid can flash off, and consequently, the pH will rise to an undesirable level. The pH is monitored and controlled by using an in-line pH meter and verified by analyzing in-process samples using a laboratory pH meter.

Similarly, the pH of the stored product is routinely monitored by obtaining samples that are analyzed in the lab. Should the pH rise to a level that would no longer inhibit microbial growth, corrective action must be taken.

Sanitizing Standard Operating Procedures

Finally, Sanitizing Standard Operating Procedures (SSOPs) specify methods, frequency, materials used, and recordkeeping requirements addressing:

1. Safety of the water.
2. Condition and cleanliness of food contact surfaces.
3. Prevention of cross-contamination
4. Maintenance of hand washing/sanitizing facilities
5. Protection from adulteration with lubricants, fuel, pesticides, cleaning compounds.
6. Proper labeling, storage, and use of toxic compounds.
7. Control of employee health.
8. Control of pests.

Conjoined to the implementation of HACCP, DAP, and SSOP principles are proper recordkeeping and verification procedures. “If it wasn’t written, it wasn’t done...” Standard operating procedures must be linked with batch record forms completed by operators as they perform the procedures. In addition, systematic verification routines must be described and executed assuring procedures were followed and batch records properly completed. Finally, if there are deviations from the standard operating procedures, they must be documented along with any corrective actions taken.

The creation and implementation of practical *Hazard Analysis and Critical Control Point* and *Defect Action Plans*, coupled with effective *Sanitation Standard Operating Procedures* will assure the manufacture the highest probability of successfully producing the maximal and most consistent quality fish protein hydrolysate attainable with the available equipment and raw materials.