Seafood HACCP: What Have We Learned?

Lisa Weddig
National Fisheries Institute
Who is NFI?

- Nation’s leading advocacy organization for the seafood industry.
- NFI’s members represent every element of the industry
  - fishing vessels
  - processors
  - importers
  - restaurant and retail chains
- NFI and members support and promote sound public policy based on science.
“Seafood HACCP Regulation”

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

21 CFR 123

– Proposed: March 3, 1994
– Final rule: December 18, 1995
– Implementation: December 18, 1997
Who is Covered?

*Processor* means any person *engaged in* commercial, custom, or institutional *processing* of fish or fishery products, either in the United States or in a foreign country.
What is Covered?

*Processing* means, with respect to fish or fishery products: Handling, **storing**, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or **holding**.
What is **Not** Covered?

- Harvesting or **transporting** fish or fishery products, without otherwise engaging in processing.
- Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
- The operation of a retail establishment.
What is Required

• Conduct a hazard analysis
  – hazards that are reasonably likely to occur specific for each product and process

• Develop and implement a HACCP plan
  – ID critical control points, critical limits, monitoring activities, recordkeeping and verification procedures.

• Take corrective actions

• Monitor 8 key sanitation control procedures
<table>
<thead>
<tr>
<th>Parallels</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Seafood HACCP</strong></td>
</tr>
<tr>
<td>21 CFR 123.6</td>
</tr>
<tr>
<td>(a) <em>Hazard analysis.</em></td>
</tr>
<tr>
<td>(b) <em>The HACCP plan</em></td>
</tr>
<tr>
<td>21 CFR 123.12 – Special</td>
</tr>
<tr>
<td>Requirements for</td>
</tr>
<tr>
<td>Imported Products</td>
</tr>
</tbody>
</table>
The legislation transforms FDA’s approach to food safety from a system that far too often responds to outbreaks rather than prevents them. It does so by requiring food facilities to evaluate the hazards in their operations, implement and monitor effective measures to prevent contamination, and have a plan in place to take any corrective actions that are necessary.
The legislation transforms FDA’s approach to food safety from a system that far too often responds to outbreaks rather than prevents them. It does so by requiring food facilities to evaluate the hazards in their operations, implement and monitor effective measures to prevent contamination, and have a plan in place to take any corrective actions that are necessary.
WHAT DID WE LEARN?
BE PREPARED
Implementation takes time

- Industry – Processors, domestic and foreign
- FDA – Inspection system
- Industry - Importers
BE AWARE
Scope of the regulation

**Question:** Are public cold storage facilities exempt from the Seafood HACCP Regulation?

**Answer:** No, they are covered by the regulation. They are defined as "processors" for purposes of the regulation.

Processor is required to comply with the regulation regardless of who owns the product.
While HACCP plans are required only if the hazard analysis identifies a hazard that is reasonably likely to occur;

All processors are required to comply with the sanitation control provisions of the regulations
GUIDANCE IS MORE THAN JUST GUIDANCE
Fish and Fishery Products
Hazards and Controls Guidance

4th Edition - April 2011
This guidance represents the agency's current thinking on the hazards associated with fish and fishery products and appropriate controls for those hazards. ... An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.
Control Strategy Example 1 - Transit Control

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Transit Control." This example illustrates how a processor receiving pasteurized crabmeat can control pathogenic bacteria growth and toxin formation as a result of time and temperature abuse during transit. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. Pathogenic bacteria growth and toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, pathogen survival through cooking and pasteurization, and metal fragments).

Example Only
See Text for Full Recommendations

<table>
<thead>
<tr>
<th>Critical Control Point</th>
<th>Significant Hazard(s)</th>
<th>Critical Limits for Each Preventive Measure</th>
<th>Monitoring</th>
<th>Corrective Action(s)</th>
<th>Records</th>
<th>Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving pasteurized crabmeat</td>
<td>Pathogenic bacteria growth and toxin formation</td>
<td>All lots received are accompanied by truck records that show temperature was maintained at or below 40°F</td>
<td>Temperature of truck refrigerated compartment, Digital time and temperature data logger</td>
<td>Continuous, with visual review and evaluation of temperature monitoring records for each shipment, Receiving employee</td>
<td>Reject the shipment, Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation-handling practices have been improved</td>
<td>Data logger printout, Check accuracy of the temperature data logger upon receipt of each lot</td>
</tr>
</tbody>
</table>
LEARN FROM OTHERS
Your firm does not have written HACCP plans for the *receipt* and subsequent *refrigerated storage* of canned, pasteurized crabmeat and ready-to-eat seafood salads containing shrimp, tuna or surimi. In order to comply with 21 CFR 123.6(b), you must have written HACCP plans to control the potential food safety hazards of *Clostridium botulinum* toxin formation, histamine production and pathogen growth for these products. ... Further, no monitoring records were generated to document that these lots were not subjected to temperature abuse.
Your plan provides that you will take the temperature of "every shipment" at the "receiving" critical control point. However, this action provides no information related to the temperatures of the products during transit to your facility. FDA recommends that firms maintain a record of the transit temperatures for the entire duration of the transit time to the facility to ensure that proper temperatures are continuously maintained during transit.
Your significant violations were as follows:

1. You must implement the monitoring procedures and frequency that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b) and (c)(4). However, your firm did not

   a) follow the monitoring procedure(s) frequency of 24 hour continuous monitoring at the storage critical control point to control histamine formation listed in your two separate HACCP plans identified as "histamine producing fish".
HACCP IS NOT ALWAYS HACCP
Thank you