Hazard Analysis Worksheet

STEP #10: ***Understand the potential hazard.***

The introduction of pathogens after pasteurization can cause consumer illness. Pasteurization is a mild or moderate heat treatment, usually performed on fishery products after the product is placed in the finished product container. The purpose of pasteurization is to either: 1) make the product safe for an extended refrigerated shelf-life, which, in most cases, involves eliminating the spores of *Clostridium botulinum* type E and nonproteolytic B and F (the types of *C. botulinum* most commonly found in fish); or 2) eliminating or reducing the numbers of other target pathogens (e.g. *Listeria monocytogenes*, *Vibrio vulnificus*).

In addition to eliminating pathogens, the pasteurization process also greatly reduces the number of spoilage bacteria present in the fishery product. These bacteria normally restrict the growth of pathogens through competition. Rapid growth of pathogens that may be introduced after pasteurization is, therefore, a concern.

Chapter 17 covers control of the pasteurization step. This chapter covers control of recontamination after pasteurization.

• Control of pathogen introduction after pasteurization

There are two primary causes of recontamination after pasteurization. They are:

- Defective container closures;
- Contaminated container cooling water.

Poorly formed or defective container closures can increase the risk of pathogens entering the container, especially during container cooling performed in a water bath. Contaminated cooling water can enter through the container closure, especially when the closure is defective. Container closure can be controlled by adherence to seal guidelines that are provided by the container or sealing machine manufacturer. Control is accomplished through periodic seal inspection. Contamination of cooling water can be controlled by ensuring that a measurable residual of chlorine, or other approved water treatment chemical, is present in the cooling water, or by ensuring that ultraviolet (UV) treatment systems are operating properly.

• Strategies for controlling pathogen growth

There are a number of strategies for the control of pathogens in fish and fishery products. They include:

- Controlling the introduction of pathogens after the pasteurization process (covered in this chapter);

- Killing pathogens by cooking (covered in Chapter 16), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113);

- Controlling the level of acidity, pH, in the product (covered by the acidified foods regulations, 21 CFR 114 for shelf-stable acidified products; and for refrigerated acidified products in Chapter 13);

- Controlling the amount of moisture that is available for pathogen growth, water activity, in the product (covered in Chapter 14 for shelf-stable dried products; and for refrigerated products in Chapter 13);

- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);

- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in batter mix, in Chapter 15).

Continued

STEP #11: ***Determine if this potential hazard is significant.***

At each processing step determine whether "introduction of pathogens after pasteurization" is a significant hazard. The criteria are:

1. Is it reasonably likely that pathogens will be introduced at this processing step (consider post-pasteurization processing steps, only)?

It is reasonable to assume that, in the absence of controls, pathogens of various types may enter the finished product container during a water bath cooling process.

2. Can the introduction of pathogens after pasteurization be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12)

"Introduction of pathogens after pasteurization" should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

Step #10 discusses a number of pathogen control strategies. This section covers control of pathogen introduction that can occur after the pasteurization process. Preventive measures for the introduction of pathogens after pasteurization can include:

- Controlling container sealing;
- Controlling the residual of chlorine, or other approved water treatment chemical, in container cooling water;
- Controlling UV light intensity of bulbs used for treating container cooling water.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, for those fishery products which are currently pasteurized, it is unlikely that the intended use will affect the significance of the hazard.

STEP #12: ***Identify the critical control points (CCP).***

For each processing step where "introduction of pathogens after pasteurization" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

You should identify the container sealing step and the water bath container cooling step (where applicable) as the critical control points for this hazard. Therefore, you should answer "Yes" in Column 6 of the Hazard Analysis Worksheet for the container sealing and water bath container cooling steps. (Note: if you have not previously identified "pathogen introduction after pasteurization" as a significant hazard at the container sealing and water bath container cooling steps in Column 3 of the Hazard Analysis Worksheet, you should change the entries in Column 3 to "Yes").

This control approach is referred to as "Control Strategy Example 1" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: ***Set the critical limits (CL).***

At each processing step where "introduction of pathogens after pasteurization" is identified as a significant hazard on the HACCP Plan Form (e.g. container sealing and water bath container cooling) identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy example identified in Step #12.

• Control Strategy Example 1 - Control of recontamination

For container sealing:

CRITICAL LIMIT: Container or sealing machine manufacturer's seal guidelines.

For container cooling:

CRITICAL LIMIT: Measurable residual of chlorine, or other approved water treatment chemical, at the discharge point of the container cooling tank;
OR
Equipment manufacturer's UV light intensity guidelines.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: ***Establish monitoring procedures.***

For each processing step where "introduction of pathogens after pasteurization" is identified as a significant hazard on the HACCP Plan Form (e.g. container sealing and water bath container cooling), describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values of the feature you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control option discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

Continued

What Will Be Monitored?

• Control Strategy Example 1 - Control of recontamination

For container sealing:

WHAT: Container integrity

For container cooling:

WHAT: Residual chlorine, or other approved water treatment chemical, in the cooling water;
OR
Intensity of UV light.

How Will Monitoring Be Done?

• Control Strategy Example 1 - Control of recontamination

For container sealing:

HOW: Visual examination of containers (non-destructive):

- Recommendations for visual examinations that ensure a reliable hermetic seal should be obtained from the container or sealing machine manufacturer. They should include:
  - For double seamed metal and plastic cans: The external features of the double seam should be examined for gross closure defects, including: cutovers, seam sharpness, false seams, deadheading, droop, damage to the countersink wall indicating a broken chuck, cable cuts, and product overlapping the flange. In addition, visual examination should include examination of the entire container for product leakage or other obvious defects;

OR

  - For pouches: Visual examination should be sufficient to detect gross closure defects, including: cuts, fractures, non-bonding, malformation, puncture, abrasion, blister, contaminated seal, delamination, seal creep, wrinkle, flex cracks, crushed package or other obvious defects;

OR

  - For glass containers, visual examination should be sufficient to detect gross closure and glass defects, including: cap tilt, cocked cap, crushed lug, stripped cap, cut through, and chipped and cracked glass finish;

AND

Detailed examination of containers (destructive):

- Recommendations for seal evaluation measurements that ensure a reliable hermetic seal should be obtained from the container or sealing machine manufacturer. They should include:
  - For double seamed metal and plastic cans: The examination should include a teardown examination of the can. If the micrometer method is used, three (3) measurements, approximately 120˚ apart around the double seam, should be made. Measurements should include: cover hook, body hook, width, tightness, and thickness. If the optical method (seamscope or projector) is used, cuts should be made at least two (2) different locations, excluding the side seam juncture. Optical measurements should include body hook, overlap, tightness, and thickness;

OR

  - For pouches: The examination should include: burst testing, vacuum or bubble testing. It may also include: drop testing, peel testing (tensile strength), residual gas testing, electroconductivity testing, and dye testing;

OR

  - For glass containers: The examination should include cold water vacuum testing. Additional examinations can include: security values (lug-tension) for lug-type caps; and, pull-up (lug position) for lug-type, twist caps.

For container cooling:

HOW: Measure residual of chlorine, or other approved water treatment chemical, at the discharge point of the container cooling tank;
OR
UV light meter.

How Often Will Monitoring Be Done (Frequency)?

• Control Strategy Example 1 - Control of recontamination

For container sealing:

FREQUENCY: Visual examination of containers: At least one container from each sealing head at least every 30 minutes of sealing machine operation. At a minimum this should include visual examinations made at the beginning of production, and immediately following a jam in the sealing machine, or machine adjustment, repair, or prolonged shut down;
AND
Detailed examination of containers: At least one container from each sealing head at least every four hours of sealing machine operation. At a minimum this should include examinations made at the beginning of production and immediately following a jam in the sealing machine, or machine adjustment, repair, or prolonged shut down.

For container cooling:

FREQUENCY: For residual water treatment chemical: Sufficient frequency to assure control, but no less frequently than once every four hours of use;
OR
For UV light meter: at least daily.

Who Will Perform the Monitoring?

• Control Strategy Example 1 - Control of recontamination

For container sealing:

WHO: Monitoring may be performed by the sealing machine operator, a production supervisor, a member of the quality control staff, or any person who is trained and qualified to conduct container examinations.

For container cooling:

WHO: Monitoring may be performed by the equipment operator, a production supervisor, a member of the quality control staff or any other person who has an understanding of the testing procedure and the critical limits.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: ***Establish corrective action procedures.***

At each processing step in which "introduction of pathogens after pasteurization" is identified as a significant hazard in the HACCP Plan Form (e.g. container sealing and water bath container cooling), describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control option discussed in Step #12.

• Control Strategy Example 1 - Control of recontamination

For container sealing:

CORRECTIVE ACTION: Identify and correct the source of the defect after a CL deviation;
AND
Evaluate the seriousness of the defects, and, if necessary, identify, segregate, and hold the affected product for appropriate follow-up action. That may include, but is not limited to, 100% visual inspection of all affected containers to remove the defective containers;
OR
Repack the affected product.

Continued

For container cooling:

CORRECTIVE ACTION: If no measurable residual chlorine, or other approved water treatment chemical, is detected, add chlorine or adjust the chlorine metering system and recheck for chlorine residual;
OR
If UV intensity is inadequate, replace or clean the bulbs or shields.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: ***Establish a recordkeeping system.***

At each processing step in which "introduction of pathogens after pasteurization" is identified as a significant hazard and critical control point in the HACCP Plan Form (e.g. container sealing and water bath container cooling), list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control option discussed in Step #12.

• Control Strategy Example 1 - Control of recontamination

For container sealing:

RECORDS: Record of visual examination of containers;
AND
Record of detailed examination of containers.

For container cooling:

RECORDS: Record of residual chlorine, or other approved water treatment chemical, levels;
OR
Record of UV intensity testing.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: ***Establish verification procedures.***

At each processing step in which "introduction of pathogens after pasteurization" is identified as a significant hazard in the HACCP Plan Form (container sealing and water bath container cooling), establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "introduction of pathogens after pasteurization"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control option discussed in Step #12.

• Control Strategy Example 1 - Control of recontamination

For container sealing:

VERIFICATION: Obtain container seal guidelines from container or sealing machine manufacturer;
AND
Review monitoring and corrective action records within one week of preparation.

For container cooling:

VERIFICATION: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #18-1

Control Strategy Example 1 - Control of recontamination

This table is a an example of a portion of a HACCP plan relating to the control of the introduction of pathogens after pasteurization for a processor of pasteurized blue crab meat, packed in 301 X 408 size steel cans, using Control Strategy Example 1 - Control of recontamination. It is provided for illustrative purposes only. Pathogen recontamination after pasteurization may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, pathogen growth and toxin formation during processing, pathogen survival through pasteurization, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Container sealing	Pathogen introduction	• No visible cutovers, seam sharpness, false seams, deadheading, droop, damage to the countersink wall indicating a broken chuck, cable cuts, product overlapping the flange, product leakage, or other obvious defects.	• Container integrity	• Visual seam examination	• One can per seaming head every 1/2 hr, at startup, after jams, adjustments, repairs, and prolonged shutdowns	• Seamer operator	• Identify and correct the source of the defect, and • Evaluate the seriousness of the defect, and hold for further evaluation if necessary	• Visual seam examination record	• Review monitoring and corrective action records within one week of preparation • Can seam guide-lines from can manufacturer
		• Cover hook: .070" minimum; body hook .072-.088"; width: .125" maximum; thickness .052-.058"; tightness 80%.	• Container integrity	• Double seam teardown examination, using micrometer at 3 points on seam, 120°F apart.	• One can per seaming head every 4 hrs, at startup, after jams, adjustments, repairs, and prolonged shutdowns	• Seamer operator	• Same	• Double seam teardown record	• Same
Water bath container cooling	Pathogen introduction	Measurable residual chlorine	Residual chlorine in water bath	Rapid test	Every batch	Pasteurizer operator	Add chlorine and recheck for residual	Processing record	Review monitoring and corrective action records within one week of preparation

Note: The critical limits in this example are for illustrative purposes only, and are not related to any recommended process.

Notes: