

## Hazard Analysis Worksheet

### STEP #10: UNDERSTAND THE POTENTIAL HAZARD.

Survival of pathogens through the pasteurization process can cause illness to the consumer. Pasteurization is a mild or moderate heat treatment, usually performed on fishery products after the product is placed in the hermetically sealed 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) eliminate or reduce the numbers of other target pathogens (e.g. *Listeria monocytogenes*, *Vibrio vulnificus*).

Selection of the target pathogen is critical. If a target pathogen other than *C. botulinum* type E and nonproteolytic types B and F is selected, you must consider the potential that *C. botulinum* type E or nonproteolytic types B and F will survive the pasteurization process and grow under normal storage conditions or moderate abuse conditions. Ordinarily, the potential exists if the product is reduced oxygen packaged (e.g. vacuum packaged, modified atmosphere packaged), does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen, and is stored or distributed refrigerated (not frozen). For example, vacuum packaged lobster meat that is pasteurized to kill *L. monocytogenes* but not *C. botulinum* type E or nonproteolytic types B and F must be frozen to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F. Surveys of retail display cases and home refrigerators indicate that temperatures above the minimum growth temperature of *C. botulinum* type E and nonproteolytic types B and F (38°F [3.3°C]) are not uncommon. Therefore, refrigeration alone cannot be relied upon for control of the *C. botulinum* hazard.

For pasteurization processes that target nonproteolytic *C. botulinum*, generally a reduction of six orders of magnitude (six logarithms, e.g. from  $10^3$  to  $10^{-3}$ ) in the level of contamination is suitable. This is called a “6D” process. However, lower degrees of destruction may be acceptable if supported by a scientific study of the normal inoculum in the food. It is also possible that higher levels of destruction may be necessary in some foods, if there is an especially high normal inoculum. Table #A-4 provides 6D process times for a range of cooking temperatures, with *C. botulinum* type B (the most heat resistant form of nonproteolytic *C. botulinum*) as the target pathogen. The lethal rates and process times provided in the table may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential that naturally occurring substances, such as lysozyme, may enable the pathogen to more easily recover after heat damage.

Examples of properly pasteurized products are: blue crabmeat pasteurized to a cumulative lethality of  $F_{185^{\circ}\text{F}} (F_{85^{\circ}\text{C}}) = 31 \text{ min.}$ ,  $z=16^{\circ}\text{F} (9^{\circ}\text{C})$ ; surimi-based products pasteurized at an internal temperature of 194°F (90°C) for at least 10 minutes.

In some pasteurized surimi-based products, salt in combination with a milder pasteurization process in the finished product container work to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F. An example of a properly pasteurized surimi-based product in which 2.5% salt is present is one that has been pasteurized at an internal temperature of 185°F (85°C) for at least 15 minutes. This process may not be suitable for other types of products, because of the unique formulation and processing involved in the manufacture of surimi-based products.

Reduced oxygen packaged foods that are pasteurized to control nonproteolytic *C. botulinum*, but not proteolytic *C. botulinum*, and that do not contain barriers to its growth, must be refrigerated or frozen to control proteolytic *C. botulinum*. Control of

refrigeration is critical to the safety of these products. Further information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

In cases where *Listeria monocytogenes* is selected, a 6D process is also generally suitable. FDA's draft *L. monocytogenes* risk assessment indicates that approximately 7% of raw fish are contaminated with from 1 to 10<sup>3</sup> CFU/g, and that approximately 92% are contaminated at less than 1 CFU/g. Less than 1% of raw fish are contaminated at levels greater than 10<sup>3</sup> CFU/g, and none at levels greater than 10<sup>6</sup> CFU/g. FDA's action level for *L. monocytogenes* in ready-to-eat products, nondetectable, corresponds to a level of less than 1 CFU/25g. Table #A-3 provides 6D process times for a range of pasteurization temperatures, with *L. monocytogenes* as the target pathogen.

Lower degrees of destruction may be acceptable if supported by a scientific study of the normal innoculum in the food. It is also possible that higher levels of destruction may be necessary in some foods, if there is an especially high normal innoculum.

Products that are pasteurized in the finished product container are at risk for recontamination after pasteurization. Controls, such as container seal integrity and protection from contamination by cooling water, are critical to the safety of these products. They are covered in Chapter 18.

- **Control of pasteurization**

In order to ensure that the targeted pathogens are eliminated, it is critical that the pasteurization process be scientifically established. The pasteurization equipment must also be designed and operated so that every unit of product receives at least the established minimum process.

- **Strategies for controlling pathogen growth**

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

- Killing pathogens by pasteurization (covered in this chapter), cooking (covered in Chapter 16), or retorting (covered by the low acid canned foods regulation, 21 CFR 113);

- Controlling the introduction of pathogens after the pasteurization process (covered in Chapter 18);
- Controlling the level of acidity, pH, in the product (covered by the acidified foods regulation, 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 by drying (covered in Chapter);
- Controlling the amount of moisture that is available for pathogen growth, water activity, in the product by formulation (covered 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 hydrated batter mix, in Chapter 15).

### **STEP #11: DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.**

At each processing step, determine whether “pathogen survival through pasteurization” is a significant hazard. The criteria is:

1. Is it reasonably likely that unsafe levels of pathogens will be introduced at this processing step (do unsafe levels of pathogens come in with the raw material or will the process introduce unsafe levels of pathogens)?

It is reasonable to assume that pathogens of various types, including those listed in Table #A-1 (Appendix 4), will be present on raw fish and fishery products. They may only be present at low levels or only occasionally, but even such occurrences warrant consideration because of the potential for growth and toxin production.

Pathogens may also be introduced during processing, from the air, unclean hands, insanitary utensils and

equipment, unsafe water, and sewage. Well designed sanitation programs will minimize the introduction of pathogens. Such sanitation controls need not be part of a HACCP plan if they are monitored under your sanitation program (prerequisite program). In most cases it is not reasonable to assume that they will fully prevent the introduction of pathogens. For this reason, you should consider it reasonably likely that low numbers of pathogens will be present in the product, even after a cook step.

2. Can unsafe levels of pathogens, which were introduced at an earlier processing step, 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.)

“Pathogen survival through pasteurization” should also 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 the control of pathogens by pasteurization. Delivering a properly designed pasteurization process can be an effective preventive measure for the control pathogens. If this preventive measure is applied, list it in Column 5 of the Hazard Analysis Worksheet at the pasteurization step.

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 none of the criteria 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 and method of storage and distribution

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 most fishery products which are currently pasteurized, it is unlikely that the intended use will affect the significance of the hazard.

However, if your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. “Important, keep frozen until used, thaw under refrigeration immediately before use”), then formation of *C. botulinum* toxin may not be a significant hazard.

### **STEP #12: IDENTIFY THE CRITICAL CONTROL POINTS (CCP).**

For each processing step where “pathogen survival through 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 #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

You should identify the pasteurization processing step as the critical control point for this hazard. Therefore, you should answer “Yes” in Column 6 of the Hazard Analysis Worksheet at the pasteurization step, and “No” in that column at the other processing steps for which the hazard was identified as a significant hazard. (Note: if you have not previously identified “pathogen survival through pasteurization” as a significant hazard at the pasteurization step in Column 3 of the Hazard Analysis Worksheet, you should change the entry 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).

For the pasteurization step identify the minimum or maximum value to which a feature of the process must be controlled in order to control the hazard.

The CL will be the minimum or maximum parameters established by a scientific study (see Step #18 - Verification) as necessary for adequate pasteurization (e.g. time and temperature of the pasteurization process, container size). If you set a more restrictive CL (e.g. 2°F higher/2 minutes longer) you could 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 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 pasteurization step:

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION**

**Critical Limit:** The minimum or maximum values for the critical factors established by a scientific study. These may include length of the pasteurization cycle (speed of the belt for a continuous pasteurizer), temperature of the water bath, initial temperature of the product, container size (e.g. can dimensions, pouch thickness), and product formulation. Product internal temperatures during the pasteurization cycle are not ordinarily suitable CLs because of variability from container to container.

As described in Step #10, the critical limits must be established for the target pathogen. In most cases this will be *C. botulinum* type E and nonproteolytic types B and F. However, in certain cases the target patho-

gen may be a vegetative pathogen such as *L. monocytogenes* or *V. vulnificus*.

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

### STEP #15: ESTABLISH MONITORING PROCEDURES.

For the pasteurization step, 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 critical limit is being met. That is, the monitoring process should directly measure the feature for which you have established a critical limit.

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

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

### What Will Be Monitored?

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION**

**WHAT:** Critical factors established by a scientific study. These may include length of the pasteurization cycle (speed of the belt for a continuous pasteurizer), temperature of the water bath, initial temperature of the product, container

size (e.g. can dimensions, pouch thickness), and product formulation.

## How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

### For batch pasteurizers:

**How:** Monitor the pasteurization time and temperature with a temperature recording device or a digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the coldest temperature of the pasteurizing equipment (cold spot to be determined by study);

AND

The start and end of each pasteurization cycle should be determined visually;

AND

Monitor other critical factors with equipment appropriate to the critical factor (e.g. initial temperature with a dial thermometer or equivalent).

### For continuous pasteurizers:

**How:** Monitor the pasteurization temperature with a temperature recording device or a digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the coldest temperature of the pasteurizing equipment (cold spot to be determined by study);

AND

Monitor the time by measuring either:

- The RPM of the belt drive wheel, using a stop watch or tachometer;

OR

- The time necessary for a test unit or belt marking to pass through the tank, using a stop watch;

AND

Monitor other critical factors with equipment appropriate to the critical factor (e.g. initial temperature with a dial thermometer or equivalent).

## How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

### For batch pasteurizers:

**Frequency:** Monitor the pasteurization temperature continuously, with a visual check at least once per batch;

AND

The start and end of each pasteurization cycle should be determined visually;

AND

Monitor other critical factors with sufficient frequency to achieve control.

### For continuous pasteurizers:

**Frequency:** Monitor the pasteurization temperature continuously, with a visual check at least once per day;

AND

Monitor the time at least once per day, and whenever any changes in belt speed are made;

AND

Monitor other critical factors with sufficient frequency to achieve control.

## Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

### For batch pasteurizers:

**Who:** Monitoring of pasteurization temperature is performed by the equipment itself. However, a visual check should be made at least once at the end of each cycle in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the pasteurization time and other critical factors 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 equipment and the monitoring procedure.

### For continuous pasteurizers:

**Who:** Monitoring of pasteurization temperature is performed by the equipment itself. However, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the pasteurization time and other critical factors 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 equipment and the monitoring procedure.

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.**

For the pasteurization step, describe the procedures that you will use when your monitoring indicates that the critical limit 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 pasteurization.

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION**

**Corrective Action:** Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Adjust the steam supply to increase water bath temperature;

OR

- Extend the length of the pasteurization cycle to compensate for a temperature drop or a low initial temperature;

OR

- Process at a higher temperature to compensate for a low initial temperature;

OR

- Adjust the belt speed to increase the length of the pasteurization cycle;

AND

Take one of the following actions to the product involved in the critical limit deviation:

- Destroy the product;

OR

- Reprocess the product;

OR

- Segregate and hold the product for an evaluation of the adequacy of the pasteurization process. If the product has not received adequate pasteurization, the product should be destroyed, diverted to a non-food use, or reprocessed to eliminate potential pathogens of public health concern;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. divert improperly pasteurized crabmeat to a crabmeat canning operation);

OR

- Divert to a non-food use.

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

### **STEP #17: ESTABLISH A RECORDKEEPING SYSTEM.**

For the pasteurization step, 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 record-keeping system for pasteurization.

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION**

### For batch pasteurizers:

**Records:** Temperature recorder chart or a digital time/temperature data logger printout;

AND

Pasteurization log that indicates the start and end of each pasteurization cycle;

AND

Records that are appropriate for the other critical factors (e.g. pasteurization log that indicates the initial temperature).

**For continuous pasteurizers:**

**Records:** Temperature recorder chart or a digital time/temperature data logger printout;

AND

Pasteurization log that indicates the RPM of the belt drive wheel or the time necessary for a test unit or belt marking to pass through the tank;

AND

Records that are appropriate for the other critical factors (e.g. pasteurization log that indicates the initial temperature).

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

**STEP #18: ESTABLISH VERIFICATION PROCEDURES.**

For the pasteurization step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of pathogen survival through pasteurization; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for pasteurization.

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION**

**Verification:** Process establishment: The adequacy of the pasteurization process should be established by a scientific study. It should be designed to ensure an appropriate reduction in the numbers of the target pathogen. Expert knowledge of thermal process calculations and the dynamics of heat transfer in processing equipment is required to determine the target pathogen and to establish such a pasteurization process. Such knowledge can be obtained by

education or experience, or both. Establishing pasteurization processes requires access to suitable facilities and the application of recognized methods. The pasteurization equipment should be designed, operated, and maintained to deliver the established process to every unit of product. In some cases, thermal death time, heat penetration, temperature distribution and inoculated pack studies will be required to establish the minimum process. In other instances, existing literature or federal, state or local regulations which establish minimum processes or adequacy of equipment, are available. Characteristics of the process, product and/or equipment that affect the adequacy of the established minimum pasteurization process should be taken into consideration in the establishment of the process. A record of process establishment should be maintained;

AND

Check the accuracy of the temperature recording device or time/temperature data logger by comparing it to a mercury-in-glass thermometer (or equivalent instrument) at least once per day. The recording device should be adjusted to agree as nearly as possible, but never higher than the thermometer.

AND

Calibrate the mercury-in-glass thermometer (or equivalent instrument) at the pasteurization temperature against a known accurate standard thermometer (NIST-traceable). This should be done when the thermometer is installed and at least once per year after that. (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

AND

Calibrate other instruments as necessary to ensure their accuracy.

AND

Review monitoring, corrective action and verification records within one week of preparation.

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

TABLE #17-1

**Control Strategy Example 1 - Control of pasteurization**

This table is an example of a HACCP plan relating to the control of pasteurization for pasteurized, refrigerated blue crab meat, using Control Strategy Example 1 - Control of pasteurization. It is provided for illustrative purposes only. Pathogen survival through 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, recontamination after 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	Who	Who					
Batch Pasteurization	Pathogen survival	<ul style="list-style-type: none"> <li>Minimum initial product temperature 37°F</li> <li>Minimum length of pasteurization cycle 120 minutes</li> <li>Minimum water bath temperature 189°F</li> </ul>	<ul style="list-style-type: none"> <li>Initial temperature</li> <li>Time up to 189°F and time cycle ends</li> <li>Temperature of water bath</li> </ul>	<ul style="list-style-type: none"> <li>Dial thermometer</li> <li>Wall clock/temperature recording device</li> <li>Temperature recording device</li> </ul>	<ul style="list-style-type: none"> <li>Coldest can entering each batch</li> <li>Each batch</li> <li>Continuously, each batch. Visual check at end of batch.</li> </ul>	<ul style="list-style-type: none"> <li>Pasteurizer operator</li> <li>Pasteurizer operator</li> <li>Recorder thermometer with visual by pasteurizer operator</li> </ul>	<ul style="list-style-type: none"> <li>Extend process or elevate temperature to compensate for deviation from CL</li> <li>AND</li> <li>Segregate and hold for evaluation.</li> </ul>	<ul style="list-style-type: none"> <li>Pasteurization log</li> <li>Pasteurization log</li> <li>Recorder thermometer chart</li> </ul>	<ul style="list-style-type: none"> <li>Documentation of process establishment</li> <li>Review monitoring, verification, and corrective action records within one week of preparation</li> <li>Check the accuracy of the temperature recording device against the mercury-in-glass thermometer daily</li> <li>Calibrate the mercury-in-glass thermometer yearly</li> </ul>					

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