Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Pathogen survival through a cook step can cause consumer illness. Cooking is a relatively severe heat treatment, usually performed before the product is placed in the finished product container.

Generally, after cooking, fishery products are referred to as cooked, ready-to-eat. Examples of cooked, ready-to-eat products are: crab meat, lobster meat, crayfish meat, cooked shrimp, surimi-based analog products, seafood salads, seafood soups and sauces and hot-smoked fish.

• Goal of cooking — most products

One of the purposes of cooking products that will be aerobically packaged is to eliminate vegetative cells of pathogens (or reduce them to an acceptable level) that may have been introduced to the process by the raw materials or by processing that occurs before the cook step. Selection of the target pathogen is critical. Generally, *Listeria monocytogenes* is selected, because it is regarded as the most heat tolerant, foodborne pathogen that does not form spores. Cooking processes are not usually designed to eliminate spores of pathogens. Determining the degree of destruction of the target pathogen is also critical. Generally, a reduction of six orders of magnitude (six logarithms) in the level of contamination is suitable. This is called a "6D" process. FDA's draft *L. monocytogenes* risk assessment indicates that approximately 7% of raw fish are contaminated with from 1 to 10^3 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 10^3 CFU/g, and none at levels greater than 10^6 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 cooking 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.

• Goal of cooking — refrigerated, reduced oxygen packaged products

When cooking is performed immediately before reduced oxygen packaging (e.g. vacuum packaging, modified atmosphere packaging), for product that will be marketed under refrigeration, it may be necessary for the cooking process to be sufficient to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F. This is the case when the product does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen (e.g. many refrigerated, vacuum packaged hot-filled soups and sauces). Generally, a 6D process is suitable. However, 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. 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. An example of a product that is properly cooked to eliminate nonproteolytic *C. botulinum* is a soup or sauce that is pasteurized at an internal temperature of 194˚F (90˚C) for at least 10 minutes. The lethal rates and process times provided in the table may not be sufficient for the destruction of nonproteolytic *C. botulinum* in soups or sauces containing dungeness crabmeat, because of the potential that naturally occuring substances, such as lysozyme, may enable the pathogen to more easily recover after damage.

Continued

Reduced oxygen packaged soups or sauces that are cooked immediately before packaging 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.

Cooking processes that target nonproteolytic *C. botulinum* have much in common with pasteurization processes, which are discussed in Chapter 17. Like products that are pasteurized in the final container, products that are cooked and then placed in the final container also are at risk for recontamination after they are placed in the finished product container. 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. Additionally, because these products are cooked before they are packaged, they are at risk for recontamination between cooking and packaging. The risk of this recontamination must be minimized by filling the container in a continuous filling system while the product is still hot (i.e. hot filling), another critical step for the safety of these products. This control strategy is suitable for products that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It is not ordinarily suitable for products such as crabmeat, lobster meat, or crayfish meat, or other products that are handled between cooking and filling. Hot filling is also covered in Chapter 18.

• Control of cooking

Controlling pathogen survival through the cook step is accomplished by:

- Scientifically establishing a cooking process that will eliminate pathogens of public health concern or reduce their numbers to acceptable levels; and,

- Designing and operating the cooking equipment 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 cooking (covered in this chapter), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113);

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

- Controlling the amount of moisture that is available for pathogen growth, water activity, in the product by drying (covered in Chapter 14);

- 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);

- 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).

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

At each processing step, determine whether "pathogen survival through cooking" is a significant hazard. The criteria are:

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, as described in Step #10. Well designed sanitation programs will minimize the introduction of pathogens. Such sanitation controls need not be part of your 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. Remember, control of pathogen growth (e.g. after a cook step) is covered in Chapter 12.

2. Can unsafe levels of pathogens that were introduced at an earlier processing step be eliminated or reduced to an acceptable level at this processing step? (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 cooking" 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 during a cook step. Delivering a properly designed cooking process can be an effective preventive measure for the control of pathogens. If this preventive measure is applied list it in Column 5 of the Hazard Analysis Worksheet at the cooking 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 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 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 cooked, ready-to-eat fishery products, 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 POINT (CCP).*

For each processing step where "pathogen survival through cooking" 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.

The following guidance will also assist you in determining whether a processing step is a CCP for "pathogen survival through cooking":

Continued

Will the finished product be pasteurized in the final container?

1. If it will be, you may identify the pasteurization step as the CCP. In this case you will not need to identify the cook step as a CCP for the hazard of "pathogen survival through cooking."

Example:
A crabmeat processor cooks, picks, packs, and pasteurizes the crabmeat. The processor sets the critical control point for "pathogen survival through cooking" at the pasteurization step, and does not identify the cooking step as a critical control point for this hazard.

In this case, 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 though cooking" 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.") If you choose to follow this approach you should refer to Chapter 17, Pathogen survival through pasteurization, for further guidance. In particular, you should note that, if the cook step is not identified as a CCP, the pasteurization step must be effective in eliminating pathogens that may be present in an improperly cooked product.

2. If the product will not be pasteurized, you should identify the cooking step as the CCP. Therefore, you should answer "Yes" in Column 6 of the Hazard Analysis Worksheet at the cooking 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 though cooking" as a significant hazard at the cooking step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes").

This control approach will be 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 cook 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 cooking (e.g. time and temperature of the cooking process). 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 cook step:

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

Critical Limit: The minimum or maximum values for the critical factors established by a scientific study. These will likely include length of the cook cycle (speed of the belt for a continuous cooker), and temperature of the steam or water used for cooking (or visual observation of minutes at a boil). Other critical factors that affect the rate of heating of the product may also be established by the study. Product internal temperatures at the end of the cooking cycle are not ordinarily suitable CLs, because of variability from unit to unit.

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

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For the cook 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 cooking. 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 COOKING

What: Critical factors of the established cooking process. These may include:
- Time and temperature of the cooking process;

AND
- Other critical factors that affect the rate of heating of the product, as specified by the study, including, but not limited to, initial temperature and size of product.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

For batch cooking equipment:

How: Monitor the cooking 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 cooking equipment (cold spot to be determined by study). Where cooking is performed at the boiling point, visual observation of minutes at a boil may be an acceptable alternative;

AND

The start and end of each cooking 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).

Continued

For continuous cooking equipment:

How: Monitor the cooking 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 cooking equipment (cold spot to be determined by study). Due to the extended time of operation of such equipment, it is unlikely that visual observation of boiling will be an acceptable alternative, even if cooking is performed at the boiling point;

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 equipment, 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 COOKING

For batch cooking equipment:

Frequency: Monitor the cooking temperature continuously by the instrument itself, with a visual check of the monitoring instrument at least once per batch;

AND

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

AND

Monitor other critical factors with sufficient frequency to achieve control.

For continuous cooking equipment:

Frequency: Monitor the cooking temperature continuously by the instrument itself, with a visual check of the monitoring instrument 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 COOKING

For batch cooking equipment:

Who: Monitoring of cooking temperature is performed by the equipment itself, except in the case of visual observation of minutes at a boil. However, a visual check should be made of the recorded data 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 cooking time, visual observations of boiling, where applicable, and monitoring of 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 cooking equipment:

WHO: Monitoring of cooking 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 cooking time and of 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 cook 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 cooking:

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

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 the processing temperature;

OR
- Extend the length of the cooking cycle to compensate for a temperature drop;

OR
- Adjust the belt speed to increase the length of the cook 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 cooking process. If the product has not received an adequate cook, 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 cooked shrimp to a shrimp 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 cook 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 recordkeeping system for cooking.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

For batch cooking equipment:

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

OR
- Cooking log that indicates visual observation of boiling, where cooking is performed at the boiling point;

AND

Cooking log that indicates the start and end of each cooking cycle;

For continuous cooking equipment:

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

AND

Cooking 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.

Continued

For all cooking equipment:

Records: Records that are appropriate for the other critical factors (e.g. cooking 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 cook step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "pathogen survival through cooking"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for cooking.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

Verification: Process establishment: The adequacy of the cooking process should be established by a scientific study. It should be designed to ensure an appropriate reduction in the numbers of pathogens of public health concern. Selecting the target organism is critical. In most cases it will be a relatively heat tolerant vegetative pathogen, such as *Listeria monocytogenes*. However in some cases where outgrowth of spore-forming pathogens, such as *Clostridium perfringens* and *Bacillus cereus*, during the post-cook cooling step must be prevented by eliminating these pathogens during the cook (e.g., because cooling after cooking is not controlled – see Chapter 12) then they will be the target organisms. Additionally, when cooking is performed immediately before reduced oxygen packaging (e.g. vacuum packaging, modified atmosphere packaging), for product that will be marketed under refrigeration, it may be necessary for the cooking process to be sufficient to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F. This is the case when the product does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen (e.g. refrigerated, vacuum packaged hot-filled soups and sauces). Generally, a 6D process is suitable, regardless of the target pathogen. However, lower degrees of destruction may be acceptable if supported by a scientific study of the normal innoculum in the food. Tables #A-3 and A-4 provide 6D process times for a range of internal product temperatures, with *L. monocytogenes* and *C. botulinum* type B (the most heat resistant form of nonproteolytic *C. botulinum*) as the target pathogens, respectively. The values provided in Table #A-4 may not be sufficient for the destruction of nonproteolytic *C. botulinum* in products containing dungeness crabmeat, because of the potential protective effect of naturally occuring substances, such as lysozyme. Expert knowledge of thermal process calculations and the dynamics of heat transfer in processing equipment is required to establish such a cooking process. Such knowledge can be obtained by education or experience, or both. Establishing cooking processes requires access to suitable facilities and the application of recognized methods. The cooking 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 many cases, establishing the minimum process may be simplified by repetitively determining the process needed to reach an internal product temperature that will assure the inactivation of all vegetative pathogens of public health concern under the most difficult heating conditions likely to be encountered during processing. 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 ability of the established minimum cooking 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 digital 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 cooking 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 #16-1

Control Strategy Example 1 - Control of cooking

This table is an example of a portion of a HACCP plan relating to the control of pathogen survival through cooking for a processor of wild-caught cooked shrimp, using a continuous steam cooker, using Control Strategy Example 1 - Control of cooking. It is provided for illustrative purposes only. Pathogen survival through cooking 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, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Cooking	Pathogen survival	• Minimum time: 2.5 min.	• Length of the cook cycle	• Belt speed measurement with stopwatch	• Once per day and after any adjustment	• Cooker operator	• Extend process or elevate temperature to compensate for deviation from CL AND	• Cooking record	• Documentation of process establishment • Review monitoring, verification, and corrective action records within one week of preparation
		• Minimum temperature: 210°F (Note: To achieve a 6D reduction of *L. monocytogenes*)	• Temperature of steam in the cooker	• Digital time/ temperature data logger	• Continuous. Visual check once per day	• Cooker operator	• Segregate and hold for evaluation.	• Data logger printout	• Check the accuracy of the data logger against the mercury-in-glass thermometer daily • Calibrate the mercury-in-glass thermometer yearly
		• Maximum shrimp size: 40 count/pound	• Shrimp size	• Scale	• Hourly and after every raw material lot change or grader adjustment	• Grader operator		• Grading record	• Calibrate the scale monthly

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