**Time and Temperature Controls during Unrefrigerated Processing**

Pathogenic bacterial growth and toxin formation resulting from time and temperature abuse of food can cause consumer illness. Time and temperature abuse occurs when food is allowed to remain at temperatures favorable to pathogen growth for sufficient time to result in unsafe levels of pathogens or toxins in the food.

FDA's Fish and Fishery Products Hazards and Controls Guidance, or the Hazards Guide, lists common bacterial pathogens capable of causing foodborne illness. Species such as *Listeria monocytogenes, Escherichia coli and Salmonella* grow in a food and cause illness when an individual consumes the pathogenic cells in the food. Other bacteria such as *Clostridium botulinum, Bacillus cereus* and *Staphylococcus aureus,* grow in the food and produce toxins that cause illness when the toxins are consumed in the food

Pathogens can enter the process on raw materials. They can also be introduced into the foods during processing from the air, unclean hands, insanitary utensils and equipment, contaminated water or sewage, and through cross-contamination between raw and cooked product. Refrigeration at 40 degrees Fahrenheit or less will control the growth of most foodborne pathogens. Pathogenic growth occurs over a wide range of temperatures. In seafood products, bacterial pathogens can enter a phase of rapid growth when temperatures are between 50 and 135 degrees Fahrenheit. In this temperature range, the growth rate will increase as the temperature rises. Typically, pathogen growth between 40 and 50 degrees Fahrenheit is very slow and the time necessary for significant growth exceeds most processing practices. For additional useful information on pathogen growth and inactivation see Appendix 4 of the Hazards Guide.

Raw ready-to-eat products typically have spoilage bacteria present that can compete with bacterial pathogens. Cooking will reduce the number of spoilage bacteria and pathogens, allowing any pathogens that recontaminate the cooked product the opportunity to grow without competition. This recontamination can occur as a result of cross-contamination from significant handling after heating, but before cooling is completed, or when the product comes into contact with unclean equipment that was not heated along with it. Time and temperature abuse at one step alone might not result in an unsafe product. However, time and temperature abuse that occurs at successive processing steps, including transit and storage, when added all together, may be sufficient to result in unsafe product. So, the key to controlling pathogen growth is by managing the amount of cumulative time the product is exposed to unrefrigerated conditions in the range of 50 to 135 degrees Fahrenheit during processing.

In Chapter 12 of the Hazards Guide, FDA recommends 4 different time and temperature control strategies for controlling the hazard of pathogen growth and toxin formation. Control Strategy 1 is applied at receiving for products during transportation. Control Strategy 2 is for refrigerated storage and processing that occurs at 40 degrees Fahrenheit or below. Controls for receiving and storage are discussed in detail in another video called Secondary Processor Receiving and Storage Controls. Control Strategy 3 is for cooling after cooking where there is no significant handling during cooling and there is a need to control spore-forming pathogenic bacteria. Control Strategy 4 is for unrefrigerated processing that occurs at temperatures above 40 degrees Fahrenheit. In Control Strategy 4, the critical limits are separated into raw ready-to-eat and cooked ready-to-eat.

In this video, we'll focus mainly on Control Strategy 4 for unrefrigerated processing. We'll use examples of raw ready-to-eat and cooked ready-to-eat products to demonstrate how to evaluate cumulative time and temperature exposures and select the appropriate critical limit option from Control Strategy 4 to control pathogenic bacterial growth and toxin formation in your process.

The critical limit recommendations in Control Strategy 4 are based on cumulative exposure times for processing that occurs below 50 degrees Fahrenheit, between 50 and 70 degrees, between 70 and 80 degrees, and above 80 degrees.

To determine cumulative exposure time for unrefrigerated processing, start by constructing a flow diagram that lists all of your processing steps. Then identify any steps that occur at temperatures above 40 degrees, such as filleting, washing, grading, weighing, and labeling. Now look at each unrefrigerated processing step and determine the exposure temperatures and exposure time for each. For raw ready-to-eat products, exposure time typically begins when the product is removed from the refrigerated storage into ambient temperatures above 40 degrees. For cooked ready-to-eat products, exposure time will likely begin when the product is first handled after cooking. You'll need to determine how long each unrefrigerated processing step lasts and the internal product temperatures during each step, taking into consideration the exposures that are reasonably likely to occur under the worst conditions at any given step. Once you know the exposure time and temperatures for each process step, separately add up all of the time where exposures are below 50 degrees, between 50 and 70 degrees, between 70 and 80 degrees and above 80 degrees to obtain cumulative exposure time for each temperature range. Compare these with the critical limit options listed under Control Strategy 4 to identify the option that best suits your operation.

Let's pull this together with some examples. We'll start with a raw ready-to-eat product and then look at 2 cooked ready-to-eat products.

This firm processes swordfish that will be consumed either raw in sushi or cooked by the consumer. The firm develops a flow diagram for this process like this: Swordfish already headed, gutted with the tail removed is received on ice from a primary processor. The fish is stored on ice in cooler #1 overnight. The next day at 6 a.m., the swordfish is taken out of the cooler, is removed from the ice, cut into loins, chunks, wheels and steaks based on customer orders, weighed, and packed in labeled boxes. By 11 a.m., all the boxed finished product is stored in cooler #2 until shipment.

You can see this processor has listed each step in the flow diagram and has combined the weigh, pack and label steps as a single processing step. According to Table 3-2 in the Hazards Guide, swordfish has no potential species related hazards; however, Table 3-3 shows that raw fish, not in reduced oxygen packaging, have pathogen growth and toxin formation, allergens and metal inclusion as potential process related hazards. You can refer to Chapters 19 and 20 of the Hazards Guide for more information on controlling the allergens and metal inclusion hazards. This processor does an assessment to evaluate internal product temperature, ambient air temperature and exposure time, and uses the data to develop a time temperature profile.

Let's look at the time-temperature profile for this process. A time-temperature profile is a graphic representation of cumulative time and temperature exposures to unrefrigerated conditions. It should represent the worst-case scenarios -- in other words, the most time that you can reasonably expect product to be exposed to temperatures between 50 and 135 degrees Fahrenheit during unrefrigerated

processing. This profile shows that the fish is taken out of the refrigerator at 6 a.m., and after cutting the fish into loins, chunks, wheels, steaks and packing in labeled boxes, the fish is placed back in refrigerator by 11 a.m.. During that time, the highest ambient temperature was 65 degrees Fahrenheit and the internal temperature of the fish was over 50 degrees for 4 hours. Based on this information, this processor has established that unrefrigerated processing should be one of the critical control points. This processor looks up the critical limit options for raw ready-to-eat products to find the critical limits applicable to their unrefrigerated processing. The processor chooses critical limit option 2 because the product is exposed to temperatures above 50 degrees, but below 70 degrees Fahrenheit. This critical limit option allows 5 hours for processing or 12 hours if *Staphylococcus aureus* is the only pathogen of concern. Because this fish is raw, ready to eat and *Staph. aureus* is not the only pathogen of concern the recommendation for 12 hours is not applicable. Since the fish temperatures are only above 50 degrees for 4 hours, this firm's process is within the recommended 5 hours.

Here is what this processor's unrefrigerated processing critical control point looks like in the HACCP plan when the ambient air temperature of the processing room is held below 70 degrees. The critical limits are 5 hours when the internal product temperatures are between 50 and 70 degrees Fahrenheit. This processor uses a continuous temperature recording device to monitor the ambient air temperature of the processing room and checks the recorded data twice per day, and manually records the processing start and finish time using a clock. Monitoring the ambient temperature of the processing room is acceptable because the product temperature is below 40 degrees when unrefrigerated processing begins and the ambient air temperature of the processing room is below the 70 degree critical limit. In this example, if the ambient air temperature doesn't exceed 70 degrees, then neither will the internal product temperature. However, if the cumulative processing times and/or temperatures exceed the critical limits, then a corrective action needs to be taken. The corrective action is to chill, hold and evaluate the product for safety to ensure unsafe product doesn't reach the consumer and to modify the process to correct the cause of the critical limit deviation. The verification procedures include calibration and accuracy checks for the temperature recording device and a weekly review of the monitoring records. This processor also identifies the records where monitoring data is recorded. More detailed information on calibration procedures and accuracy checks are discussed in another video on Secondary Processor Receiving and Storage Controls.

Now we'll talk about cooked, ready-to-eat products.

Earlier we said that exposure time for cooked ready to eat products typically begins when cooling is finished or at the time product is first significantly handled after cooking, whichever occurs first. This is because cooking will reduce the number of spoilage bacteria, so, if the product is recontaminated after cooking, the pathogens will have the opportunity to grow without competition. Our next 2 examples are for cooked ready to eat crabmeat where significant handling occurs at different temperatures after cooking. Let's see how handling impacts the selection of the critical limit option. For this discussion, you can reference Figures 12-1 and 12-2, found in Chapter 12 of the Hazards Guide; these figures are similar to the examples we're about to discuss.

Here's a flow diagram for crabs that are cooked, backed, picked and packed. While both processers have the same flow diagram, and have the same unrefrigerated processing critical control point, their processing critical limits will be different based on when handling begins. Here, one processor handles the cooked meat before it's cooled and the other handles the cooked meat after cooling the product to below 50 degrees Fahrenheit. Both processors do an assessment to evaluate internal product

temperature, ambient air temperature and exposure time, and use the data to develop a time temperature profile.

In this first graph, the processor removes the back shell of the crab called backing while the product temperature is above 80 degrees Fahrenheit. After backing, the crab is placed in the cooler and the internal temperature of the product is monitored, showing the product is below 70 degrees within the first hour after the initial handling. Then, as the product continues to cool, monitoring shows the internal temperature is below 50 degrees during an additional hour. The crab is taken out of the cooler for picking, where the cooked crab meat is removed from the shell by hand. During the picking and packing steps, the temperature of the crabmeat goes above 50 degrees for an additional 2 hours. Now remember we said that times and temperatures during unrefrigerated conditions are cumulative. So here, the processor's assessment has shown that the product was above 50 degrees Fahrenheit for a total of 4 hours and that only 1 of those hours was above 70 degrees. Because the internal temperature of the product exceeds the ambient air processing temperature during unrefrigerated processing, this processor decided to monitor internal product temperatures. Based on the assessment, the processor also determines that unrefrigerated processing should be listed as a critical control point in the HACCP plan.

In order to establish appropriate critical limits, the processor looks up the options under Cooked ready to eat and chooses critical limit 1. As you see, there are 2 options for this critical limit. The first option is very strict and assumes that after the initial backing, there's no additional handling. Since the backed crab cools to less than 70 degrees within 1 hour before picking and packing, this processor should choose the alternative option. The alternative allows a total of 4 hours of processing time so long as no more than 1 of those hours is above 70 degrees Fahrenheit.

Here is what this firm's unrefrigerated processing critical control point looks like in the HACCP plan. The critical control point includes backing, picking, and packing. The critical limits are 4 hours for product held at internal temperatures above 50 degrees Fahrenheit and no more than 1 of those hours can be above 70 degrees. The monitoring procedure is to visually observe and record time using the clock and product internal temperature using a thermometer every hour. The processor starts monitoring and recording the time and internal product temperatures when backing begins and continues while the product is in the cooler. It's important that the monitoring records show that product internal temperatures are below 70 degrees within 1 hour after backing starts. Monitoring and recording continues during picking and packing. It is also important that the monitoring records show that the total cumulative time of unrefrigerated processing does not exceed 4 hours. If the cumulative processing time and/or temperatures exceed the critical limits, then the corrective action is to destroy the product and modify the process. The verification procedures include thermometer calibration and accuracy checks and a weekly review of the monitoring records.

In this second graph, the processor places the crab directly into the cooler in its original container and allows it to cool below 50 degrees before processing begins. Since the crabs are not handled before cooling, the cooling time isn't considered part of the cumulative time and temperature exposure even though the temperatures are above 50 degrees. When the temperatures are below 40 degrees, the crab is removed from the cooler for backing, picking and packing. This processor monitors the internal temperature and determines that the product was above 50 degrees, but below 70 degrees Fahrenheit for a total of 5 hours during backing picking and packing. Because the ambient air processing temperature goes above 70 degrees Fahrenheit, this processor decided to monitor internal product

temperatures. Based on the assessment, this processor also determines that unrefrigerated processing should be listed as a critical control point in the HACCP plan. The processor looks up the critical limit options under Cooked ready to eat and chooses critical limit option 3, which allows more processing time than our previous example. Here the processor has up to 5 hours, cumulatively, between 50 and 70 degrees to complete backing, picking, and packing.

Here's what this unrefrigerated processing critical control point looks like in the HACCP plan. The critical control point includes backing, picking, and packing. The critical limits are 5 hours when the internal product temperatures are between 50 and 70 degrees Fahrenheit. The monitoring procedure is to visually observe and record time using the clock and product internal temperature using a thermometer every two hours. If the cumulative processing times and/or temperatures exceed the critical limits, then the corrective action is to chill, hold and evaluative the product for safety and modify the process. The verification procedures include thermometer calibration and accuracy checks and a weekly review of the monitoring records.

Our sample HACCP plans included monitoring procedures for the critical limits, corrective actions for when the critical limit deviation occurs, and verification procedures. Let's go over some important points related to these parts of the HACCP plan.

Monitoring procedures should directly measure the critical limit parameters you've established. Established monitoring procedures will identify what will be monitored, how monitoring will be done, how often monitoring will be done, and who will do the monitoring.

FDA recommends monitoring cumulative processing time and, when applicable, either internal product temperature or ambient air temperature during unrefrigerated processing. Temperatures can be measured using a temperature indicating device, such as a thermometer or with a temperature-recording device, such as a recording thermometer. A temperature recording device is always desirable, and in some cases necessary. These devices produce a record of temperature over time and can show that the critical limits were consistently maintained throughout processing. Also, the record produced will provide you more information for evaluating product safety when taking corrective action after a critical limit deviation. If you choose a device that doesn't produce a record, then you should manually monitor time by visually observing a clock and thermometer at set intervals throughout processing. A detailed discussion on the various types of temperature indicating devices, the advantages and disadvantages of each, and accuracy and calibration can be found in the companion video "Secondary Processor Receiving and Storage Controls."

A corrective action must be taken whenever there is a critical limit deviation. An appropriate corrective action procedure must accomplish two goals; ensure that an unsafe product doesn't reach the consumer and correct the problem that caused the critical limit deviation. Corrective actions should relate to the specific critical limit and FDA's recommendations are included with each Control Strategy listed in the Hazards Guide.

Verification procedures ensure that your HACCP plan is adequate to address the hazards and is consistently being followed. Verification activities include calibration and accuracy checks of monitoring equipment, and review of monitoring, corrective action, and verification records. Monitoring equipment, such as temperature measuring devices, should be checked for accuracy before first use and then at least daily after that. Calibration should be done at least annually or more frequently if

recommended by the device manufacturer. All monitoring records should be reviewed within 1 week of preparation, and keep all HACCP records on file for at least 1 year for refrigerated products and at least 2 years for frozen, preserved, or shelf-stable products.

We know that pathogens can be present on fish and fishery products and, if not controlled, can cause consumer illness. In this video, we talked about growth characteristics of pathogens; the Control Strategies listed in Chapter 12 of FDA's Fish and Fishery Products Hazards and Controls Guidance, evaluating cumulative time and temperature, how to use the time-temperature profile to select an appropriate critical limit; and how to use all this information to develop an unrefrigerated processing critical control point for your HACCP plan. We also touched on monitoring procedures; corrective actions; verification procedures; and records. Careful application of these time and temperature controls should enable you to minimize the growth of pathogenic bacteria that cause foodborne illness.