Secondary Processor Receiving and Storage Controls

Everyone in the seafood supply chain is responsible for providing safe seafood products to consumers. In 1997, the Food and Drug Administration issued the Hazard Analysis and Critical Control Point regulation, also known as the Seafood HACCP regulation. The regulation requires processors to identify significant hazards associated with their seafood product and manufacturing process, and apply preventive controls as necessary during the process. FDA's Fish and Fishery Products Hazards and Controls Guidance, or the Hazard Guide, provides valuable information to assist the seafood industry in developing food safety plans. These food safety plans, also known as HACCP plans, outline controls for specific hazards and can be applied during the processing operation. This video will focus on FDA's recommended receiving and storage controls for Secondary Processors along with a discussion on continuous temperature monitoring.

When receiving seafood from another processor, it's the responsibility of the secondary processor to identify and control any significant hazards during transit to their facility as well as during processing and storage at their facility. Certain types of finfish produce histamine if time-temperature abused; leading to possible scombrotoxin poisoning. Other products that may be ready-to-eat by the consumer, those without the need for further cooking, can have a pathogen growth hazard if time-temperature abused. Both histamine and pathogen growth can cause consumer illness and both can be controlled by keeping the product cold in transit and during storage. This may sound simple when, in fact, it requires detailed knowledge of the hazards associated with the product and process, its intended use, the packaging, and how it's shipped, received and stored.

Let's break it down starting with transit temperature controls.

There are basically three types of products that require temperature control during transit.

The first type includes refrigerated finfish that are naturally susceptible to scombrotoxin. Scombrotoxin consists of histamine and other biogenic amines produced by enzyme activity from naturally occurring bacteria in the marine environment. They exist on the gills, external surfaces, and in the gut of the live fish. Upon death, the fish's defense mechanism no longer inhibits their growth and may allow histamine to form in the muscle tissue when time-temperature abused. Some common histamine producing species include tuna, mahi-mahi, mackerel, sardines, and herring, and less common species include escolar, sailfish and saury. For more detailed information on scombrotoxin, see the companion video on Primary Processor Scombrotoxin Controls.

The next type includes refrigerated, raw or cooked ready-to-eat products in oxygen permeable packaging. These products are not intended to be further cooked by the consumer and are susceptible to pathogen growth. Some examples include seafood salads, cooked shrimp, and sushi.

The last type includes refrigerated, reduced oxygen packaged – or ROP products. With these products, the ROP creates an anaerobic environment perfect for *Clostridium botulinum* growth. If time-temperature abused, botulinum toxin can form and result in consumer illness and even death. Some examples include smoked fish, pasteurized canned crab meat, refrigerated seafood soups, and salted fish like caviar.

For each of these hazards, control is simple – keep the product cold in transit. Let's take a look at how to do that.

Let's start with 4 control strategies for transit temperatures that apply to scombrotoxin forming species of finfish and refrigerated ready-to-eat seafood products, both oxygen and reduced oxygen packaged, that are susceptible to pathogen growth. Afterwards, we'll briefly discuss a 5th strategy that only applies to scombrotoxin forming species delivered under ice in an open bed truck, and a temperature adjustment for what we call "single barrier" products where refrigeration is the only control for *C. botulinum*. These transit control strategies are found in the Hazards Guide: Chapters 7 – for scombrotoxin, Chapter 12 for pathogen growth, and Chapter 13 for *Clostridium botulinum*.

For transit controls, the secondary processor needs to know how the fish are delivered – on ice, refrigerated, or with chemical cooling media, and how long they are in transit from the previous processor. Remember, both histamine formation and pathogen growth are controlled by keeping the product cold. The Hazards Guide recommends maintaining product or ambient air temperatures at 40 degrees Fahrenheit or below throughout the transit.

When receiving products in a refrigerated truck, the product or ambient air temperature of the truck should not exceed 40 degrees Fahrenheit. To ensure this, a continuous temperature recording device can be used, and upon arrival, the data from the device can be checked. The recording device itself does the monitoring, but the data should be visually checked by someone who understands the nature of the temperature controls. The chart from the recording device can be used as the record itself and the visual check of the data should also be recorded. If during transit the temperature exceeds 40 degrees Fahrenheit, then a corrective action is taken. The corrective action should be two-fold, to ensure the product involved in the temperature deviation is not distributed until it's determined to be safe; and to identify and correct the cause of the deviation. Because a temperature recording device is used to monitor transit temperatures, the HACCP plan should include verification procedures to check the accuracy of the device during each shipment received, and to calibrate the device at least annually, or sooner as advised by the instrument manufacturer.

Another way to keep products cold during transit is to ship them in ice. If products are in ice, then you know they are kept at 40 degrees or below. For this to work, the product must be completely surrounded by ice during transit, and upon receipt, a visual check on the adequacy of the ice surrounding the product can be made on a representative number of containers in the shipment. The results of the ice check need to be recorded on a receiving record. And, just like refrigerated transit, if the product is not completely surrounded by ice, a corrective action should be taken to make sure product involved in the deviation is not distributed until it's determined to be safe; and that the cause of the deviation is fixed. Also, the internal temperature of the product should be checked periodically to verify its being kept cold. Since a thermometer is used to take the internal temperature, the thermometer should be verified for accuracy each time it's used and calibrated at least annually or sooner per manufacturer's recommendation.

Some processors use chemical cooling media, such as gel packs instead of ice. Like ice, the cooling media is intended to keep the product at 40 degrees or below, during transit. It's important that there's an adequate quantity of media and that it's still frozen when you take delivery of the seafood shipment. Also, with this control, at receipt, select a representative number of containers from the shipment and take internal product temperatures. In the case of packaged product such as sealed bags or cans where sampling may be destructive, using infrared thermometers to measure surface temperatures may be adequate. Record the results of the chemical media checks along with the temperatures observed on a

receiving record. Remember, thermometers used to take the internal temperatures also need to be checked for accuracy and calibrated.

Last, there's a slightly different control strategy for products that are only in transit for 4 hours or less. Because there's a time limit on transit, you'll need to know what date and time the previous processor removed the product from a temperature controlled environment before shipping and the date and time the product was delivered to your facility. In addition, measure the internal temperatures at receipt. A monitoring record showing transit time and internal temperature at receipt must be maintained. If the transit time exceeds 4 hours, or the internal temperature exceeds 40 degrees, take corrective action to make sure the product involved in the deviation is not distributed until it's determined to be safe; and that the cause of the deviation is fixed. Again, since a thermometer is used it must be checked for accuracy and calibrated.

Earlier, we said that there's another control strategy that only applies to scombrotoxin forming species of fish delivered under ice in an open bed truck. Here, the control strategy is similar to products delivered under ice in a refrigerated truck because you check the adequacy of ice at receipt. Also check internal temperatures of a representative number of fish selected randomly from throughout the shipment. Be sure all observations are recorded on a receiving record and that the thermometer used to take internal temperatures is routinely checked for accuracy and calibrated at least annually.

Monitoring records of the visual checks of ice and chemical cooling media should include the number of containers examined, the sufficiency of the cooling media in each container, when the check was performed, and by whom.

Finally a note on the temperatures required to control *Clostridium botulinum* in refrigerated ROP products. Most reduced oxygen packaged fish and fishery products have more than one hurdle or barrier to growth. That's because there are two types of *C. bot.* that need to be controlled, the proteolytics, like Type A and the non-proteolytics, like Type E. We can define barriers to growth as things like pH, water phase salt, and temperature that when used together, can control both types of *C. bot*. Examples of these products are smoked fish that use a minimum water phase salt to control Type E, and refrigeration to control Type A; or a seafood soup that uses a cook step to control Type E, and refrigeration to control type A, or imitation crabmeat that uses pasteurization to control Type E and refrigeration to control type A. These products always use at least two barriers to control *C. bot*. so, control is achieved by maintaining temperatures at 40 degrees Fahrenheit or less.

However, there are products that use ONLY refrigeration as the barrier to both Type E and Type A *C. bot.* These include ROP products such as raw, refrigerated fish like Hamachi or kampachi and crabmeat that is first cooked, then manually picked, placed in a reduced oxygen package and sold refrigerated. Although these products can use the same transit control strategies we've already discussed, their maximum temperature during transit must be maintained below 38 degrees Fahrenheit.

While it's worth bringing these types of products to your attention because they require a different temperature to control *C. bot.*, we will not be discussing them further in this video. For more information on controlling the *Clostridium botulinum* hazard in these products, please refer to Chapter 13 of the Hazards Guide and the companion video titled "Time Temperature Indicators."

Let's move to product storage.

For all of the products we've discussed so far, storage controls are much simpler. In fact, to control scombrotoxin formation and pathogen growth including *Clostridium botulinum*, there is only one goal – keep the product cold. FDA recommends two possible storage control strategies. You can either measure the ambient air temperature continuously by using a temperature recording device or store the product completely surrounded by ice. Let's take a look.

First, continuous temperature monitoring of ambient air temperature during storage ensures that temperature limits were not exceeded. Continuous temperature recording devices are commonly used and produce a record showing that the ambient temperature was consistently maintained. The device should be visually checked at least once a day to ensure the temperature has not exceeded a maximum limit. If the temperature is exceeded, take corrective action to ensure the product involved is not distributed until it's determined to be safe; and that the cause of the deviation is fixed. These temperature recording devices also need to be checked for accuracy daily, and calibrated at least annually or per manufacturer's recommendations.

Many processors find that during defrost cycles, or when opening and closing the cooler doors, minor temperature spikes above the critical limit can occur. These minor variations can be avoided by submerging the sensor for the temperature recording device in a liquid that mimics the characteristics of the product. Many processors have found glycol or food grade oils work well.

It's easy to monitor temperatures during storage. However, temperature limits that specify a cumulative time and temperature exposure are not ordinarily suitable to control the hazard because of the difficulty in tracking the products and cumulative temperatures. This type of monitoring is nearly impossible. It's much simpler to just monitor the ambient air temperature of the storage cooler with a continuous temperature recording device.

Continuous temperature recording devices monitor the temperature and generate a record – a printout, or chart of ambient temperature. These records along with the visual check information are used as monitoring records showing that temperatures were maintained.

A second option is to store product under ice. If you choose to use this control strategy, the Hazards Guide recommends selecting a representative number of containers in the storage area and visually monitoring the adequacy of ice surrounding the products. The Hazards Guide recommends that monitoring for iced product should be with sufficient frequency to ensure that product temperatures are maintained. For example, some may choose to check the ice once a day and others once every other day. The monitoring frequency will depend on different factors such as if the iced product isn't stored in a cooler – where the ice will melt faster. So, monitoring should be often enough to ensure that the ice is always surrounding the product. If adequate ice is not maintained, change the frequency of monitoring, and of course take corrective actions. And remember a corrective action is two-fold - to make sure the product involved in the deviation is not distributed until it's determined to be safe; and to fix the cause of the deviation. For the product no longer covered by the ice, it's not a sufficient corrective action to simply add more ice.

As with our transit control examples, monitoring records of the visual checks of ice should include the number of containers examined, the sufficiency of ice in each container, when the check was performed and by whom.

Finally, let's talk about verification procedures. Verification procedures serve two purposes; to ensure that the HACCP plan is adequate to address the hazard, and that it's being consistently followed. Throughout this video we've referred to accuracy checks and calibration of temperature recording devices; so what do these mean? Since temperature recording devices provide information about temperature exposures of the product, it's important to ensure that these devices are performing adequately. Checking for accuracy means they are checked at one temperature – either cold or hot – depending on the temperature at which they are used. Calibration is a two point check – both hot and cold to show the device works consistently throughout its range. The Hazards Guide outlines when to check for accuracy and when to calibrate. For example, it states that accuracy checks should be made when the device is first used and daily from that point forward. Calibration is typically on an annual basis, but it's best to check the manufactures' recommendations – it may be more often.

Another integral part of verification is record review. A thorough review of records, such as monitoring, and verification will ensure that critical limits are met, corrective actions are taken, if necessary, and equipment used for measuring temperature is correct.

No matter what the product type is or the control strategy used, here are some important points to remember.

For Critical Limits, identify the maximum or minimum value for each parameter. Set the value to ensure the safety of the product.

For Monitoring, directly measure the parameter established for the critical limit. All monitoring should be performed by someone who understands the importance of maintaining proper transit and storage temperatures. Monitoring frequency depends on individual circumstances; and continuous monitoring is always desirable, and in some cases, necessary. The greater the time span between measurements, the more products you are putting at risk should a critical limit deviation occur. When a critical limit deviation occurs, assume that the critical limit had not been met since the last "good" value showing when the critical limit was met.

Corrective Actions, should ensure that products involved in critical limit deviations don't reach the consumer and, they should correct the problem that caused the deviation.

When Keeping Records, include the actual observation, the time the observation was made, and who made the observation. The HACCP plan should contain the names of the individual records being kept.

When performing Verification Procedures, ensure that the HACCP plan is adequate to address the hazard, and ensure that the plan is consistently being followed by reviewing records within 1 week of completion. Be sure to retain all records for at least 1 year for refrigerated and 2 years for frozen product.

We've discussed several possible control strategies for scombrotoxin and pathogen growth during this video. Additional information and examples are available in FDA's Fish and Fishery Products Hazards and Controls Guidance.

Keeping seafood cold during transit and storage is critical to keeping products safe. Also, monitoring and recordkeeping at receipt and storage ensures and documents that the hazards have been

controlled. It's up to each processor to evaluate the hazards associated with their seafood products and to choose a strategy that's best suited for their operation.