Primary Processor Scombrotoxin Controls - Overview and Testing at Receiving

We all rely heavily on food producers and handlers to ensure that the products we eat are safe. The Food and Drug Administration's seafood Hazard Analysis Critical Control Point regulation, or HACCP, is a powerful tool to help fish and fishery processors prevent unsafe food from reaching consumers. One of the specific safety issues a seafood processor must address through HACCP is the threat of scombrotoxin poisoning caused by the improper handling of certain types of fish. In this video, we'll provide an overview of scombrotoxin poisoning and FDA's recommendations to primary processors when receiving fish from harvesters.

Fishermen are exempt from the seafood HACCP regulation. However, FDA requires primary processors, who generally are the first to receive fish from the harvest vessels, take steps to ensure the fish they receive are safe for consumption. When fishermen or primary processors fail to take appropriate precautions, consumers of these fish could become ill. This means that the fish are to be harvested and handled in a way to prevent scombrotoxin from forming.

Scombrotoxin is an accumulation of compounds, including histamine, in the fish. Throughout this video we will refer to scombrotoxin in a general sense when discussing the formation and controls of these toxic compounds. However, because histamine is a primary component of scombrotoxin and is easily measured in the fish, we will refer to histamine specifically when we are talking about testing for scombrotoxin.

Scombrotoxin occurs in certain species of finfish if bacterial growth isn't controlled by adequately chilling the fish after they die. When time and temperature exposures are not controlled, consumers of the fish can get sick with scombrotoxin poisoning, which is sometimes called histamine poisoning. It can form with or without other spoilage indicators, so even fish that appear and smell fresh and safe may contain these toxic compounds and can make consumers sick. Susceptible fish include tuna, mahi-mahi, marlin, bluefish, mackerel, sardines, anchovies, and many others. A full list of susceptible fish can be found in FDA's Fish and Fishery Products Hazards and Controls Guidance located on FDA's web site.

The bacteria occur naturally in the gut, gills, and exterior surfaces of the fish. Live fish have natural defenses preventing a bacterial invasion. But once the fish dies, bacteria can grow, multiply, and produce enzymes, which cause scombrotoxin to form. The best way to prevent this microbial activity is to chill the fish soon after death and keep the fish chilled. Abusive time-temperature exposures can occur while the fish is dead on a line or in a net before landing; while on the boat deck; or while stored in the boat's hold. It can also form when improperly handled at processing plants, in transit, at retail, or even in the hands of the consumers. Therefore, the harvesting and handling practices onboard the harvest vessels may well be the most critical of all the steps the fish will receive before reaching the consumer. And, once scombrotoxin has formed, it cannot be removed or destroyed.

Here you see a list of symptoms associated with Scombrotoxin. Symptoms may last from 12 hours to a few days. However, the rapid and intense onset of the symptoms, which usually occur within a few minutes to a few hours of consuming the bad fish, can cause the victim serious concern and distress. Some victims seek professional medical attention and some are hospitalized.

FDA recommends two general strategies for preventing scombrotoxin formation at the receiving critical control point. In the harvest vessel records strategy, the processor typically obtains records from the fishermen that document the harvesting, handling, and storage of the catch to show that the fish were chilled rapidly and held chilled throughout the fishing trip. In the histamine testing strategy, the processor collects meaningful samples from the vessel lots received and conducts analytical testing to ensure histamine levels are low. In both strategies, the processor measures the internal temperatures of the representative fish and conducts sensory examinations of the fish collected from the lots to ensure that there are no signs of time and temperature abuse detected in the fish.

Working cooperatively with the fishermen, processors using the harvest vessel records strategy should develop recordkeeping forms to be used by the fishermen to capture pertinent chilling and handling activities on the boats that ensure their critical limits for chilling the fish are met. The details of this strategy are covered in another video titled Primary Processor Scombrotoxin Controls – Harvest Vessel Records.

In this video, we'll be focusing on monitoring internal temperatures and sensory examinations. We'll also discuss histamine testing considerations important in both control strategies and we'll touch on some corrective action and verification procedures associated with the receipt of scombrotoxin-forming fish by the primary processor.

Whether using the harvest vessel record strategy or the histamine testing strategy, processors should measure the internal temperatures of the fish as they're off-loaded from the vessels. These measurements won't guarantee that the fish were chilled onboard within the proper timeframes or that they remained properly chilled throughout the fishing trip. However, elevated fish temperatures taken at off-loading serve as a signal to the processor that the harvester's practices and controls may be inadequate and the potential for conditions favorable to scombrotoxin formation may have been permitted by the boat operators. FDA recommends the following critical limits for the internal temperatures of fish when off-loading a supplier's vessel:

If it's been 24 hours or more since the fish being measured died, the internal temperatures should be 40 degrees Fahrenheit or less.

For fish that have been dead for 15 to 24 hours, internal temperatures should be 50 degrees or less.

Fish that have been dead for 12 to 15 hours should have internal temperatures of 60 degrees or less.

For fish that have been dead for less than 12 hours, the temperatures should indicate that appropriate efforts were made to chill the fish onboard. In this situation, the processor could effectively use cooling profiles established for the types of fish received under typical ambient temperatures of harvest to determine if the fish were properly chilled within the short timeframes till delivery. The processor may use other time and temperature limits that are scientifically established for the particular fishery if the criteria recommended by FDA aren't applicable to its fishery.

These recommendations won't fit every situation. For example, fishermen who deliver fish that have been dead 14 hours and have an internal temperature of 60 degrees would technically meet FDA's recommendation. But, suppose the air and seawater temperatures for the fishing trip were 62 degrees? Then, depending on the harvest method or the size of the fish, the 60 degree internal temperature could indicate that the fisherman didn't make much of an effort to chill the fish or to keep the fish chilled for the 14 hours after death. In that case, the processor should take corrective action on the lot.

FDA's recommendations are based on the cooling of fairly large fish. Because smaller fish chill more rapidly, it may be appropriate to establish limits with lower temperatures or shorter timeframes in order to better ensure that the small fish were handled and stored properly onboard. When handling very large fish that chill more slowly at the core, a processor might establish temperature limits that are more pertinent to the fishery, such as temperatures at a designated depth within the fish muscle in addition to the deep backbone or core temperatures of the fish. This processor should also validate the adequacy of these newly established limits.

FDA recommends monitoring the internal temperature of a representative number of the largest fish in every vessel lot at off-loading. Processors should concentrate on any fish showing signs of mishandling, such as inadequate icing. A minimum of 12 fish randomly selected and representative of the lot is advised; but larger sample sizes may be applicable to ensure adequate representation of larger lots or where increased temperature variability is expected or found in the lot.

Portions of fish no longer surrounded by ice or other coolant, as well as smaller fish with inadequate coolant, may warm more rapidly than the core of larger fish or portions of the same fish that are properly iced. So, checking the core temperature of only the larger fish may not provide sufficient information. When a vessel lot arrives with depleted coolant, a processor should measure the temperature of some of the smaller fish in the lot, in addition to muscle nearer the surface of any exposed fish portions. Obtaining meaningful temperature measurements of extremely small fish can be a little trickier. Although small fish chill quickly when surrounded by ice or coolant, coolant doesn't easily penetrate clusters of small fish that may form in the hold. Ensuring that every fish is, in fact, adequately surrounded with coolant may be challenging for the fishermen. In these circumstances, processors may find it necessary to measure the temperature of far more than the recommended minimum 12 fish for a better representation of the overall condition of the fish in the lot.

FDA's recommendations for internal temperatures of fish at receipt are based on the time of death of the fish. So, processors using the histamine testing control strategy may still need some record of time of death from the fishermen in order to make sure the temperatures at receipt meet the appropriate critical limit. On the other hand, you may not need the time of death when using the histamine testing control strategy if you can safely assume that all the fish in the vessel lot have been dead for 24 hours or more. In this case, only the 40 degree internal temperature limit would apply.

Most harvest vessels deliver fish that have been dead for different lengths of time. Recently caught fish may have higher internal temperatures than those that were caught earlier in the trip and had longer exposures to coolant. The processor can't rely on the temperatures of only the last-caught or first-caught fish when assessing the condition of a lot. The fish measured

should be randomly selected to represent the entire vessel lot and the processor may need time of death records from the fishermen to make an appropriate assessment of those fish.

Internal temperatures are an indication of onboard handling practices, so off-loading fish shouldn't be delayed simply so the fish can further cool to meet the temperature critical limits. That would make the monitoring useless. Nor should a processor delay off-loading the fish after temperature measurements have been made. If a delay is unavoidable, for example when a glut of vessel deliveries prevents immediate off-loading, either the processor or the vessel operator should ensure the fish being held up on the boats are stored in sufficient coolant during the entire period until offloading can commence. Documentation of the holding conditions may be warranted.

Let's review some issues primary processors may have with collecting samples for histamine testing or sensory examinations.

Proper sample collection will help the processor to make good decisions about the lot. Meaningful sampling begins with the proper designation of lots. Many primary processors consider all of the fish on a vessel delivered at a particular time to be one lot. Processors receiving very large freezer vessel loads often break up the vessel lot into smaller, more manageable, sublots. These may or may not be appropriate sampling approaches. With any sampling approach, the designation of "lots" should be done in a way to minimize the variability of time and temperature exposure history in the particular group of fish to be sampled. This better ensures that the few samples taken will provide a reliable indication of the presence of scombrotoxin in the lot.

Sometimes lots are expected to have a great deal of variability in the kind of exposures that the fish were subjected to. For example, longline vessels land everything from live fish to fish that have been dead at sea for many hours. Subdividing the lot into smaller portions wouldn't typically reduce the inherent variability caused by the harvest method. When faced with this kind of scenario, processors should consider larger sample sizes than the minimums recommended to ensure that any problems in the lot are more likely to be detected.

When very large lots are subdivided into smaller, more manageable sublots as a means of expanding the sampling and representation of the harvest vessel delivery, the processor should recognize that the purpose of the sampling and testing is still intended to provide an indication of the care and handling practices implemented by the vessel operators. The sampling sizes are typically still far too small to conclude that when one sublot has deviated from the critical limit the other sublots will be safe. Instead, a critical limit deviation in any sublot should trigger an alarm for the processor that there may be undesirable handling practices by the vessel operators and the entire vessel delivery, all sublots, should be suspect and subject to corrective action.

FDA generally recommends separately sampling and testing each species of scombrotoxin-forming fish received in a vessel lot. This is a good practice where vessel lots containing sizeable quantities of different species and allows the processor to give consideration to the different morphology and composition of the species that could affect their cooling rates.

Lots delivered from collection vessels or transporters usually contain fish from more than one harvest vessel. These lots should be delivered with each harvest vessel's load clearly identified and remain intact for separate sampling by the processor. If commingled loads are delivered in a manner that prevents testing fish from each harvest vessel separately, a practice that's strongly discouraged, then a much more extensive sampling plan should be implemented to deal with the increased variability in the commingled lot. Also, when these collection vessels or transporters off-load fresh fish from harvest vessels for subsequent delivery to the processors, it's desirable for the operators of the collection vessel or transporter to measure and record internal temperatures of each harvest vessel lot, much as a primary processor would do, to provide appropriate documentation to the land-based processor upon delivery.

Processors should not pass on responsibility for sampling and testing of off-loaded fish to other processors unless lots are kept intact, are clearly identified, and there's a written arrangement with the subsequent processor on file describing specific sampling and testing terms. These arrangements should be limited to histamine testing or sensory examinations, never temperature measurements of unfrozen fish. Delaying temperature measurements until after transport and receipt by the next processor defeats the purpose of those measurements as an indication of vessel practices. Temperature measurements intended to help the processor assess the safety of the fish as they're off-loaded are only meaningful if they're performed at the time fish are off-loaded from the vessel.

Now let's look at the sensory examination and histamine testing control elements.

Along with internal temperature measurements at receiving, FDA recommends that primary processors of scombrotoxin-forming fish conduct sensory examinations for both the harvest vessel record control strategy and the histamine testing control strategy.

FDA recommends a receiving critical limit that alerts the processor when a lot consists of two and a half percent or more of decomposed fish. This can be determined by sensory examinations of a representative sample by properly trained examiners. Examinations should include at least 118 fish from any given lot and if more than 2 of the 118 fish are decomposed, take corrective actions. Examine additional fish when increased variability in potential time and temperature exposures is expected in the lot or for large volume lots.

Processors are reminded that this critical limit recommendation of two and a half percent decomposition for the HACCP control is intended only to warn the processor that the fish have been exposed to some levels of time and temperature abuse. The recommendation does not mean that the lots containing some decomposed fish are acceptable for commerce as long as the total is less than two and a half percent. Processors are obligated under the law to prevent product from entering commerce if it consists in whole or in part of any decomposed substance.

Further, for HACCP applications, the processor shouldn't reject individual fish only after they've reached advanced stages of decomposition. Instead, the decomposition criteria should be indicative of time and temperature abuse, as in the loss of fresh quality attributes and entering the earliest reject stages. These can be determined by properly trained and qualified sensory analysts. After all, none of the fish coming off of the vessel should already exhibit decomposition if harvested and handled properly.

In the histamine testing control strategy, the receiving critical control point should include testing of a representative number of fish, a minimum of 18 fish, from each lot received to ensure that all the fish contain less than 50 parts per million histamine. Testing additional fish is recommended when high variability in histamine content is expected or observed in the lot or for large volume lots.

Processors should recognize that fish with histamine in excess of 50 parts per million are adulterated. If the fish will be subjected to further processing steps with significant exposures to temperatures above 40 degrees Fahrenheit, additional histamine may form during the processing. In this case, the processor should consider a receiving critical limit below 50 parts per million to avoid adulterating the food during the subsequent processes.

It's important for processors to recognize that histamine will not form in fish without gross time and temperature abuse. Experts find that freshly harvested fish typically contain less than 2 parts per million histamine. And vigilant harvesters and processors applying effective Good Manufacturing Practices and HACCP controls can produce fishery products containing histamine levels well below 15 parts per million. Consequently, FDA is reassessing the appropriate levels of histamine expected in samples of fish. Processors are encouraged to do research on their own fishery to establish applicable acceptance criteria to ensure high quality and safe fish from their suppliers.

In addition to the general sampling issues previously discussed, a very important part of the histamine testing strategy is the location on each fish where the histamine sample is collected. When fresh fish are time and temperature abused on the harvest vessels in a manner that allows for histamine formation, the lower anterior loin of the affected fish provides a good likelihood of detecting the elevated histamine. Therefore, sampling procedures should target the lower anterior loins during receiving.

FDA recommends collecting a minimum of 250 grams of muscle from one of the lower anterior loins of each fish to be tested. Because it's not unusual for histamine to form more on one side of a fish than another, processors that choose to obtain the sample from equal portions of both anterior loins of each fish should consider halving the appropriate critical limit histamine level trigger to account for the potential dilution factor. However, rather than sampling muscle from both sides of the same fish, in most instances, FDA recommends sampling from only one side of each fish selected for testing. By alternating sides for each test fish, bias toward one side or another will be minimized. If the morphology of the fish makes it difficult to get 250 grams from the lower anterior loin of one side of the fish, the processor may include some of the upper anterior loin portion but never in lieu of the lower anterior portion. When both the upper and lower anterior loin portions of the test fish still don't provide 250 grams, the processor may include the middle section of the lower loin as well. If the fish are smaller yet, such that all three portions don't provide 250 grams, the processor should collect multiple fish for each sample unit and collect the three portions from one side of each fish until the target 250 grams is obtained. When the fish are so small such that the entire edible portion from both sides of the fish yields less than 250 grams, the processor can collect multiple fish for each test unit and utilize the entire edible portions from each fish until 250 grams of edible portion are obtained. The sample portions should be individually ground and the amount to be tested, called the test aliquot, should be taken from each of the ground samples.

Some processors may choose to reduce the testing costs by combining fish samples into fewer composite samples. Here's an example.

Collect 250 grams from each of the 18 fish and grind each sample separately. Then, divide the 18 samples into 6 groups consisting of 3 samples each. Take a minimum of 100 grams from each of the 3 ground portions per group, combine them, and re-grind them together to make one composite sample. Repeat this for each of the six groups. A test aliquot is taken from each of the six composite samples. When compositing, the processor should reduce the critical limit level according to the number of fish represented in each composite sample so that elevated histamine levels in any one fish sample won't be masked or diluted by the other portions in the composite. So, in our example, if 18 individual fish samples are composited into 6 composites of 3 fish each, the critical limit for each composite sample would be a maximum of 16.7 parts per million histamine rather than a maximum of 50 parts per million because we would divide 50 parts per million by 3 for the number of fish in the composite.

Processors should use a validated test method for histamine determination. The test method should be specified in the HACCP plan and any changes made in the method should be re-validated. The validation should ensure reliable results under the specific testing conditions at the processing plant for the specific species received.

There are several commercial test kits for histamine available. If a test kit is used, it's up to the processor to ensure that the kit gives reliable results under the processor's specific conditions. It's not enough to simply buy a kit based on the kit manufacturer's promotions without validating the results. If compositing subsamples for analysis, then the kit's ability to perform reliably at the lower detection limits should also be verified.

Be aware, test kit sampling instructions may not be designed for HACCP control applications. FDA's recommended sample of a minimum of 250 grams from the lower anterior loin of an appropriate number of fish should be collected regardless of the kit's instructions. If compositing samples, follow the procedures previously described to prepare the samples for analysis with the kit. Once the samples are ground and prepared, follow the kit instructions for the size of the test aliquot and further analysis.

Now let's look at some issues related to the best time to conduct the monitoring.

The receiving controls recommended so far are intended to be applied at the time fish are off-loaded from the vessels to allow processors to make a decision about the safety and acceptability of the fish from the harvest vessel. However, sometimes a processor may receive fish at a wharf while its actual processing facility is at another location. Monitoring for some receiving critical limits should be done immediately at the wharf while monitoring for others can wait until the fish are delivered to the processing facility.

Sensory exams and histamine testing can be delayed until the fish are transported to the processing facility because decomposition and histamine levels won't improve with time. However, for this delayed testing to have meaning, the fish should be transported with each vessel delivery intact, separate, and clearly identified. This allows the processor to make reliable vessel-by-vessel delivery acceptance decisions just as it would at the wharf.

In contrast, you should not delay temperature measurements of the fish coming off the boats. Remember that temperature measurements of fish at receiving are an indication of control practices onboard the vessel and are only meaningful at the time of off-loading. Temperature measurements taken after the fish are off-loaded, re-iced, and transported, no longer reflect the temperature control practices onboard the vessel.

Reviews of harvest vessel records are also best done at the wharf. Inadequate records or indications in the records that the catch wasn't chilled, handled, or stored properly may be reason to reject the catch before off-loading.

In addition to the primary processor controls discussed so far, transit controls associated with secondary processors may also be necessary whenever a processing facility is somewhere other than the wharf. The transit controls ensure that the fish are delivered from the wharf to the processing facility in a safe manner. We discuss these transit controls in another video for Secondary Processor Receiving and Storage Controls. In these cases, processors would have two receiving critical control points – receipt from fishermen at the wharf and receipt at the processing facility after transport from the wharf.

Further processing won't mitigate scombrotoxin formed in the fish during harvest, onboard handling, or prior to receipt at the processing facility. Therefore, if the processor plans to further process the fish, such as by salting, drying, pickling, smoking, canning, or fermentation, it's still responsible for controlling scombrotoxin in the raw fish it receives from the harvest vessels, just as it would if it were marketing the fish as fresh. Even in the case of natural fermentations, researchers have shown that elevated histamine in the final product can be prevented by proper chilling and handling of the fish on the harvest vessels and proper initial preparation steps of the fish for fermentation.

Also, histamine is water soluble and can form and remain in the muscle of the fish despite substantial processing. So, even when the finished product no longer resembles the fish from which it came, such as fish protein concentrate, processors should have the same primary processor scombrotoxin control concerns as processors of other fishery products. Processors of fish oil products, in which histamine is not soluble, may not require controls for the scombrotoxin hazard for those products.

The critical limits and monitoring procedures we've discussed so far aren't all that processors should do to control scombrotoxin formation. The HACCP plan should also outline corrective actions to take if the critical limits are not met and verification procedures to ensure the established controls are effective.

Appropriate corrective actions may well be the most crucial element of any HACCP program. No matter how well the critical limits and monitoring procedures of a HACCP plan are designed and followed, the processor's decisions and actions following a critical limit deviation will greatly determine if the food distributed is safe. After all, consumers are most vulnerable when product is produced outside the measured controls.

If the processor determines that the fish received were exposed to conditions potentially favorable to scombrotoxin formation, it's required to take corrective action. The processor has two options; either reject the lot or, if elevated histamine wasn't already detected during the

histamine monitoring, to conduct expanded sampling and histamine testing to ensure no portions of the lot contain elevated histamine and the fish are still safe for consumption.

Re-icing fish doesn't eliminate scombrotoxin that may have already formed during time and temperature abuse. Once formed, scombrotoxin will remain even if the fish are frozen. So, it's not an appropriate corrective action to simply re-ice or freeze the time-temperature abused fish.

Histamine can't be reliably detected by sensory examinations or temperature monitoring alone. So, culling out decomposed fish or fish with elevated temperatures from an affected lot doesn't provide an adequate scombrotoxin control; elevated histamine might still be in the remaining fish. If the decomposition or temperature critical limits are exceeded, processors should reject the entire lot or conduct extensive histamine testing before accepting any portion of the lot.

When histamine testing is conducted as a corrective action in a lot that failed the internal temperature or the sensory criteria, FDA recommends testing a minimum of 60 fish in the lot including all fish that have elevated temperatures or are decomposed. Additionally, if high histamine is not found in the fish tested following a deviation in the sensory exam critical limit, processors should perform a 100 percent inspection of the lot to cull and reject all decomposed fish before further processing or distributing the lot of fish.

FDA's current guidance no longer includes subdividing and retesting of lots as a viable corrective action for fish that have tested positive for elevated histamine. This subdividing approach didn't provide adequate protection for consumers.

Addressing the cause of a critical limit deviation is an important part of taking corrective action. FDA recommends that processors discontinue the use of a supplier until evidence shows that the supplier's harvesting and onboard practices and controls have been improved. A proactive processor won't just rely on testing and monitoring of a supplier's future deliveries to determine if improvements were made. Primary processors should seek improvements by working with the fishermen to identify any of the fishermen's practices that may be deficient and appropriate actions to correct the deficient practices. Processors can document observations of their supplier's modifications as part of the evidence that improvements have been made. The processor should then consider increased levels of histamine testing from several subsequent deliveries of fish from the same supplier and revert back to its original receiving controls only after the supplier has documented improvements in harvesting and onboard practices and has delivered several consecutive problem-free vessel lots.

Further, when a critical limit is not met, and a processor applies FDA's recommendation to "reject the lot," appropriate means of rejection at the time of receiving can include refusal to accept the lot from the supplier, destruction of the lot, or diversion of the lot to a non-food use.

The HACCP plan must also include verification procedures to ensure a processor's controls are adequate and that its plan is effectively implemented. This includes the verification procedures common to most seafood HACCP plans, such as reviewing records and calibrating temperature-monitoring devices. But there are a couple of verification elements specifically related to handling of scombrotoxin-forming fish worth emphasizing.

FDA recommends that new sensory examiners receive training to ensure reliable identification of decomposition in fish. All sensory examiners should also receive periodic refresher training.

As a verification procedure for primary processors using the harvest vessel record control strategy, FDA recommends conducting histamine testing of a representative sample at least quarterly. This sample can come from raw material, in-process product, or finished product. However, because the testing is intended to serve as a measure of the adequacy of the processor's receiving controls, the lower anterior loins of raw material accepted may serve as the best verification sample for this application. Fish further along in the processing line may introduce unwanted variability due to the commingling of fish from various vessels and, depending on the type of processes performed, could make identification of the lower anterior loins more difficult or could result in portions other than the lower anterior loins having higher histamine levels. To obtain the most useful information about the effectiveness of the control program, verification samples should be collected from lots containing marginally acceptable fish or from suppliers with questionable or lax vessel records. Concentrating on these types of lots provides processors greater confidence in the effectiveness of their HACCP controls than testing pristine lots from vessels known to handle the fish properly or simple random selection of lots.

When doing periodic histamine testing for verification, processors should test a minimum of 18 fish from the selected lot; more if the histamine content is expected to vary considerably. Processors should also increase the amount or frequency of verification testing if they receive fish from many different vessels or any time they have concerns about the condition of fish received or the validity of the harvest vessel records received.

FDA emphasizes the critical role that harvesters and primary processors play in protecting consumers from scombrotoxin poisoning. Without vigilance by the harvesters and the primary processors, controls applied later in the distribution chain may be futile. Providing safe products to the consumers requires emphasis on proper preventative controls from the moment the fish are caught so that fish are brought to the market free of time-temperature abuse or elevated concentrations of scombrotoxin.