CHAPTER 7: Scombrotoxin (Histamine) Formation

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UNDERSTAND THE POTENTIAL HAZARD.

Scombrotoxin (histamine) formation as a result of time and temperature abuse of certain species of fish can cause consumer illness. The illness is closely linked to the development of histamine in these fish. In most cases, histamine levels in illness-causing fish have been above 200 ppm, often above 500 ppm. However, there is some evidence that other chemicals (e.g., biogenic amines such as putrescine and cadaverine) may also play a role in the illness. The possible role of these chemicals in consumer illness is the subject of Chapter 8.

Seafood-related scombrotoxin poisoning is primarily associated with the consumption of tuna, mahi-mahi, marlin, and bluefish. Table 3-2 (Chapter 3) identifies other species that are also capable of developing elevated levels of histamine when temperature abuse occurs.

The illness caused by the consumption of fish in which scombrotoxin has formed is most appropriately referred to as "scombrotoxin poisoning." The illness has historically been known by other names. Originally, the illness was termed "scombroid poisoning" because of its association with fish in the families Scombridae and Scomberesocidae. However, other species of fish are now known to cause the illness. The terms "histamine poisoning" and "histamine fish poisoning" have also been applied to the illness. However, because biogenic amines other than histamine have been associated with the illness, these terms also present difficulties. Nonetheless, this chapter refers to control measures to prevent the formation of histamine. It is expected that the methods of control used to inhibit the bacteria that result in histamine formation will also inhibit the bacteria that produce other biogenic amines.

Symptoms of scombrotoxin poisoning include tingling or burning in or around the mouth or throat; rash or hives on the upper body; drop in blood pressure; headache; dizziness; itching of the skin; nausea; vomiting; diarrhea; asthmatic-like constriction of the air passage; heart palpitation; and respiratory distress. Symptoms usually occur within a few minutes to a few hours of consumption and last from 12 hours to a few days.

- **Scombrotoxin (histamine) formation**

Certain bacteria produce the enzyme histidine decarboxylase during growth. This enzyme reacts with histidine, a naturally occurring amino acid that is present in larger quantities in some fish than in others. The result is the formation of scombrotoxin (histamine).

Histamine-forming bacteria are capable of growing and producing histamine over a wide temperature range. Growth of histamine is more rapid, however, at high-abuse temperatures (e.g., 70°F (21.1°C) or higher) than at moderate-abuse temperatures (e.g., 45°F (7.2°C)). Growth is particularly rapid at temperatures near 90°F (32.2°C). Histamine is more commonly the result of high temperature spoilage than of long-term, relatively low-temperature spoilage, which is commonly associated with organoleptically detectable decomposition. Nonetheless, there are a number of opportunities for histamine to form under more moderate-abuse temperature conditions.

Once the enzyme histidine decarboxylase is present in the fish, it can continue to produce histamine in the fish even if the bacteria are not active. The enzyme can be active at or near refrigeration temperatures. The enzyme remains stable while in the frozen state and may be reactivated very rapidly after thawing.

Freezing may inactivate some of the enzyme-forming bacteria. Both the enzyme and the bacteria can be inactivated by cooking. However, once histamine is produced, it cannot be eliminated by heat (including retorting) or freezing. After cooking, recontamination of the fish with the enzyme-producing bacteria is necessary for additional histamine to form. For these reasons, histamine development is more likely in raw, unfrozen fish but should not be discounted in other product forms of scombrotoxin-forming fish species.

The kinds of bacteria that are associated with histamine development are commonly present in the saltwater environment. They naturally exist on the gills, on external surfaces, and in the gut of live, saltwater fish, with no harm to the fish. Upon death, the defense mechanisms of the fish no longer inhibit bacterial growth in the muscle tissue, and histamine-forming bacteria may start to grow, resulting in the production of histamine. Evisceration and removal of the gills may reduce, but not eliminate, the number of histamine-forming bacteria. Packing of the visceral cavity with ice may aid in chilling large fish in which internal muscle temperatures are not easily reduced. However, when done improperly, these steps may accelerate the process of histamine development in the edible portions of the fish by spreading the bacteria from the visceral cavity to the flesh of the fish.

With some harvesting practices, such as longlining and gillnetting, death may occur many hours before the fish is removed from the water. Under the worst conditions, histamine formation can already be underway before the fish is brought onboard the vessel. This condition can be further aggravated with certain tuna species that generate heat, resulting in internal temperatures that may exceed environmental temperatures and increasing the likelihood of conditions favorable to growth of enzyme-forming bacteria.

The potential for histamine formation is increased when the scombrotoxin-forming fish muscle is in direct contact with the enzyme-forming bacteria. This direct contact occurs when the fish are processed (e.g., butchering or filleting) and can be particularly problematic when the surface-to-volume ratio of the exposed fish muscle is large, such as minced tuna for salads. Even when such products are prepared from canned or pouch retorted fish, recontamination can occur during salad preparation, especially with the addition of raw ingredients. The mixing in of the bacteria throughout the product and the high surface-to-volume ratio can result in substantial histamine formation if time and temperature abuse occurs.

At least some of the histamine-forming bacteria are halotolerant (salt tolerant) or halophilic (salt loving). Some are more capable of producing histamine at elevated acidity (low pH). As a result, histamine formation is possible during processes such as brining, salting, smoking, drying, fermenting, and pickling until the product is fully shelf-stable. Refrigeration can be used to inhibit histamine formation during these processes.

A number of the histamine-forming bacteria are facultative anaerobes that can grow in reduced oxygen environments. As a result, reduced oxygen packaging (e.g., vacuum packaging, modified atmosphere packaging, and controlled atmosphere packaging) should not be viewed as inhibitory to histamine formation.

Histamine is water soluble (dissolves in water) and would not be expected in significant quantity in products such as fish oil that do not have a water component. However, histamine could be present in products such as fish protein concentrate that are prepared from the muscle or aqueous (water-based) components of fish tissue.

- **Controlling scombrotoxin (histamine) formation**

Rapid chilling of scombrotoxin-forming fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin (histamine), especially for fish that are exposed to warm waters or air, and for tunas which generate heat in their tissues. Some recommendations follow:

- Fish exposed to air or water temperatures above 83°F (28.3°C) should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than 6 hours from the time of death; or
- Fish exposed to air and water temperatures of 83°F (28.3°C) or less should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than 9 hours from the time of death; or
- Fish that are gilled and gutted before chilling should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than 12 hours from the time of death; or
- Fish that are harvested under conditions that expose dead fish to harvest waters of 65°F (18.3°C) or less for 24 hours or less should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than the time limits listed above, with the time period starting when the fish leave the 65°F (18.3°C) or less environment.

Note: If the actual time of death is not known, an estimated time of the first fish death in the set may be used (e.g., the time the deployment of a longline begins).

TABLE 7-1

RECOMMENDED MAXIMUM TIME TO GET SCOMBROTOXIN-FORMING FISH INTO CHILLING MEDIUM ONBOARD HARVEST VESSELS TO PREVENT SCOMBROTOXIN FORMATION[1]

WHEN…		THEN, THE MAXIMUM TIME IN HOURS TO GET THE FISH INTO CHILLING MEDIUM (≤ 40°F) FROM THE TIME OF…	
THE WATER TEMPERATURE (°F) IS…	AND THE AIR TEMPERATURE (°F) IS…	DEATH OF THE FISH OR EARLIEST ESTIMATED TIME OF DEATH IS…	ONBOARD LANDING IS…
FOR UNEVISCERATED FISH:			
> 65	> 83	6	--
> 83	Any	6	--
> 65, but ≤ 83	≤ 83	9	--
≤ 65[2]	> 83	--	6
≤ 65[2]	≤ 83	--	9
FOR FISH EVISCERATED ONBOARD BEFORE CHILLING:			
> 65	Any	12	--
≤ 65[2]	Any	--	12

1. This table is a summary of the preceding recommendations. For complete understanding of the recommendations, refer to the text above.
2. Provided exposure of the fish in the water at 65°F or less is ≤ 24 hours.

The controls listed above for onboard chilling will prevent the rapid formation of the enzyme histidine decarboxylase. Once this enzyme is formed, control of the hazard is unlikely. It is important to recognize that the parameters listed above are intended to control scombrotoxin formation; these criteria may not effectively control the activity of other spoilage organisms, raising the possibility that fish may become adulterated because of decomposition (not a food safety hazard covered by the Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123, called the Seafood Hazard Analysis Critical Control Point (HACCP) Regulation in this guidance document) before scombrotoxin (histamine) is formed.

Further chilling toward the freezing point is also desirable to safeguard against the less common, longer term, lower temperature development of histamine. Additionally, the shelf life and quality of the fish are significantly compromised when product temperature is not rapidly dropped to near freezing.

Although it may be possible for a harvest vessel to completely avoid onboard chilling and still deliver fish to the processor within the time and temperature limitations recommended above for chilling the fish, this practice is discouraged. Failure to chill onboard may permit bacteria and enzymes, including those that form scombrotoxin (histamine), to increase unnecessarily.

The time required to lower the internal temperature of fish after capture will be dependent upon a number of factors, including:

- The harvest method:
  - Delays in removing fish from the water after capture, such as those captured by a longline, may significantly limit the amount of time left for chilling and may allow some fish to heat up;
  - Large quantities of fish captured in a single fishing set, such as those captured on a purse seiner, may exceed a vessel's ability to rapidly chill the product;
- The size of the fish;
- The chilling method:
  - Ice alone takes longer to chill fish than does an ice slurry or recirculated refrigerated seawater or brine, a consequence of reduced contact area and heat transfer;
  - The quantity of ice or ice slurry and the capacity of refrigerated seawater or brine systems, as well as the physical arrangement of the fish in the chilling media, should be suitable for the quantity of catch.

Once chilled, the scombrotoxin-forming fish should be maintained as close as possible to the freezing point (or held frozen) until it is consumed. Exposure to temperatures above 40°F (4.4°C) should be minimized. The amount of post-harvest time at elevated temperatures (after proper chilling onboard the harvest vessel) to which a fish can be exposed (e.g., during processing, storage, and distribution) without adverse effects is dependent primarily upon whether the fish was previously frozen (e.g., onboard the harvest vessel) or heat processed sufficiently to destroy scombrotoxin-forming bacteria.

Extended frozen storage (e.g., 24 weeks) or cooking minimizes the risk of additional histamine development by inactivating the enzyme-forming bacteria and, in the case of cooking, the enzyme itself. As previously mentioned, recontamination with enzyme-forming bacteria and significant temperature abuse is necessary for histamine formation following cooking. Such recontamination may not be likely if the fish is processed under a conscientious sanitation program. However, addition of raw ingredients, employee contact, or poor sanitary conditions could reintroduce contamination. Further guidance is provided below:

- Scombrotoxin-forming fish that have not been previously frozen or heat processed sufficiently to destroy scombrotoxin-forming bacteria should not be exposed to

temperatures above 40°F (4.4°C) for:

- More than 4 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C); or
- More than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C).

- Scombrotoxin-forming fish that have been previously frozen, or heat processed sufficiently to destroy scombrotoxin-forming bacteria and are subsequently handled in a manner in which there is an opportunity for recontamination with scombrotoxin-forming bacteria (e.g., contact with fresh fish, employees, or introduction of raw ingredients), should not be exposed to temperatures above 40°F (4.4°C) for:
  - More than 12 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C); or
  - More than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C);
- Scombrotoxin-forming fish that have been heat processed sufficiently to destroy scombrotoxin-forming bacteria and enzymes and are not subsequently handled in a manner in which there is an opportunity for recontamination with scombrotoxin-forming bacteria (e.g., no contact with fresh fish, employees, or raw ingredients) are at low risk for further scombrotoxin (histamine) development.

TABLE 7-2

RECOMMENDED MAXIMUM HOURS OF EXPOSURE OF SCOMBROTOXIN-FORMING FISH TO AMBIENT TEMPERATURES GREATER THAN 40°F TO PREVENT SCOMBROTOXIN FORMATION AFTER PROPER ONBOARD HARVEST VESSEL CHILLING, FOR DIFFERING TEMPERATURE EXPOSURE AND PREVIOUS PROCESSING CONDITIONS[1]

WHEN THE AMBIENT TEMPERATURE (°F) OF EXPOSURE IS…	THEN, THE MAXIMUM HOURS OF EXPOSURE TIME FOR…	
	Fresh fish (not heat processed or previously frozen) is …	Previously frozen fish, or heat processed fish (that has been exposed to possible recontamination), is…
> 70 AT ANY TIME	≤ 4	≤ 12
≤ 70 DURING ENTIRE EXPOSURE	≤ 8	≤ 24

1. This table is a summary of the preceding recommendations. For complete understanding of the recommendations, refer to the text above.

- **Detection**

Sensory evaluation

Sensory evaluation is generally used to screen fish for indicators of spoilage that develop when the fish is exposed to time and temperature abuse. Odor in particular is an effective means of detecting fish that have been subjected to a variety of abusive conditions. However, odors of decomposition that are typical of relatively low temperature spoilage may not be present if the fish has undergone high temperature spoilage. This condition makes sensory examination alone an ineffective control for preventing scombrotoxin (histamine) formation.

It is important to recognize that the Federal Food, Drug, and Cosmetic Act (the FFD&C Act) prohibits interstate commerce of adulterated foods (21 U.S.C. 331). Under the FFD&C Act, a food that is decomposed is considered adulterated (21 U.S.C 342). Accordingly, a fish or fishery product that is decomposed in whole or in part is prohibited from entering interstate commerce even if the type of decomposition may not lead to scombrotoxin (histamine) formation. You should distinguish between recommendations in this chapter for sensory screening, as a component of a HACCP control strategy for scombrotoxin formation, and your obligation to avoid otherwise violating the FFD&C Act with regard to the distribution of decomposed food.

Chemical testing

Chemical testing is an effective means of detecting the presence of histamine in fish flesh. However, the variability in histamine levels between fish and within an individual fish can be large, even in fish from the same harvest vessel. For this reason, a guidance level has been set of 50 ppm histamine in the edible portion of fish. If 50 ppm is found in one section of a fish or lot, there is the possibility that other sections may exceed 500 ppm.

Because histamine is generally not uniformly distributed in a fish or a lot, the validity of histamine testing is dependent upon the design of the sampling plan. The amount of sampling required to accommodate such variability of distribution is necessarily quite large. The method of collection of the fish sample is also critical. In large scombrotoxin-forming fish, the lower, anterior (forward) portion of the fish loin (not the belly flap) is likely to provide the best information about the histamine content of the fish. The number of samples (i.e., scombrotoxin-forming fish) necessary to make a judgment about a lot depends on the anticipated variability, but should not be fewer than 18 samples per lot, unless the lot contains less than 18 fish, in which case a sample should be collected from each fish.

Where samples are composited to reduce the number of analyses needed on a lot, it should be done in a manner that ensures meaningful results. No more than three samples should be composited, in order to minimize masking of problematic fish. Furthermore, the analytical method and instrument used should be capable of reliably detecting histamine at the lower levels that are necessary for composited samples (e.g., 17 ppm histamine in a three-sample composite, rather than 50 ppm in an uncomposited sample).

Combining additional indicators of conditions that can lead to histamine formation, such as sensory examination and internal temperature measurement, with histamine testing can provide better assurance of product safety. Observation for the presence of honeycombing (voids in the fish flesh) in cooked tuna loins intended for canning is a valuable means of screening for fish that have been exposed to the kinds of temperature abuse that can lead to histamine development. Any scombrotoxin-forming fish that demonstrate the trait should be destroyed or diverted to a non-food use.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether scombrotoxin (histamine) formation is a significant hazard at a processing step:

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

   Table 3-2 (Chapter 3) lists those species of fish that are generally known to be capable of producing elevated levels of histamine if temperature abused. Such species of fish have this capability because they contain naturally high levels of histidine. They also have this capability because they are marine fish that are likely to harbor the kinds of bacteria that produce histidine decarboxylase. It is, therefore, reasonable to assume that without proper onboard vessel controls, these species of fish will contain unsafe levels of histamine upon receipt by the primary (first) processor.

   However, if the worst case environmental conditions (i.e., air and water temperatures) during the harvest season in a particular region would not permit the formation of histamine during the time necessary to harvest and transport the fish to the primary processor, onboard controls may not be necessary. For example, such conditions might exist if the fish are harvested when air and water temperatures do not exceed 40°F (4.4°C), as evidenced by supporting data.

   It is also reasonable to assume that without proper controls during refrigerated (not frozen) transportation between processors, scombrotoxin-forming species of fish will contain unsafe levels of histamine upon receipt by the secondary processor (including warehouses). In addition, you may need to exercise control to prevent pathogen growth or toxin formation when receiving a refrigerated (not frozen) raw or cooked product from another processor (see Chapter 12). The in-transit controls for secondary processors recommended in Chapter 12 are similar to those recommended in this chapter.

2. Is it reasonably likely that unsafe levels of histamine will form at this processing step?

   To answer this question, you should consider the potential for time and temperature abuse in the absence of controls. You may already have controls in your process that minimize the potential for time and temperature abuse that could result in unsafe levels of histamine. This guidance will help you determine whether those or other controls should be included in your HACCP plan.

   Time and temperature abuse that occurs at successive processing and storage steps may be sufficient to result in unsafe levels of histamine, even when abuse at one step alone would not result in such levels. For this reason, you should consider the cumulative effect of time and temperature abuse during the entire process. Information is provided above to help you assess the significance of time and temperature abuse that may occur in your process.

3. Can unsafe levels of histamine formation that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Scombrotoxin (histamine) formation should also be considered a significant hazard at any processing or storage step where a preventive measure is or can be used to eliminate the hazard if it is reasonably likely to occur. Preventive measures for scombrotoxin (histamine) formation can include:

   - Examining harvest vessel records to ensure that incoming fish were properly handled onboard the harvest vessel, including:
     - Rapidly chilling the fish immediately after death;

- Controlling onboard refrigeration (other than frozen storage) temperatures;
- Performing proper onboard icing;

- Testing incoming fish for histamine levels;
- Ensuring that incoming fish were handled properly during refrigerated transportation from the previous processor, including:
  - Controlling refrigeration temperatures during transit;
  - Performing proper icing during transit;
- Checking incoming fish to ensure that they are not at an elevated temperature at time of receipt;
- Checking incoming fish to ensure that they are properly iced or refrigerated at time of receipt;
- Performing sensory examination on incoming fish to ensure that they do not show signs of decomposition;
- Controlling refrigeration temperatures in your plant;
- Performing proper icing in your plant;
- Controlling the amount of time that the product is exposed to temperatures that would permit histamine formation during processing.

These preventive measures are ordinarily employed at receiving, processing, and storage steps.

- **Intended use**

Because of the heat stable nature of histamine, the intended use of the product is not likely to affect the significance of this hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for scombrotoxin (histamine) formation:

1. If scombrotoxin (histamine) formation is a significant hazard at the receiving step, you should identify receiving as a CCP for this hazard.

   a. If you are the primary processor of the scombrotoxin-forming fish (i.e., if you receive the fish directly from the harvest vessel) and have a relationship with the operator of the harvest vessel(s) from which you purchase fish that enables you to obtain documentation of onboard practices, you should identify the following preventive measures for control of this hazard:

      - Examining harvest vessel records to ensure that incoming fish were properly handled onboard the harvest vessel, including:
        - Rapidly chilling the fish immediately after death;
        - Controlling onboard refrigeration (other than frozen storage) temperatures;
        - Performing proper onboard icing;
      - Checking incoming fish to ensure that they are not at an elevated temperature at time of receipt; and,
      - Performing sensory examination of incoming fish to ensure that they do not show signs of decomposition.

      Example:

      A mahi-mahi processor that regularly purchases from the same harvest vessels should require harvest vessel records as a condition of purchase.

The processor should also check the internal temperatures of incoming fish and perform sensory examination of these fish. The processor should then set a CCP for histamine formation at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Harvest Vessel Control."

b. If you are the primary processor of the scombrotoxin-forming fish (i.e., if you receive the fish directly from the harvest vessel) and do not have a relationship with the operator of the harvest vessel(s) that enables you to obtain documentation of onboard practices, you should identify the following preventive measures for control of this hazard:

- Testing incoming fish for histamine levels;
- Checking incoming fish to ensure that they are not at an elevated temperature at time of receipt and,
- Performing sensory examination of incoming fish to ensure that they do not show signs of decomposition.

Example:

A canned tuna processor that purchases from a variety of harvest vessels should subject incoming fish from each harvest vessel to histamine testing, internal temperature checks, and sensory examination. The processor should then set a CCP for histamine formation at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Histamine Testing."

c. If you are a secondary processor of the scombrotoxin-forming fish (i.e., if you receive the fish from another processor), you should identify the following preventive measures for control of this hazard:

- Ensuring that incoming fish were properly refrigerated during transportation from the previous processor, by controlling refrigeration temperatures during transit or,
- Checking incoming fish to ensure that they are properly iced at time of receipt.

Example:

A tuna processor that receives fish from another processor should require evidence of temperature control throughout transit as a condition of receipt. The processor should then set a CCP for histamine formation at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 3 - Transit Control." This control strategy, in addition to "Control Strategy Example 1 - Harvest Vessel Control" or "Control Strategy Example 2 - Histamine Testing," may also be applicable if you are a primary processor and transport the fish by truck from your harvest vessel unloading site to your processing facility.

2. If scombrotoxin (histamine) formation is a significant hazard at one or more processing steps, you should identify the processing step(s) as a CCP for this hazard.

a. The preventive measure for this type of control is:

- Controlling the amount of time that the scombrotoxin-forming product is exposed to temperatures that would permit histamine formation during processing.

Example:

A mahi-mahi processor should control histamine formation by limiting exposure time and temperature of the product during processing. The processor should then set CCPs for histamine formation at the processing steps.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Processing Control." This control strategy is intended for processing at ambient and air-conditioned temperatures. "Control Strategy Example 5 - Storage Control" may be more appropriate for processing under refrigerated conditions.

3. If scombrotoxin (histamine) formation is a significant hazard at a storage step for raw material, in-process product, or finished product, you should identify the storage step(s) as a CCP for this hazard.

   a. The preventive measures for this type of control are:

      - Controlling refrigeration temperatures in your plant or,
      - Performing proper icing in your plant.

   Example:

   A mahi-mahi processor should control histamine formation by icing the product during raw material, in-process product, and finished product storage. The processor should then set CCPs for histamine formation at the storage steps.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 5 - Storage Control."

- **Likely CCPs**

  Following is further guidance on processing steps that are likely to be identified as CCPs for this hazard:

  - Receiving;
  - Processing, such as:
    - Thawing;
    - Brining and salting;
    - Smoking;
    - Heading and gutting;
    - Manual filleting and steaking;
    - Fermenting;
    - Pickling;
    - Drying;
    - Stuffing;
    - Mixing (e.g., salad preparation);
    - Portioning;
  - Packaging;
  - Final chilling after processing and packaging;
  - Storing raw material, in-process product, and finished product under refrigeration.

Note: Rather than identify each processing step as an individual CCP when the controls are the same at those steps, it may be more convenient to combine into one CCP those processing steps that together contribute to a cumulative time and temperature exposure.

- **Unlikely CCPs**

  Time and temperature controls will usually not be needed at processing steps that meet the following conditions:

  - Continuous, mechanical processing steps that are brief, such as:
    - Mechanical filleting;
  - Processing steps that are brief and unlikely to contribute significantly to the cumulative time and temperature exposure, such as:
    - Date code stamping;
    - Case packing;
  - Processing steps where the product is held in a frozen state, such as:
    - Assembly of orders for distribution;
    - Frozen product storage;

- Retorting and post-retorting steps (if the product is covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (called the Low-Acid Canned Foods Regulation in this guidance document));

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of five control strategies for scombrotoxin (histamine) formation. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Harvest vessel control	✓	
Histamine testing	✓	
Transit control	✓	✓
Processing control	✓	✓
Storage Control	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

The critical limits for this control strategy should include three components:

- Harvest vessel records;
- Sensory examination;
- Internal temperature measurements.

Harvest vessel records:

- All scombrotoxin-forming fish lots received are accompanied by harvest vessel records that show:
  - Fish exposed to air or water temperatures above 83°F (28.3°C) were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not longer than 6 hours from the time of death;

    OR
  - Fish exposed to air and water temperatures of 83°F (28.3°C) or less were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not longer than 9 hours from the time of death;

    OR
  - Fish that were gilled and gutted before chilling were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not longer than 12 hours from the time of death;

    OR
  - Fish that were harvested under conditions that expose dead fish to harvest waters of 65°F (18.3°C) or less for 24 hours or less were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than the time limits listed above, with the time period starting when the fish left the 65°F (18.3°) or less environment;

    OR
  - Other critical limits for onboard handling (e.g., maximum refrigerated brine or seawater temperature, maximum fish size, maximum fish to brine/seawater/ ice ratio, maximum initial temperature of

the fish) necessary to achieve a cooling rate that will prevent development of an unsafe level of histamine in the specific species, as established through a scientific study.

Note: If the actual time of death is not known, an estimated time of the first fish death in the set may be used (e.g., the time the deployment of a longline begins). Table 7-1 provides a summary of the preceding recommended critical limits.

AND

- For fish held refrigerated (not frozen) onboard the vessel:
  - The fish were stored at or below 40°F (4.4°C) after cooling;

    OR
  - The fish were stored completely and continuously surrounded by ice after cooling;

AND

Sensory examination:

- Sensory examination of a representative sample of scombrotoxin-forming fish shows decomposition (persistent and readily perceptible) in less than 2.5% of the fish in the sample. For example, no more than 2 fish in a sample of 118 fish may show signs of decomposition. Note that the FFD&C Act prohibits interstate commerce of any decomposed fish whether or not the HACCP critical limit has been exceeded;

AND

Internal temperature measurements:

- For fish held iced or refrigerated (not frozen) onboard the vessel 24 or more hours after death:
  - The internal temperature should be 40°F (4.4°C) or below;

    OR
- For fish held iced or refrigerated (not frozen) onboard the vessel from 15 to less than 24 hours after death:
  - The internal temperature should be 50°F (10°C) or below;

    OR
- For fish held iced or refrigerated (not frozen) onboard the vessel from 12 to less than 15 hours after death:
  - The internal temperature should be 60°F (15.6°C) or below;

    OR
- For fish held iced or refrigerated (not frozen) onboard the vessel less than 12 hours after death:
  - The internal temperature should be sufficiently below water and air temperatures to indicate that appropriate chilling methods were implemented onboard the harvest vessel. Chilling of the fish should begin on the harvest vessel regardless of the time from death until off-loading from the vessel by the processor unless the environmental conditions (e.g., air and water temperatures) are below 40°F (4.4°C) from the time of death until off-loading from the vessel by the processor;

    OR
- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Elapsed time from death and internal temperatures at the time of off-loading from the vessel by the processor should be consistent with cooling curves that will prevent development of an unsafe level of histamine in the specific species, as established through a scientific study.

Establish Monitoring Procedures.

» What Will Be Monitored?

Harvest vessel records containing the following information:

- Method of capture*;

  AND
- Where applicable to the critical limit, the

date and time of landing the fish onboard the harvest vessel;

AND

- Where applicable to the critical limit, the estimated earliest date and time of death for fish brought onboard in the fishing set (e.g., trawl, gillnet, longline, or purse seine);

AND

- Where applicable to the critical limit, the air and water temperatures at the time of landing the fish onboard the harvest vessel*;

AND

- Where applicable to the critical limit, the water temperature at the depth where dead fish may remain until harvest;

AND

- Where applicable to the critical limit, the method of cooling* and temperature of the cooling medium;

AND

- Where applicable to the critical limit, the date and time cooling began and/or the date and time when the last fish in a fishing set (e.g., trawl, gillnet, longline, or purse seine) was placed in the cooling medium;

AND

- Where applicable to the critical limit, those factors of the cooling process that have been established through a scientific study as critical to achieving the cooling rate critical limits (e.g., refrigerated brine or seawater temperature, fish size, fish to brine/seawater/ice ratio, maximum initial temperature of the fish);

AND

- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - The storage temperature, as evidenced by:
    - The temperature of refrigerated seawater or brine in which the fish are stored;

    OR

    - The presence of ice that completely and continuously surrounds the fish.

(*These items may be documented by the primary (first) processor, on the receiving records, rather than by the harvest vessel operator, on the harvest vessel records, provided the primary processor has direct knowledge about those aspects of the harvesting practices and has made first-hand observations for each lot received. The vessel operator should document other onboard handling information. The primary processor should maintain all relevant information.)

AND

Sensory examination:

- Amount of decomposition in the lot;

AND

Internal temperature measurement:

- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - The internal temperature of a representative number of the largest fish in the lot at the time of off-loading from the harvest vessel, concentrating on any fish that show signs of having been mishandled (e.g., inadequately iced);

    AND

  - Date and time of off-loading.

    Example:

    A primary processor receives bluefish from several day-boats that catch the fish when the air and water temperatures are below 83°F (28.3°C). The day-boats take on ice at the processor's facility immediately before setting out for the day and return within 9 hours to the processor's facility with the iced catch. The processor monitors and records the date and time of departure of the vessels after they take on ice; the date and time of the return of the vessels; the ambient water and air temperatures of the fishing grounds; and the adequacy of icing of the catch at the time of off-loading. The processor also conducts sensory evaluations and checks the internal

temperature of the catch upon arrival. The harvest vessel operators perform no monitoring or record keeping.

» **How Will Monitoring Be Done?**

- For harvest vessel records:
  - Review controls documented in the records;

  AND
- For sensory examination:
  - Examine at least 118 fish, collected representatively throughout each lot (or the entire lot, for lots smaller than 118 fish). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Lots should consist of only one species of fish; for vessels delivering multiple species, testing should generally be done separately on each species. All fish within a lot should have a similar history of harvest. If the fish are received frozen, this monitoring procedure may be performed by a sensory examination on the warmed flesh produced by drilling the frozen fish (drill method). It may also be performed after thawing, rather than at receipt;

  AND
- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Use a temperature-indicating device (e.g., a thermometer) to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on any that show signs of having been mishandled (e.g., inadequately iced). For example, when receiving 10 tons or more of fish, measure a minimum of one fish per ton, and when receiving less than 10 tons of fish, measure a minimum of one fish per 1,000 pounds. Measure a minimum of 12 fish, unless there are fewer than 12 fish in the lot, in which case measure all of the fish. Randomly select fish from throughout the lot. Lots that show a high level of temperature variability or lots of very small fish may require a larger sample size;

    AND
  - Visually determine the date and time of off-loading.

» **How Often Will Monitoring Be Done (Frequency)?**

- Every lot of scombrotoxin-forming fish received.

» **Who Will Do the Monitoring?**

- For sensory examination:
  - Any person who is qualified by experience or training to perform the examination;

  AND
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective actions to a product involved in a critical limit deviation:

- In the absence of harvest vessel records or when one of the harvester-related critical limits has not been met, or when the internal temperature critical limit at receiving has not been met:
  - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including any fish measured to have temperatures that exceeded the critical limit (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited for analysis if the action point is reduced accordingly. For

example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

OR

- Reject the lot;

AND

- When the sensory examination critical limit has not been met:
  - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including all fish in the lot that show evidence of decomposition (persistent and readily perceptible odors) (or the entire lot for lots smaller than 60 fish), and reject the lot if any fish is found with histamine greater than or equal to 50 ppm;

    AND

  - If any fish in the lot are to proceed into commerce for food use, perform a sensory examination of all fish in the lot to ensure that no decomposed fish proceed;

    AND

  - Any individual fish found to be decomposed (persistent and readily perceptible) should be destroyed or diverted to a non-food use;

    OR

  - Reject the lot.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Discontinue use of the supplier until evidence is obtained that the identified harvesting and onboard practices and controls have been improved.

Establish a Recordkeeping System.

- Harvest vessel records containing the information described above;

  AND

- Receiving records showing the date and time of off-loading;

  AND

- Results of sensory examination;

  AND

- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Internal temperatures of the fish.

Establish Verification Procedures.

- Collect a representative sample of the raw material, in-process product, or finished product, and analyze it for histamine at least quarterly;

  AND

- Ensure that new sensory examiners receive training to calibrate their ability to identify decomposed fish and that all sensory examiners receive periodic refresher training;

  AND

- Where histamine testing is part of a corrective action plan, periodically verify the findings (e.g., by comparing results with those obtained using an Association of Official Analytical Chemists (AOAC) method);

  AND

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a

known accurate reference device (e.g., a thermometer traceable to the National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

OR

- Following the manufacturer's instructions;

AND

- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

AND

- Calibrate the temperature-indicating device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 7-3

CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Harvest Vessel Control." This example illustrates how a fresh mahi-mahi processor that receives the fish on ice directly from harvest vessels that use a hook and line technique (fish brought onboard alive) can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving fresh mahi-mahi on ice from harvest vessels	Scombrotoxin formation	All lots received are accompanied by harvest vessel records that show (1) placement of fish on ice within 9 hours of death if the maximum exposure temperature does not exceed 83°F or within 6 hours if the maximum exposure temperature exceeds 83°F; (2) The fish were stored completely and continuously surrounded by ice after capture	Harvest vessel records	Review of controls documented in the records	Every lot received	Receiving supervisor	Reject the lot Discontinue use of the supplier until evidence is obtained that harvesting and onboard practices and controls have been improved	Harvester vessel records	Perform histamine analysis on 1 incoming lot every 3 months (18 fish per sample) Review monitoring, corrective action, and verification records within 1 week of preparation
		Less than 2.5% decomposition (persistent and readily perceptible) in the incoming lot	Amount of decomposition in the incoming lot	Sensory examination (118 fish per lot; or all fish in the lot if less than 118 fish)	Every lot received	Quality control staff		Receiving record	Provide sensory training for new fish examiners and annual training for all fish examiners Review monitoring, corrective action, and verification records within 1 week of preparation
		Internal temperatures of all fish are to meet the following criteria based on the time since the death of the fish: >24 hours → ≤ 40° 15 to < 24 hours → ≤ 50° 12 to < 15 hours→ ≤ 60° < 12 hours → below ambient air and water temperatures commensurate with size of fish and time since death	Internal temperature of the fish at time of off-loading from vessel; Date and time of off-loading	Digital thermometer (1 fish/1,000 pounds; minimum of 12 fish per lot)	Every lot received	Receiving supervisor		Receiving record	Check the digital thermometer for accuracy and damage and to ensure that it is operational before putting it into operation; perform these same checks daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

The critical limits for this control strategy should include three components:

- Histamine testing;
- Sensory examination;
- Internal temperature measurements.

Histamine testing:

- Analysis of a representative sample of scombrotoxin-forming fish shows less than 50 ppm histamine in all fish in the sample;

AND

Sensory examination:

- Sensory examination of a representative sample of scombrotoxin-forming fish shows decomposition (persistent and readily perceptible) in less than 2.5% of the fish in the sample. For example, no more than 2 fish in a sample of 118 fish may show signs of decomposition. Note that the FFD&C Act prohibits interstate commerce of any decomposed fish whether or not the HACCP critical limit has been exceeded;

AND

Internal temperature measurements:

- For fish held iced or refrigerated (not frozen) onboard the vessel 24 or more hours after death:
  - The internal temperature should be 40°F (4.4°C) or below;

  OR
- For fish held iced or refrigerated (not frozen) onboard the vessel from 15 to less than 24 hours after death:
  - The internal temperature should be 50°F (10°C) or below;

  OR
- For fish held iced or refrigerated (not frozen) onboard the vessel from 12 to less than 15 hours after death:
  - The internal temperature should be 60°F (15.6°C) or below;

  OR
- For fish held iced or refrigerated (not frozen) onboard the vessel less than 12 hours after death:
  - The internal temperature should be sufficiently below water and air temperatures to indicate that appropriate chilling methods were implemented onboard the harvest vessel. Chilling of the fish should begin on the harvest vessel regardless of the time from death until off-loading from the vessel by the processor, unless the environmental conditions (e.g. air and water temperatures) are below 40°F (4.4°C) from the time of death until off-loading from the vessel by the processor;

  OR
- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Elapsed time from death and internal temperatures at the time of off-loading from the vessel by the processor should be consistent with cooling curves that will prevent development of an unsafe level of histamine in the specific species, as established through a scientific study.

Establish Monitoring Procedures.

» What Will Be Monitored?

Histamine testing:

- Histamine content in the scombrotoxin-forming fish flesh;

AND

Sensory examination:

- Amount of decomposition in the scombrotoxin-forming fish lot;

AND

Internal temperature measurement:

- For scombrotoxin-forming fish held iced or refrigerated (not frozen) onboard the vessel:
  - The internal temperature of a representative number of the largest fish in the lot at the time of off-loading from the harvest vessel by the processor, concentrating on any fish that show signs of having been mishandled (e.g., inadequately iced);

    AND
  - Date and time of off-loading.

» How Will Monitoring Be Done?

- For histamine analysis:
  - Test a minimum of 18 fish, collected representatively throughout each lot (or the entire lot when there are fewer than 18 fish in the lot). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Lots should consist of only one species of fish; for vessels delivering multiple species, testing should generally be done separately on each species. Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the critical limit is reduced accordingly. For example, a sample of 18 fish may be composited into 6 units of 3 fish each, provided the critical limit is reduced from 50 ppm to 17 ppm for each unit;

    AND
- For sensory examination:
  - Examine at least 118 fish, collected representatively throughout each lot (or the entire lot, for lots smaller than 118 fish). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Lots should consist of only one species of fish; for vessels delivering multiple species, testing should generally be done separately on each species. If the fish are received frozen, this monitoring procedure may be performed by a sensory examination on the warmed flesh produced by drilling the frozen fish (drill method). It may also be performed after thawing, rather than at receipt;

    AND
- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Use a temperature-indicating device (e.g., a thermometer) to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on any that show signs of having been mishandled (e.g., inadequately iced). For example, when receiving 10 tons or more of fish, measure a minimum of one fish per ton, and when receiving less than 10 tons of fish, measure a minimum of one fish per 1,000 pounds. Measure a minimum of 12 fish, unless there are fewer than 12 fish in the lot, in which case measure all of the fish. Randomly select fish from throughout the lot. Lots that show a high level of temperature variability or lots of very small fish may require a larger sample size;

    AND
  - Visually determine the date and time of off-loading.

» **How Often Will Monitoring Be Done (Frequency)?**

- Every lot of scombrotoxin-forming fish received.

» **Who Will Do the Monitoring?**

- For sensory examination and histamine testing:
  - Any person who is qualified by experience or training to perform the work;

  AND

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective actions to a product involved in a critical limit deviation:

- When the histamine-level critical limit at the receiving step has not been met, reject the lot;

  AND

- When the internal temperature critical limit has not been met:
  - If histamine did not exceed 50 ppm in the initial testing:
    - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including any fish measured to have temperatures that exceeded the critical limit (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited for analysis if the action point is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

    OR

    - Reject the lot;

  AND

- When the sensory examination critical limit has not been met:
  - If histamine did not exceed 50 ppm in the initial testing:
    - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including all fish in the lot that show evidence of decomposition (persistent and readily perceptible odors) (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited for analysis if the action point is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

    AND

  - If any fish in the lot are to proceed into commerce for food use, perform a sensory examination of all fish in the lot to ensure that no decomposed fish proceed;

    AND

  - Any individual fish found to be decomposed (persistent and readily perceptible) should be destroyed or diverted to a non-food use;

    OR

  - Reject the lot.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Discontinue use of the supplier until evidence is obtained that the identified harvesting and onboard practices have been improved.

Establish a Recordkeeping System.

- Receiving records showing:
  - Date and time of off-loading;

  AND
- Results of histamine analysis;

  AND
- Results of sensory examination;

  AND
- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Internal temperatures of the fish.

Establish Verification Procedures.

- Periodically verify histamine findings (e.g., by comparing results with those obtained using an AOAC method or by analyzing proficiency samples);

  AND
- Ensure that new sensory examiners receive training to calibrate their ability to identify decomposed fish and that all sensory examiners receive periodic refresher training;

  AND
- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

    OR
  - Following the manufacturer's instructions;

  AND
- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

  AND
- Calibrate the temperature-indicating device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND
- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 7-4

CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Histamine Testing." This example illustrates how a canned tuna processor that receives frozen tuna directly from the harvest vessel can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., Clostridium botulinum growth and toxin formation).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving frozen tuna from harvest vessels	Scombrotoxin formation	Less than 50 ppm histamine in all fish in the sample	Fish flesh for histamine content	Histamine testing using the AOAC 977.13 method on a minimum of 18 fish per lot (36 fish from vessels with high variability of histamine detected between fish or when 1 of the first 18 fish exceeds 30 ppm histamine)	Every lot received	Quality assurance staff	Reject the lot; Discontinue use of the supplier until evidence is obtained that harvesting and onboard practices have been improved If the initial histamine sample was <50 ppm, perform histamine analysis on a min, of 60 fish, collected representatively from the lot and reject the lot if any fish contains ≥50 ppm histamine; and if all fish <50 ppm	Reports of histamine analysis	Do a quarterly comparison of histamine test results with AOAC method Review monitoring, corrective action, and verification records within 1 week of preparation
		Less than 3 decomposed fish (persistent and readily perceptible) in a 118-fish sample	Amount of decomposition in the incoming lot	Sensory examination (118 fish per lot, or all fish if lot is less than 118 fish)	Every lot received	Quality assurance staff	Conduct sensory evaluation of all fish in the lot, removing and destroying all decomposed fish Discontinue use of the supplier until evidence is obtained that harvesting and onboard practices have been improved	Sensory examination record	Provide sensory training for new fish examiners and annual training for all fish examiners Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- For fish delivered refrigerated (not frozen):
  - All lots received are accompanied by transportation records that show that the fish were held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit. Note that allowance for routine refrigeration defrost cycles may be necessary;

  OR
- For fish delivered under ice:
  - Fish are completely surrounded by ice at the time of delivery;

  OR
- For fish delivered under ice on an open-bed truck:
  - Fish are stored completely surrounded by ice;

    AND
  - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;

  OR
- For fish delivered under chemical cooling media such as gel packs:
  - There is an adequate quantity of cooling media that remain frozen to have maintained product at an internal temperature of 40°F (4.4°C) or below throughout transit;

    AND
  - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;

  OR
- For fish delivered refrigerated (not frozen) with a transit time (including all time outside a controlled temperature environment) of 4 hours or less (optional control strategy):
  - Time of transit does not exceed 4 hours;

    AND
  - Internal temperature of the fish at the time of delivery does not exceed 40°F (4.4°C).

Note: Processors receiving fish with transit times of 4 hours or less may elect to use one of the controls described for longer transit times instead.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For scombrotoxin-forming fish delivered refrigerated (not frozen):
  - The internal temperature of the fish throughout transportation;

    OR
  - The ambient temperature within the truck or other carrier throughout transportation;

  OR
- For scombrotoxin-forming fish delivered under ice:
  - The adequacy of ice surrounding the product at the time of delivery;

  OR
- For scombrotoxin-forming fish delivered under ice on an open-bed truck:
  - The adequacy of ice surrounding the product at the time of delivery;

    AND
  - The internal temperature of the fish at time of delivery;

  OR
- For scombrotoxin-forming fish held under chemical cooling media such as gel packs:
  - The quantity and frozen status of cooling media at the time of delivery;

    AND
  - The internal temperature of the fish at the time of delivery;

OR

- For scombrotoxin-forming fish delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - The date and time fish were removed from a controlled temperature environment before shipment and the date and time delivered;

    AND
  - The internal temperature of a representative number of fish at the time of delivery.

» **How Will Monitoring Be Done?**

- For fish delivered refrigerated (not frozen):
  - Use a continuous temperature-recording device (e.g., a recording thermometer) for internal product temperature or ambient air temperature monitoring during transit;

    OR
- For fish delivered under ice:
  - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the shipment, at delivery;

    OR
- For fish delivered under ice on an open-bed truck:
  - Make visual observations of the adequacy of ice surrounding the product in a representative number of containers (e.g., cartons and totes) from throughout the shipment, at delivery;

    AND
  - Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of fish from throughout the shipment, at delivery;

    OR
- For fish delivered under chemical cooling media such as gel packs:
  - Make visual observations of the adequacy and frozen state of the cooling media in a representative number of containers (e.g., cartons and totes) from throughout the shipment;

    AND
  - Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of fish from throughout the shipment, at delivery;

    OR
- For fish delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - Review carrier records to determine the date and time fish were removed from a controlled temperature environment before shipment and the date and time delivered;

    AND
  - Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of fish randomly selected from throughout the shipment, at delivery. Measure a minimum of 12 fish, unless there are fewer than 12 fish in a lot, in which case measure all of the fish. Lots that show a high level of temperature variability or lots of very small fish may require a larger sample size.

» **How Often Will Monitoring Be Done (Frequency)?**

- Every scombrotoxin-forming fish lot received.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls;

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the affected lot until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including any with temperatures that exceeded a critical limit and any fish observed to have been exposed to inadequate cooling media (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish is found with histamine greater than or equal to 50 ppm.

  The fish collected for analysis may be composited if the action point is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

  OR

- Reject the lot.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation-handling practices have been improved.

Establish a Recordkeeping System.

- Receiving records showing:
  - For continuous temperature monitoring:
- Printouts, charts, or readings from temperature-recording devices (e.g., temperature recorder);

  OR

  - For ice checks:
    - The number of containers examined and the sufficiency of ice for each;

      AND

    - The number of containers in the lot;

    OR
  - For chemical cooling media checks:
    - The number of containers examined and the frozen status of the cooling media for each;

      AND

    - The number of containers in the lot;

    AND
  - Results of internal product temperature monitoring, where applicable, including:
    - The number of containers examined and the internal temperatures observed for each;

      AND

    - The number of containers in the lot;

    AND
  - Date and time fish were initially removed from a controlled temperature environment and the date and time fish were delivered, when applicable.

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used

(e.g., product internal temperature) within the temperature range at which it will be used;

OR

- Following the manufacturer's instructions;

AND

- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

AND

- Calibrate the temperature-indicating device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions upon receipt of each lot. The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

- When visual checks of ice are used, periodically measure internal temperatures of fish to ensure that the ice are sufficient to maintain product temperatures at 40°F (4.4°C) or less;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 7-5

CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Transit Control." This example illustrates how a fresh mahi-mahi secondary processor that receives the product by air under chemical coolant (gel packs) can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving	Scombrotoxin formation	Adequate quantity of frozen gel packs to maintain the product at 40°F or less throughout transit; and	Quantity and frozen condition of gel packs	Visual observation of a minimum of 25% of shipping containers in the lot but not fewer than 12 containers (or all containers if lot has less than 12 containers)	Every lot received	Receiving clerk	Reject the lot Discontinue use of the supplier or carrier until evidence is obtained that transportation-handling practices have been improved	Receiving record	Check the thermometer for accuracy and damage, and to ensure that it is operational before putting into operation; perform these same checks daily at the beginning of operations, and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
		Internal temperatures of all fish at delivery are 40°F or below	Internal core temperature and a near-surface temperature of each fish	Digital thermometer for internal temperature of one fish in 25% of shipping containers but not fewer than 12 containers (or all containers if lot has less than 12 containers)	Every lot received	Receiving clerk	Reject the lot Discontinue use of the supplier or carrier until evidence is obtained that transportation-handling practices have been improved	Receiving record	

- **CONTROL STRATEGY EXAMPLE 4 - PROCESSING CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- During processing (e.g., butchering, cleaning, brining, salting, smoking, drying, fermenting, pickling, mixing, fermenting, stuffing, packing, labeling, and staging) of scombrotoxin-forming fish that have not been previously frozen or heat processed sufficiently to destroy scombrotoxin-forming bacteria:
    - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C);

      OR
    - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C).

Note: Only one of the two limits above should be selected. They should not be added for a total exposure of 12 hours.

OR

- During processing (e.g., thawing, butchering, cleaning, brining, mixing, fermenting, stuffing, packing, labeling, and staging) of scombrotoxin-forming fish or fishery products that have been (1) previously frozen or (2) heat processed sufficiently to destroy scombrotoxin-forming bacteria and are processed in a manner where there is an opportunity for recontamination with scombrotoxin-forming bacteria (e.g., contact with fresh fish, employees, or introduction of raw ingredients), such as in a tuna salad made from canned tuna with added raw ingredients:
    - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 12 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C);

      OR
    - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C).

Note: Only one of the two limits above should be selected. They should not be added for a total exposure of 36 hours.

Establish Monitoring Procedures.

» What Will Be Monitored?

- The length of time the scombrotoxin-forming fish are exposed to unrefrigerated conditions (i.e., above 40°F (4.4°C));

  AND
- The ambient temperatures during the exposure periods.

Note: If the critical limit is based on an assumption that temperatures may exceed 70°F (21.1°C), then only the length of exposure may need to be monitored.

» How Will Monitoring Be Done?

- Make visual observations of the length of time of product exposure to unrefrigerated conditions (i.e., above 40°F (4.4°C));

  AND
- Measure ambient air temperature, using:
    - A continuous temperature-recording device (e.g., a recording thermometer) located in the processing area;

      OR
    - A temperature-indicating device (e.g., a thermometer) located in the processing area.

Note: Where multiple processing locations are combined in a cumulative exposure control strategy, temperature monitoring may be needed in each of the processing locations.

Example:

A fresh tuna processor using raw material that was not previously frozen has identified a series of processing steps (i.e., from raw material cooler to finished product cooler) as CCPs for scombrotoxin formation. The processor establishes a critical limit of no more than 4 cumulative hours of exposure to unrefrigerated temperatures in excess of 40°F (4.4°C) during these processing steps. The processor uses a marked product to monitor the progress of the product through the processing steps. The time that the marked product is removed from refrigeration to the time the last of the marked product is placed in the finished product cooler is monitored visually and recorded. It is not necessary for the processor to measure temperature because the critical limit is based on an assumption that the product temperature may exceed 70°F (21.1°C).

» **How Often Will Monitoring Be Done (Frequency)?**

- For exposure time:
  - At least every 2 hours;

  AND
- For temperature measurements:
  - For a continuous temperature-recording device:
    - Continuous monitoring during processing operations is accomplished by the device itself, with a visual check of the device at least once per lot or batch, but no less often than once per day;

    OR
  - For a temperature-indicating device:
    - At least every 2 hours.

» **Who Will Do the Monitoring?**

- For a continuous temperature-recording device:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls;

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the action plan is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Add ice to the product;

  OR
- Return the affected product to the cooler;

  AND

- Modify the process as needed to reduce the time and temperature exposure.

Establish a Recordkeeping System.

- Processing records showing the results of time and temperature exposure measurements.

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) or a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR
  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device or temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and has sufficient ink and paper, where applicable;

  AND
- Calibrate the temperature-indicating device or temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND
- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 7-6

CONTROL STRATEGY EXAMPLE 4 - PROCESSING CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Processing Control." This example illustrates how a fresh bluefish processor that butchers, cleans, packs, labels, and boxes the fish at ambient temperature can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Processing (butchering, cleaning, packaging, labeling, and boxing)	Scombrotoxin formation	The product is not out of refrigeration for more than 4 hours cumulatively	Time of product exposure to unrefrigerated conditions during processing operations	Visual tracking of time for a marked batch of product to move from raw material cold storage to final product cold storage	Every batch of fish removed from raw material cold storage for processing	Quality control supervisor	Ice and hold the affected batch in raw material cooler Perform histamine analysis on a minimum of 60 fish in the affected batch Destroy the entire batch if any fish exceeds 50 ppm histamine Modify the process, if necessary, to reduce delays	Processing record	Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 5 - STORAGE CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- For refrigerated (not frozen) storage or processing of raw material, in-process product, or finished product:
  - The product is held at a cooler temperature of 40°F (4.4°C) or below. Note that allowance for routine refrigeration defrost cycles may be necessary. On the other hand, minor variations in cooler temperature measurements can be avoided by submerging the sensor for the temperature-recording device (e.g., temperature-recorder) in a liquid that mimics the characteristics of the product. Also note that critical limits during refrigerated storage that specify a cumulative time and temperature of exposure to temperatures above 40°F (4.4°C) are not ordinarily suitable because of the difficulty in tracking the specific products and the specific cumulative temperature exposures that those products experience. The cumulative exposure for each product would then need to be determined prior to shipping. If you chose this approach, the critical limit for cumulative exposure to temperatures above 40°F (4.4°C) should include time during transit, refrigerated storage, and refrigerated and unrefrigerated processing;

  OR
- For raw material, in-process product, or finished product stored under ice:
  - The product is completely and continuously surrounded by ice throughout the storage time.

Establish Monitoring Procedures.

» What Will Be Monitored?

- For refrigerated storage of scombrotoxin-forming fish:
  - The temperature of the cooler;

  OR
- For storage under ice of scombrotoxin-forming fish:
  - The adequacy of ice surrounding the product.

» How Will Monitoring Be Done?

- For refrigerated storage:
  - Measure cooler temperature using a continuous temperature-recording device (e.g., a recording thermometer);

  OR
- For storage under ice:
  - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the cooler.

» How Often Will Monitoring Be Done (Frequency)?

- For continuous temperature-recording devices:
  - Continuous monitoring during storage is accomplished by the device itself, with a visual check of the recorded data at least once per day;

  OR
- For storage under ice:
  - Monitoring with sufficient frequency to ensure control.

» Who Will Do the Monitoring?

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls;

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations.

  OR

- Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish collected from throughout each affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the action point is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Prevent further deviation:
  - Add ice to the product;

    OR

  - Move some or all of the product in the malfunctioning cooler to another cooler;

  AND

- Address the root cause:
  - Make repairs or adjustments to the malfunctioning cooler;

    OR

  - Make adjustments to the ice application operations.

Establish a Recordkeeping System.

- For refrigerated storage:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND

  - Record of visual checks of recorded data;

  OR

- For storage under ice:
  - The number of containers examined and the sufficiency of ice for each;

    AND

  - The approximate number of containers in the cooler.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the

history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer.
- Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- When visual checks of ice are used, periodically measure internal temperatures of fish to ensure that the ice is sufficient to maintain product temperatures at 40°F (4.4°C) or less;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 7-7

CONTROL STRATEGY EXAMPLE 5 - STORAGE CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 5 - Storage Control." This example illustrates how a fresh fish processor can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Raw material and finished product cold storage (shared cooler)	Scombrotoxin formation	Maximum cooler temperature of 40°F	Cooler temperature	Time and temperature data logger	Continuous, with a visual check of recorded data once per day	Production supervisor	Ice and hold the affected product inside the cooler Check sufficiency of ice on the product two times per day until cooler is functioning reliably Perform histamine analysis on a minimum of 60 fish representative of the affected product Destroy all affected product if any fish exceeds 50 ppm histamine Adjust and repair cooler as needed	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; perform these checks daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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NOTES: