Hazard Analysis Worksheet

STEP #1O: *UNDERSTAND THE POTENTIAL HAZARD.*

Scombrotoxin formation as a result of time/temperature abuse of certain species of fish can cause consumer illness. The illness is most 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 discussed in Chapter 8.

Scombroid poisonings have primarily been associated with the consumption of tuna, mahi mahi, and bluefish. However, Table #3-1 (Chapter 3) lists a number of species that are also capable of developing elevated levels of histamine when temperature abused.

- Scombrotoxin formation

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

Histamine-forming bacteria are capable of growing and producing histamine over a wide temperature range. Growth is more rapid, however, at high-abuse temperatures (e.g. 70˚F [21.1˚C]) 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. Nonetheless, there are a number of opportunities for histamine to form under more moderate abuse temperature conditions.

Once the enzyme histidine decarboxylase has been formed, 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 is likely to remain stable while in the frozen state and may be reactivated very rapidly after thawing.

Freezing may inactivate the enzyme-forming bacteria. Both the enzyme and the bacteria can be inactivated by cooking. However, once histamine is formed, it cannot be eliminated by heat (including retorting) or freezing. After cooking, recontamination of the fish with the enzyme-forming bacteria is necessary for additional histamine to form. For these reasons, histamine development is more likely in raw, unfrozen fish.

The kinds of bacteria that are associated with histamine development are commonly present in the salt water environment. They naturally exist on the gills and in the gut of live, salt water fish, with no harm to the fish. Upon death, the defense mechanisms of the fish no longer inhibit bacterial growth, and histamine-forming bacteria start to grow and produce histamine. Evisceration and removal of the gills in a sanitary manner may reduce, but not eliminate, the number of histamine-forming bacteria. However, when done under insanitary conditions, these steps may accelerate the process of histamine development in the edible portions of the fish by spreading the bacteria to the flesh of the fish.

With some harvesting practices, such as long lining, death can occur before the fish is removed from the water. Under the worst conditions histamine formation can already be underway before the fish is landed on the vessel. This condition can be aggravated when the fish is allowed to remain on the line for a period of time after death, a situation that in certain tuna species may cause its internal temperature to increase to a more favorable growth range for the enzyme-forming bacteria.

Continued

The potential for histamine formation is increased when the flesh of the fish is directly exposed to the enzyme-forming bacteria. This occurs when the fish are processed (e.g. butchering or filleting).

At least some of the histamine-forming bacteria are halotolerant (salt-tolerant) or halophilic (salt-loving). This causes some salted and smoked fish products produced from scombrotoxin-forming species to continue to be suspect for histamine development. Further, a number of the histamine-forming bacteria are facultative anaerobes that can grow in reduced oxygen environments.

- Controlling scombrotoxin formation

Rapid chilling of fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin, especially for fish that are exposed to warmer waters or air, and for large tuna that generate heat in the tissues of the fish following death. It is recommended that:

- Generally, fish should be placed in ice or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 12 hours of death, or placed in refrigerated seawater or brine at 50˚F (10˚C) or less within 9 hours of death;
- Fish exposed to air or water temperatures above 83˚F (28.3˚C), or large tuna (i.e., above 20 lbs.) that are eviscerated before on-board chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 6 hours of death;
- Large tuna (i.e., above 20 lbs.) that are not eviscerated before on-board chilling should be chilled to an internal temperature of 50˚F (10˚C) or less within 6 hours of death.

This will prevent the rapid formation of the enzyme histidine decarboxylase. Once this enzyme is formed, control of the hazard is unlikely.

Further chilling towards the freezing point is also desirable to safe-guard against longer-term, low-temperature development of histamine. Additionally, the shelf-life of the fish is significantly compromised when product temperature is not rapidly dropped to near freezing.

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 a long line may significantly limit the amount of time left for chilling and may allow some fish to heat up after death;
  - The quantity of fish landed in a purse seine or on a long line 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 sea water or brine, a consequence of reduced contact area and heat transfer;
  - The quantity of ice or ice slurry and the capacity of refrigerated sea water or brine systems must be suitable for the quantity of catch.

Once chilled, the fish should be maintained as close as possible to the freezing point (or held frozen) until it is consumed. Exposure to ambient temperature should be minimized. The allowable exposure time is dependent primarily upon the speed with which the fish were chilled on-board the harvest vessel and whether the fish has been previously frozen (e.g. on-board the harvest vessel).

Unfrozen scombrotoxin-forming fish has a safe shelf-life (days before elevated levels of histamine are formed) that is dependent upon the harvest methods, the on-board handling, and the time/temperature exposures throughout processing, transit, and storage. This safe shelf-life can be as little as 5 to 7 days for product stored at 40˚F (4.4˚C).

Any exposure time above 40˚F (4.4˚C) significantly reduces the expected safe shelf-life. For this reason, fish that have not been previously frozen should not be exposed to temperatures above 40˚F (4.4C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish should not be 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 tempera

tures above 70˚F (21˚C) after chilling on board the harvest vessel. The safety of these limits is dependent upon proper handling at sea.

Fish that have been previously frozen can safely withstand considerably more exposure to elevated temperatures during post-harvest handling. Such fish should not be exposed to temperatures above 40˚F (4.4C) for more than 12 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish should not be 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˚C), after chilling on board the harvest vessel. The safety of these limits is again dependent upon proper handling at sea.

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 under these conditions. Such recontamination may not be likely if the fish is processed under a conscientious sanitation program.

- Detection

Sensory evaluation is generally used to screen fish for spoilage odors that develop when the fish is exposed to time/temperature abuse. It 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 scombrotoxin.

Chemical testing is an effective means of detecting the presence of histamine in fish flesh. However, the validity of such testing is dependent upon the design of the sampling plan. The amount of sampling required to accommodate such variability is necessarily quite large. For this reason, chemical testing alone will not normally provide adequate assurance that the hazard has been controlled. Because histamine is generally not uniformly distributed in a decomposed fish, a guidance level of 50 ppm has been set. If 50 ppm is found in one section, there is the possibility that other sections may exceed 500 ppm.

Observations for the presence of honeycombing in precooked tuna loins intended for canning is also a valuable means of screening for fish that have been exposed to the kinds of temperature abuse that can lead to histamine development. Any fish that demonstrate the trait should be destroyed.

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

At each processing step, determine whether "scombrotoxin formation" is a significant hazard. The criteria are:

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 #3-1 (Chapter 3) lists those species of fish that are generally known to be capable of producing elevated levels of histamine if temperature abused. This is because they contain naturally high levels of free histidine. It is also 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 on-board 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, on-board 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), or when the combination of air and water temperature and harvest/transport time are such that histamine formation is not reasonably likely to occur, as documented by a scientific study.

Continued

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). However, this may not be the case if the product being received is a cooked or frozen fish or fishery product.

Nevertheless, you may need to exercise control when receiving a refrigerated (not frozen) product from another processor to prevent pathogen growth or toxin formation (see Chapter 12).

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/temperature abuse in the absence of controls. You may already have controls in your process that minimize the potential for time/temperature abuse that could result in unsafe levels of histamine. This and the following steps will help you determine whether those or other controls should be included in your HACCP plan.

Time/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/temperature abuse during the entire process. Information is provided in Step #10 to help you assess the significance of time/temperature abuse that may occur in your process.

3. Can the formation of unsafe levels of histamine that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"Scombrotoxin 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 formation" can include:

- Making sure through harvest vessel records that incoming fish were properly handled on-board the harvest vessel, including:
  - Rapidly chilling the fish immediately after death;
  - Controlling on-board refrigeration (other than frozen storage) temperatures;
  - Proper on-board icing;
- Testing incoming fish for histamine levels;
- Making sure that incoming fish were handled properly during refrigerated transportation from the previous processor, including:
  - Controlling refrigeration temperatures during transit;
  - 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 decom position;
- Controlling refrigeration temperatures in your plant;
- Proper icing in your plant;
- Controlling the amount of time that the product is exposed to temperatures that would permit histamine formation during processing and storage.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1, 2 or 3 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If none of the criteria is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

- Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, because of the stable nature of histamine, the intended use of the product is not likely to affect the significance of this hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "scombrotoxin formation" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for scombrotoxin formation:

1. If you identified scombrotoxin formation as a significant hazard at the receiving step in Step #11, you should also identify receiving as a CCP for this hazard. Preventive measures, such as the first six described in Step #11, should be available to you at that step.

In this case you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. A control approach which includes screening incoming fish through harvest vessel records for on-board handling practices will be referred to as "Control Strategy Example 1" in Steps #14-18. A control approach which includes screening incoming fish through histamine testing will be referred to as "Control Strategy Example 2" in Steps #14-18. A control approach which includes screening incoming fish to ensure proper handling during transit from the previous processor will be referred to as "Control Strategy Example 3" in Steps #14-18.

2. If you identified scombrotoxin formation as a significant hazard at a processing or storage step in Step #11, it may be necessary for you to also identify that processing step as a CCP for this hazard. Preventive measures, such as the last three described in Step #11, should be available to you at those steps.

Example:
A fresh mahi mahi processor identifies a series of processing and storage steps (e.g. butchering, packaging, and refrigerated storage) as presenting a reasonable likelihood of scombrotoxin formation. The processor controls temperature during storage and time of exposure to unrefrigerated conditions during the processing steps. The processor identifies each of these processing and storage steps as CCPs for this hazard.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for each of those processing steps. This control approach will be referred to as "Control Strategy Example 1, 2 and 3" in Steps #14-18. It may apply to any of the three previously described control strategies.

It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

- Likely CCPs

Following is further guidance on processing steps that are likely to be identified as critical control points for this hazard:
- Receiving;
- Processing, such as:
  - Thawing;
  - Brining;
  - Heading and gutting;
  - Manual filleting and steaking;
  - Stuffing;
  - Mixing;
  - Portioning;
- Packaging;
- Final chilling after processing and packaging;
- Raw material, in-process product, and finished product refrigerated storage.

(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/temperature exposure.)

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- Unlikely CCPs

Time/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/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 LACF regulations, 21 CFR 113);
- Canned tuna "precooking" and steps after precooking, if sanitation practices are sufficient to prevent recontamination with enzyme-forming bacteria.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Critical Limit: All lots received are accompanied by harvest vessel records that show:

- Generally, the fish were:
  - Placed in ice, or in refrigerated seawater or brine at 40˚F (4.4˚C) or less, within 12 hours of death;
    OR
  - Placed in refrigerated seawater or brine at 50˚F (10˚C) or less within 9 hours of death and chilling continued to bring the internal temperature of the fish to 40˚F (4.4˚C) or less;

OR

- Fish exposed to air or water temperatures above 83˚F (28.3˚C),), or large tuna (i.e., above 20 lbs.) that are eviscerated before on-board chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 6 hours of death;

OR

- Large tuna (i.e., above 20 lbs.) that are not eviscerated before on-board chilling: The internal temperature of the fish was brought to 50˚F (10˚C) or less within 6 hours of death and chilling continued to bring the internal temperature of the fish to 40˚F (4.4˚C) or less;

OR

- Other critical limits for on-board handling (e.g. maximum refrigerated brine or seawater temperature, maximum fish size, maximum fish to brine/seawater/ice ratio, maximum ambient temperature exposure time before chilling) necessary to achieve a cooling rate that will prevent development of histamine in the specific species, as established through a scientific study;

AND

- For fish held refrigerated (not frozen) on-board the vessel: The fish were stored at or below 40˚F (4.4˚C) thereafter;

AND

- Sensory examination of a representative sample of fish shows no more than 2.5% decomposition (persistent and readily perceptible) in the sample. For example, no more than 3 fish in a sample of 118 fish may show signs of decomposition;

AND

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered 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) on-board the vessel and delivered from 12 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) on-board the vessel and delivered in less than 12 hours after death: The internal temperature should demonstrate that appropriate chilling methods were used onboard the harvest vessel. Chilling of the fish must begin on the harvest vessel regardless of the time from death to delivery, unless the environmental conditions (e.g. air and water temperatures) are consistently below 40˚F (4.4˚C) from the time of death to delivery.

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Critical Limit: Analysis of a representative sample of fish shows less than 50 ppm histamine in all fish in the sample;

AND

- Sensory examination of a representative sample of fish shows no more than 2.5% decomposition (persistent and readily perceptible) in the sample. For example, no more than 3 fish in a sample of 118 fish may show signs of decomposition;

AND

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered 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) on-board the vessel and delivered from 12 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) on-board the vessel and delivered in less than 12 hours after death: The internal temperature should demonstrate that appropriate chilling methods were used onboard the harvest vessel. Chilling of the fish must begin on the harvest vessel regardless of the time from death to delivery, unless the environmental conditions (e.g. air and water temperatures) are consistently below 40˚F (4.4˚C) from the time of death to delivery.

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- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Critical Limit: For fish delivered refrigerated (not frozen): All lots received are accompanied by transportation records that show that the fish were held at or below 40˚F (4.4˚C) throughout transit;
OR
For fish held under ice or chemical cooling media: There is an adequate quantity of ice or other cooling media at the time of delivery to completely surround the product.

- CONTROL STRATEGY EXAMPLE 1, 2 & 3

For processing steps:

Critical Limit: During processing and refrigerated (not frozen) storage that occurs before cooking (e.g. canned tuna "precook"): For fish that have not been previously frozen:

- 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˚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˚C);

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

OR

- For fish that have been previously frozen: 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˚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˚C).

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

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

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

What: Harvest vessel records containing the following information:

- Method of capture*;

AND

- Date and time of landing;

AND

- Where applicable to the critical limit, the air and water temperatures at time of landing on board the vessel*;

AND

- Estimated earliest date and time of death for fish landed at the same time (if other than time of landing)*;

AND

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

AND

- Where applicable to the critical limit, date and time cooling began;

AND

- Where applicable to the critical limit, cooling rate, as evidenced by:
  - Internal fish temperatures after 6 hours of cooling (or time when 50˚F [10˚C] is reached) for a representative number of the largest fish in the lot;

  OR

  - 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);

AND

- For fish held iced or refrigerated (not frozen) on-board 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 an adequate quantity of ice to surround the fish;

AND

Date and time of off-loading;

AND

Decomposition in the lot;

AND

For fish held iced or refrigerated (not frozen) on-board the vessel: The internal temperature of a representative number of the largest fish in the lot at the time of delivery, concentrating on those that show signs of having been mishandled (e.g. inadequately iced).

* The asterisked information above may be documented by the primary (first) processor on the receiving records, rather than by the harvest vessel operator on the harvest vessel records, if the primary processor is knowledgeable about such factors. The other on-board handling information should be documented by the vessel operator. All of the relevant information should be maintained by the primary processor.

As an alternative to the primary processor receiving harvest vessel records that are maintained by the vessel operator, certain harvest operations may lend themselves to monitoring and record keeping entirely by the primary processor. This arrangement is suitable only if the primary processor has direct knowledge about those aspects of the harvesting practices that must be controlled to ensure that the appropriate critical limits are met.

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 12 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 vessels' return; the ambient water and air temperatures of the fishing grounds; and the adequacy of icing of the catch. 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.

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- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

What: Histamine content in the fish flesh;
AND
Decomposition in the lot;
AND
Date and time of off-loading;
AND
For fish held iced or refrigerated (not frozen) on-board the vessel: The internal temperature of a representative number of the largest fish in the lot at the time of delivery, concentrating on those that show signs of having been mishandled (e.g. inadequately iced).

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

What: For fish delivered refrigerated (not frozen): The internal temperature of the fish throughout transportation;
OR
For fish delivered refrigerated (not frozen): The temperature of the truck or other carrier throughout transportation;
OR
For fish delivered refrigerated (not frozen), with a transit time of four hours or less: The internal temperature of a representative number of fish in the lot at the time of delivery;
OR
For fish held under ice or chemical cooling media: The adequacy of ice or chemical cooling media at the time of delivery.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

What: For raw material, in-process, or finished product refrigerated storage, or for refrigerated processing: The temperature of the cooler or the refrigerated processing area;
OR
For raw material, in-process, or finished product storage under ice or chemical cooling media: The adequacy of ice or chemical cooling media;
AND
For processing and packaging: The length of time the fish are exposed to unrefrigerated conditions (i.e., above 40˚F [4.4˚C]), and the ambient temperatures during the exposure periods.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

How: Review of harvest vessel records.
Temperature monitoring on the vessel should be performed using dial thermometers, digital time/temperature data loggers, or recorder thermometers;
AND
Sensory examination of at least 118 fish in each lot (or the entire lot, for lots smaller than 118 fish). Lots should consist of only one specie of fish. Note: 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) on-board the vessel: Use a dial or digital thermometer to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on those 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 1000 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 may require a larger sample size.

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

How: Histamine analysis of a minimum of 18 fish per lot where the fish are the same species and of common origin, unless there are fewer than 18 fish in the lot, in which case test all of the fish. The fish collected for analysis may be composited for analysis 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

Sensory examination of at least 118 fish in each lot (or the entire lot for lots smaller than 118 fish). Lots should consist of only one specie of fish. Note: If the fish are received frozen, this monitoring procedure may be performed using the drill method. It may also be performed after thawing, rather than at receipt;

AND

For fish held iced or refrigerated (not frozen) on-board the vessel: Use a dial or digital thermometer to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on those 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 1000 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 may require a larger sample size.

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

How: For fish delivered refrigerated (not frozen):

- Use a time/temperature integrator for internal product temperature monitoring during transit;

OR

- Use a digital time/temperature data logger for internal product temperature or ambient air temperature monitoring during transit;

OR

- Use a recorder thermometer for ambient air temperature monitoring during transit;

OR

- Use a dial or digital thermometer for internal product temperature monitoring at receipt;

OR

For fish held under ice or chemical cooling media: Make visual observations of the adequacy of ice or other cooling median a sufficient number of containers (e.g. cartons, totes, etc.) to represent all of the product.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

How: For raw material, in-process, or finished product refrigerated storage or for refrigerated processing:

- Use a digital time/temperature data logger;

OR

- Use a recorder thermometer;

OR

- Use a high temperature alarm within 24-hour monitoring;

OR

For raw material, in-process, or finished product storage under ice or chemical cooling media: Make visual observations of the adequacy of ice or chemical cooling media in a sufficient number of containers (e.g. cartons, totes, etc.) to represent all of the product.;

Continued

AND

For processing and packaging:

- Make visual observations of the length of exposure to unrefrigerated conditions (i.e., above 40˚F [4.4˚C]);

AND

- Use a dial or digital thermometer to determine ambient air temperature.

Example:
A canned tuna processor using raw material that was not previously frozen has identified a series of processing steps as critical control points for scombrotoxin formation. The processor establishes a critical limit of no more than four cumulative hours of exposure to unrefrigerated temperatures in excess of 40˚F (4.4˚C) during these processing steps. The processor uses marked product to monitor the progress of the product through the processing steps. The time that the marked product is removed from and returned to refrigeration is monitored visually and recorded and the ambient air temperature is determined using a digital thermometer and recorded.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLES 1 & 2

For receipt by primary (first) processor:

Frequency: Every lot received.

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Frequency: Every lot received.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Frequency: For raw material, in-process, or finished product refrigerated storage, or for refigerated processing: Continuous monitoring by the instrument itself, with visual check of the instrument at least once per day;

OR

For raw material, in-process, or finished product storage under ice or chemical cooling media:

- At least twice per day;

OR

- For finished product storage, at least immediately prior to shipment;

AND

For processing and packaging: At least every two hours.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

Who: With recorder thermometers, time/temperature integrators, high temperature alarms, maximum indicating thermometers, and digital data loggers, monitoring is performed by the equipment itself. However, anytime that such instruments are used, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. Monitoring on-board the harvest vessel is performed by a member of the vessel's crew. However, the on-board records should be reviewed as part of monitoring at receipt to ensure that the critical limits were consistently met. These checks, as well as dial thermometer checks, time of exposure checks, and adequacy of ice or other cooling media checks may be performed by the receiving employee, the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the process and the monitoring procedure. Sensory examinations and histamine analyses should be performed by individuals who are qualified by training and experience.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Corrective Action: In the absence of harvester records, or when one of the harvester critical limits has been violated, or when the internal temperature critical limit at receiving has been violated:

- Reject the lot;

OR

- Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit 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

When the sensory examination critical limit has been violated:

- Reject the lot;

OR

- Perform histamine analysis on all fish that show decomposition (persistent and readily perceptible) and reject the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the rate recommended above (i. e. 60 fish per lot), rejecting those portions where a unit greater than or equal to 50 ppm is found;

OR

- Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with hista mine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit 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

- Perform a sensory examination of all fish in the lot;

AND

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

AND

Discontinue use of supplier until evidence is obtained that harvesting practices have changed.

Continued

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Corrective Action: When the histamine level or internal temperature critical limit at the receiving step has been violated:
- Reject the lot;

OR
- Subdivide the lot and analyze each portion at the rate recommended above (i.e. 60 fish per lot), rejecting those portions where a unit with 50 ppm or more histamine is found. The fish collected for analysis may be composited for analysis if the critical limit 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

When the sensory examination critical limit has been violated:
- Reject the lot;

OR
- Perform histamine analysis on all fish that show decomposition (persistent and readily perceptible) and reject the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the rate recommended above (i.e. 60 fish per lot), rejecting those portions where a unit greater than or equal to 50 ppm is found;

OR
- Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit 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
- Perform a sensory examination of all fish in the lot;

AND

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

AND

Discontinue use of supplier until evidence is obtained that harvesting practices have changed.

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Corrective Action: In the absence of transportation records or when a critical limit at this processing step has been violated:
- Reject the lot;

OR
- Perform histamine analysis on the lot (i.e fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit 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
- Hold the product until it can be evaluated based on its total transit time/temperature exposure and reject any product that has exceeded the critical limits described for the "Processing Steps" at Step 14;

AND

Discontinue use of supplier or carrier until evidence is obtained that transportation practices have changed.

• CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Corrective Action: Take one or several of the following actions as necessary to regain control over the operation after a CL deviation:
- Add ice to the affected product;

OR
- Make repairs or adjustments to the malfunctioning cooler;

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

OR
- Return the affected in-process product to the cooler;

OR
- Freeze the affected product;

OR
- Modify the process as needed to reduce the exposure time/temperature;

AND

Take one of the following actions to product involved in the critical limit deviation:
- Destroy the product;

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

OR
- Perform histamine analysis on the lot of affected product by analyzing 60 fish (or the entire lot for lots smaller than 60 fish). If any fish are found with histamine at 50 ppm or greater the lot should be destroyed or diverted to a non-food use.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15.

The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

• CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Records: Harvest vessel records, containing the information described in Step #15.

AND

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

AND
- Results of sensory examination;

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

• CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Records: 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) on-board the vessel: Internal temperatures of the fish.

Continued

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Records: Receiving records showing:
- The results of the time/temperature integrator checks;

OR
- Printouts from digital time/temperature data logger;

OR
- Recorder thermometer charts;

OR
- The results of internal product temperature monitoring at receipt;

AND
- The date and time of departure and arrival of the vehicle;

OR
- The results of the ice or other cooling media checks.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Records: For raw material, in-process, or finished product refrigerated storage, or for refrigerated processing:
- Printouts from digital time/temperature data logger;

OR
- Recorder thermometer charts;

OR
- Storage records showing the results of the high temperature alarm checks;

OR

For raw material, in-process, or finished product storage under ice or chemical cooling media: Storage records showing the results of the ice or other cooling media checks;

AND

For processing and packaging: Processing records showing the results of time/temperature exposure checks.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "scombrotoxin formation"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

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

AND

When dial or digital thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

When dial or digital thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter

(Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Verification: Review monitoring, corrective action, and verification records within one week of preparation;
AND
When digital time/temperature data loggers or recorder thermometers are used for monitoring of transport conditions at receipt, check for accuracy against a known accurate thermometer (NIST-traceable). Verification should be conducted on new suppliers' vehicles and at least quarterly for each supplier thereafter. Additional verifications may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair, or readings appear to be erroneous);
OR
When dial or digital thermometers are used for monitoring conditions at receipt, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.);
OR
When visual checks of ice or cooling media are used to monitor the adequacy of coolant, periodically measure internal temperatures of fish to ensure that the ice or cooling media is sufficient to maintain product temperatures at 40˚F (4.4˚C) or less.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Verification: Review monitoring, corrective action, and verification records within one week of preparation;
AND
When digital time/temperature data loggers, recorder thermometers, or high temperature alarms are used for in-plant monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;
AND
When dial or digital thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.);
OR
When visual checks of ice or cooling media are used to monitor the adequacy of coolant, periodically measure internal temperatures of fish to ensure that the ice or cooling media is sufficient to maintain product temperatures at 40˚F (4.4˚C) or less.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #7-1

Control Strategy Example 1 - Harvest vessel control

This table is an example of a portion of a HACCP plan relating to the control of scombrotoxin formation for a fresh mahi mahi processor that receives the fish on ice from harvest vessels, using Control Strategy Example 1 - Harvest vessel control. It is provided for illustrative purposes only. Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. food and color additives, metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving - fresh mahi mahi on ice from harvest vessels	Scombrotoxin formation	• All lots received are accompanied by harvest vessel records that show: 1) icing on board the harvest vessel was performed in accordance with the vessel's cooling rate study that validates cooling to 50°F or below within 6 hrs. of death regardless of maximum exposure temperature, or placement on ice within 12 hrs. of death if the maximum exposure temperature does not exceed 83°F; 2) method of capture; 3) date and time of landing; 4) estimated time of death; 5) method of cooling; 6) date and time cooling began; 7) sea and air temperature if exposure temperature exceeds 83°F; 8) adequacy of ice during on-board holding.	• Harvest vessel records	• Visual review of the records	• Every lot received	• Receiving supervisor	• Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Harvester vessel records	• Histamine analysis on one incoming lot every three months (10 fish per sample) • Review monitoring, corrective action and verification records within one week of preparation
		• No more than 2.5% decomposition (persistent and readily perceptible) in the incoming lot	• Amount of decomposition in incoming lot	• Sensory examination (118 fish per lot; or all fish in the lot if <118 fish)	• Every lot received	• Quality control staff	• Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Receiving record	• Same
		• If the fish are delivered in less than 12 hours after death, an internal temperature below ambient air and water temperatures; if the fish are delivered 12 or more hours after death, an internal temperature of 50°F or below; if the fish are delivered 24 or more hours after death, an internal temperature of 40°F or below	• Internal temperature of fish at time of delivery	• Digital thermometer (1 fish/1000 lbs for lots up to 10 tons; 1 fish/ton for lots 10 tons or greater; minimum of 12 fish/lot)	• Every lot received	• Receiving supervisor	• Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Receiving record	• Same
			• Date and time of off-loading	• Clock	• Every lot received	• Receiving supervisor		• Receiving record	• Check accuracy of digital thermometer once per year

TABLE #7-1, continued

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Raw material storage	Scombrotoxin formation	• Product completely covered in ice throughout storage	• Adequacy of ice surrounding product	• Visual examination	• Every lot at time of removal from raw material storage cooler and at least twice a day for lots not removed	• Production supervisor	• Add ice • Hold lot and evaluate based on total time/temperature exposure during raw material and finished product storage and butchering/packaging. Destroy lot if time above 40˚F exceeds 4 hours cumulatively if any of that time is above 70˚F, or if time above 40˚F exceeds 8 hours cumulatively as long as no portion of that time is above 70˚F.	• Processing record	• Review monitoring and corrective action records within one week of preparation
Butchering/packaging	Scombrotoxin formation	• Product is not exposed to temperatures above 40˚F for more than 4 hours cumulatively if any of that time is above 70˚F, or above 40˚F for more than 8 hours as long as no portion of that time is above 70˚F hours cumulatively	• Time of product exposure to unrefrigerated conditions during butchering/packaging	• Visual tracking of time for marked product to move through butchering/packaging.	• Every batch of fish marked when removed from raw material storage.	• Quality control supervisor	• Destroy lot	• Processing record	• Review monitoring and corrective action records within one week of preparation
Finished product storage	Scombrotoxin formation	• Product completely covered in ice throughout storage	• Adequacy of ice surrounding product	• Visual examination	• Every lot at time of removal from finished product storage cooler for shipment	• Shipping supervisor	• Add ice • Hold lot and evaluate based on total time/temperature exposure during raw material and finished product storage and butchering/packaging. Destroy lot if time above 40˚F exceeds 4 hours cumulatively if any of that time is above 70˚F, or if time above 40˚F exceeds 8 hours cumulatively as long as no portion of that time is above 70˚F.	• Shipping record	• Review monitoring and corrective action records within one week of preparation

TABLE #7-2

Control Strategy Example 2 - Histamine testing

This table is an example of a portion of a HACCP plan relating to the control of scombrotoxin formation for a canned tuna processor, using Control Strategy Example 2 - Histamine testing. It is provided for illustrative purposes only. Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. *C. botulinum*).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) 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 analysis of 18 fish per lot	• Every lot received	• Quality assurance staff	• Subdivide lot and examine 60 fish per sub-lot for histamine. Reject sub-lots with one or more fish at 50 ppm or greater	• Reports of analysis	• Review monitoring, corrective action and verification records within one week of preparation
		• No more than 3 decomposed fish (persistent and readily perceptible) in a 118 fish sample	• Amount of decomposition in incoming lot	• Sensory examination (118 fish per lot, or all fish if lot is <118 fish)	• Every lot received	• Quality assurance staff	• Reject the lot • Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Quality assurance record	
Thawing, butchering and precook staging	Scombrotoxin formation	• No more than 24 hours at ambient air temperatures above 40°F or, if temperatures ever exceed 70°F, no more than 12 hours above 40°F, cumulative time for thawing, butchering, and precook staging.	• Time of product exposure to unrefrigerated conditions during thawing, butchering and precook staging	• Visual observation of time for marked product to move through process	• Start marked product at start of every thaw process	• Quality assurance staff	• Make adjustments to the thawing, butchering and precook staging process AND • Analyze representative sample of lot for histamine. Divert to non-food use if any unit is 50 ppm or greater	• Processing record	• Review monitoring and corrective action records within one week of preparation