Hazard Analysis Worksheet

STEP #10: ***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 which 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 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 be more stable than the bacteria in the frozen state and may be reactivated very rapidly after thawing. Recent studies suggest that if histamine production is advanced (i.e. high levels of histidine decarboxylase), histamine formation can continue even in frozen storage.

Freezing for an extended period of time (e.g. 24 weeks) may inactivate the enzyme-forming bacteria. Both the enzyme and the bacteria can be inactivated by cooking. However, once the toxin 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 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. 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 struggle on the line for a period of time, 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.

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).

Continued

• Controlling scombrotoxin formation

Rapid chilling of fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin. For fish other than tuna above 20 lbs., if the fish have not been exposed to temperatures above 83˚F (28.3˚C), the fish should be placed in refrigerated seawater or brine at 50˚F (10˚C) or less within 9 hours of death, or placed in ice within 12 hours of death. For tuna above 20 lbs., or if the fish have been exposed to temperatures above 83˚F (28.3˚C), the internal temperature of the fish should be brought to 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 the fish to heat up as it struggles;
  - The quantity of fish landed in a purse seine 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 than does an ice slurry or recirculated refrigerated sea water or brine, a consequence of reduced contact area;
  - 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 scrombrotoxin-forming fish has a safe shelf-life which is dependent upon the storage temperature. Table #7-1 shows an approximate safe shelf-life for fish stored at various temperatures. The safe shelf-life periods in the table include the time aboard the harvest vessel.

Table 7-1

Approximate Safe Shelf-Life for Scrombrotoxin-Forming Species at Various Storage Temperatures

Product Temperature	*Safe Shelf-Life (Days) with Rapid Cooling*	*Safe Shelf-Life (Days) with Delayed Cooling*
0˚F (-17.8˚C)	No limit	No limit
32˚F (0˚C)	14	8
38˚F (3.3˚C)	10	7
40˚F (4.4˚C)	7	5
50˚F (10˚C)	3	0
70˚F (21.1˚C)	0	0
90˚F (32.2˚C)	0	0

Any time above 40˚F (4.4˚C) significantly reduces the expected safe shelf-life. For this reason, fish should not be exposed to temperatures above 40˚F (4.4˚C) for more than four hours, cumulatively, after chilling on board the harvest vessel. The safety of this limit is dependent upon proper handling at sea.

Fish that have been handled particularly well on-board the harvest vessel may be able to safely withstand somewhat more exposure to elevated temperatures during post-harvest handling.

Fish that have undergone extended frozen storage (e.g. 24 weeks) can safely withstand considerably more exposure to elevated temperatures during post-harvest handling. Such fish should not be exposed to temperatures above 40˚F (4.4˚C) for more than twelve hours, cumulatively, after chilling on board the harvest vessel. An uninterrupted period of exposure should not exceed six hours. Intermittent refrigeration breaks the cycle of rapid bacterial growth and slows the formation of histamine. 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 easily detected 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. 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. Additionally, recent studies suggest that if histamine production is advanced, histamine formation can continue even in frozen storage.

Observations of loins of tuna after the precooking step for the presence of "honeycombing" 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 #1 (Chapter 3) lists those species of fish which 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.

It is also reasonable to assume that, without proper controls during refrigerated (not frozen) transportation between processors, these species of fish will contain unsafe levels of histamine upon receipt by the secondary processor (including warehouses). This may not be the case, however, if the product being received is a cooked or frozen fish or fishery product.

Continued

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 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 that will help you assess the significance of the time/temperature abuse that is possible 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 be considered a significant hazard at any processing 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 decomposition;
- 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.

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 the toxin, 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 #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 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 cooling after processing and packaging;
- Raw material, in-process product, and finished product storage.

- Unlikely CCPs

Time/temperature controls will usually not be needed at processing steps that meet the following conditions:
- Continuous, mechanical processing steps, 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;
- Retorting and post-retorting steps;
- Cooking (e.g. canned tuna "precooking") and post cooking steps 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.

Continued

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:

- For fish other than tuna above 20 lbs., if the fish have not been exposed to temperatures above 83˚F (28.3˚C), the fish should be placed in seawater or brine at 50˚F (10˚C) or less within 9 hours of death, or placed in ice within 12 hours of death;
  OR
- For tuna above 20 lbs., or if the fish have been exposed to temperatures above 83˚F (28.3˚C), the internal temperature of the fish should be brought to 50˚F (10˚C) or less within 6 hours of death;

AND

- For unfrozen fish: the fish were maintained at or below 40˚F (4.4˚C) thereafter;

AND

Sensory examination of a sample of the 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 unfrozen fish: there is an adequate quantity of ice, refrigerated seawater, refrigerated brine, or other cooling media at the time of delivery (e.g. adequate ice to completely surround the product);

AND

For unfrozen fish: if the fish are delivered 12 or more hours after death, the internal temperature should be at or below 50˚F (10˚C). However, if the fish are delivered 24 or more hours after death, the internal temperature should be 40˚F (4.4˚C) or below.

- Control Strategy Example 2 - Histamine testing

For receipt by primary (first) processor:

CRITICAL LIMIT: Analysis of a sample of fish shows less than 50 ppm histamine in all fish in the sample;

AND

Sensory examination of a 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 unfrozen fish: there is an adequate quantity of ice, refrigerated seawater, refrigerated brine, or other cooling media at the time of delivery (e.g. adequate ice to completely surround the product);

AND

For unfrozen fish: if the fish are delivered 12 or more hours after death, the internal temperature should be at or below 50˚F (10˚C). However, if the fish are delivered 24 or more hours after death, the internal temperature should be 40˚F (4.4˚C) or below.

- Control Strategy Example 3 - Transit control

For receipt by secondary processor (including warehouse):

CRITICAL LIMIT: For refrigerated (not frozen) fish: all lots received are accompanied by transportation records that show that the fish was maintained 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 (e.g. adequate ice to completely surround the product);
AND
For refrigerated (not frozen) fish and fish held under ice or chemical cooling media: internal temperature of fish at time of receipt not to exceed 40˚F (4.4˚C).

- Control Strategy Example 1, 2 & 3

For processing steps:

CRITICAL LIMIT: For fish that have not been previously frozen and for all fish (i.e. frozen or unfrozen) that were subjected to a corrective action as a result of a receiving critical limit deviation: The fish are exposed to temperatures above 40˚F (4.4˚C) for no more than 4 hours, cumulatively, before cooking (e.g. canned tuna "precook") or final freezing;
(Note: fish that have been handled particularly well on-board the harvest vessel may be able to safely withstand somewhat more exposure to elevated temperatures during post-harvest handling.)
OR
For fish that have been previously frozen for 24 weeks or longer: The fish are exposed to temperatures above 40˚F (4.4˚C) for no more than 12 hours, cumulatively, before cooking (e.g. canned tuna "precook") or final freezing. An uninterrupted period of exposure should not exceed six hours.
(Note: the 24 week period is based on data available to the agency. It may be possible to establish that a shorter period of time will inactivate the enzyme-forming bacteria.)

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 of the feature 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.

Continued

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
- Time of landing;

AND
- Estimated earliest 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
- Where applicable to the critical limit, time cooling began;

AND
- Where applicable to the critical limit, cooling rate, as evidenced by:
  - Temperature after hours of cooling (or time when 50˚F [10˚C] is reached) for a representative number of fish;
    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
- The air and water temperature if the cooling rate CL is based on a maximum exposure temperature of 83˚F (28.3˚C);

AND
- For unfrozen fish: the storage temperature, as evidenced by:
  - The temperature of refrigerated seawater or brine;
    OR
  - The presence of an adequate quantity of ice to surround the fish;

AND
Decomposition in the lot;

AND
For unfrozen fish: the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media at the time of delivery;

AND
For unfrozen fish: the internal temperature of a representative number of fish at time of delivery.

• Control Strategy Example 2 - Histamine testing

For receipt by primary (first) processor:

WHAT: Fish flesh for histamine content;

AND
Decomposition in the lot;

AND
For unfrozen fish: the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media at the time of delivery;

AND
For unfrozen fish: the internal temperature of a representative number of fish at time of delivery.

• Control Strategy Example 3 - Transit control

For receipt by secondary processor (including warehouse):

WHAT: For refrigerated (not frozen) fish: the internal temperature of the fish throughout transportation;
OR
For refrigerated (not frozen) fish: the temperature of the truck or other carrier throughout transportation;
OR
For fish held under ice or chemical cooling media: the adequacy of ice or chemical cooling media at time of delivery;

AND
For refrigerated (not frozen) fish and fish held under ice or chemical cooling media: the internal temperature of the fish at time of delivery.

• Control Strategy Examples 1, 2 & 3

For processing steps:

WHAT: For raw material, in-process, or finished product refrigerated storage: the temperature of the cooler;
OR
For raw material, in-process, or finished product storage under ice or chemical cooling media: the quantity of ice or chemical cooling media;
AND
For processing and packaging: the length time of exposure of the fish to unrefrigerated conditions;
AND
For fish frozen for 24 weeks or longer: the length of frozen storage.

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 thermometer charts;
AND
Sensory examination of at least 118 fish in each lot (or the entire lot, for lots smaller than 118 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 unfrozen fish: visual observation of the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media;
AND
For unfrozen fish: dial or digital thermometer for the internal temperature of the fish.

• Control Strategy Example 2 - Histamine testing

For receipt by primary (first) processor:

HOW: Histamine analysis of one fish per ton for fish greater than or equal to 20 lbs. each or two fish per ton for fish less than 20 lbs. each, where the fish are of common origin;
AND
Sensory examination of at least 118 fish in each lot (or the entire lot for lots smaller than 118 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 unfrozen fish: visual observation of the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media;
AND
For unfrozen fish: dial or digital thermometer for the internal temperature of the fish.

• Control Strategy Example 3 - Transit control

For receipt by secondary processor (including warehouse):

HOW: For refrigerated (unfrozen) fish: time/temperature integrator for product temperature monitoring;
OR
For refrigerated (unfrozen) fish: digital time/temperature data logger for product or ambient air temperature monitoring;
OR
For refrigerated (unfrozen) fish: recorder thermometer chart for ambient air temperature monitoring;
OR
For fish held under ice or chemical cooling media: visual observation of the adequacy of ice or other cooling media;
AND
For refrigerated (not frozen) fish and fish held under ice or chemical cooling media: dial or digital thermometer for product internal temperature.

Continued

• Control Strategy Examples 1, 2 & 3

For processing steps:

HOW: For raw material, in-process, or finished product refrigerated storage:
- Digital time/temperature data logger;

OR
- Recorder thermometer chart;

OR
- Maximum indicating thermometer;

OR
- High temperature alarm;

OR

For raw material, in-process, or finished product storage under ice or chemical cooling media: visual observation of the quantity of ice or chemical cooling media;

AND

For processing and packaging: visual observation of length of exposure to unrefrigerated conditions;

AND

For fish frozen for 24 weeks or longer: information from harvest or transport vessel.

Example:
A canned tuna processor using unfrozen raw material 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 temperature 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.

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: For transit temperature checks: every lot received;

OR

For ice or other cooling media checks: every lot received;

AND

For internal temperature checks: representative sample of every lot received.

• Control Strategy Examples 1, 2 & 3

For processing steps:

FREQUENCY: For raw material, in-process, or finished product refrigerated storage: continuous monitoring, with visual check 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;

AND

For fish frozen for 24 weeks or longer: every lot received.

Who Will Perform the Monitoring?

• Control Strategy Examples 1, 2 & 3

WHO: With recorder thermometer charts, 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 should be performed by a person who is 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:

- 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;

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 same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found.

AND

When any one of the other critical limits has been violated: Reject the lot;

AND

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

Continued

• Control Strategy Example 2 - Histamine testing

For receipt by primary (first) processor:

CORRECTIVE ACTION: When the histamine level critical limit at this processing step has been violated:
- Reject the lot;

OR
- Subdivide the lot and analyze each portion at the same rate, rejecting those portions where a unit with 50 ppm or more histamine is found;

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 same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found.

AND

When any one of the other critical limits has been violated: Reject the lot;

AND

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

• 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;

OR
- Hold the product until it can be evaluated based on its total time/temperature exposure.

• 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;

OR
- Make repairs or adjustments to the cooler;

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

OR
- Return the product to the cooler;

OR
- Freeze the product;

OR
- Modify the process.

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
- Collect and analyze a representative sample of the product for histamine (95% confidence). Reject the product if any unit exceeds 50 ppm.

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 the results of:
- Sensory examination. 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 unfrozen fish: visual observation of the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media;

AND
- For unfrozen fish: internal temperature of the fish.

- Control Strategy Example 2 - Histamine testing

For receipt by primary (first) processor:

RECORDS: Analytical results;
AND
Receiving records showing the results of:
- Sensory examination. 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 unfrozen fish: visual observation of the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media;

AND
- For unfrozen fish: internal temperature of the fish.

- Control Strategy Example 3 - Transit control

For receipt by secondary processor (including warehouse):

RECORDS: Receiving record showing the results of the time/temperature integrator checks;
OR
Printout from digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Receiving record showing the results of the ice or other cooling media checks;
AND
Receiving record showing product internal temperatures.

- Control Strategy Examples 1, 2 & 3

For processing steps:

RECORDS: For raw material, in-process, or finished product refrigerated storage:
- Printout from digital time/temperature data logger;

OR
- Recorder thermometer chart;

OR
- Storage record showing the results of the maximum indicating thermometer checks;

OR
- Storage record 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 record showing the results of the ice or other cooling media checks;
AND
For processing and packaging: processing records showing the results of time of exposure checks;
AND
For fish frozen for 24 weeks or longer: receiving record showing length of frozen storage.

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

Continued

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

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) at time of receipt.

- 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.)

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

TABLE #7-2

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, 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.

(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 - fresh mahi mahi	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) time of landing; 4) estimated time of death; 5) method of cooling; 6) time cooling began: and 7) sea and air temperature if exposure time is greater than 6 hrs.	• Harvest vessel records	• Visual review	• Every lot received	• Receiving supervisor	• Reject lot	• 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	• Entire lot (up to 118 fish) for every lot received	• Quality control staff	• Reject lot	• Receiving record	• Same
		• Ice completely surrounds product at time of delivery	• Amount of ice at time of delivery	• Visual examination	• Every lot received	• Receiving supervisor	• Reject lot	• Receiving record	• Same
		• 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 a representative number of fish at time of delivery	• Digital thermometer	• Every lot received	• Receiving supervisor	• Reject lot	• Receiving record	• Same • Check accuracy of digital thermometer once per year

TABLE #7-2, 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 (to ensure that product is not exposed to temperatures above 40˚F for more than 4 hours cumulatively during raw material and finished product storage and butchering/ packaging)	• Amount of ice at time of removal from raw material storage cooler	• Visual examination	• Every lot removed from raw material storage cooler	• 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 hrs.	• 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 during raw material and finished product storage and butchering/packaging	• Time of product exposure to unrefrigerated conditions during butchering/ packaging	• Visual observation of marked product	• Start marked product at beginning of every lot and at least every 2 hours	• 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 (to ensure that product is not exposed to temperatures above 40˚F for more than 4 hours cumulatively during raw material and finished product storage and butchering/ packaging)	• Amount of ice at time of removal from finished product storage cooler for shipment	• Visual examination	• Every lot removed 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 hrs.	• Shipping record	• Review monitoring and corrective action records within one week of preparation

TABLE #7-3

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: What	(5) Monitoring: How	(6) Monitoring: Frequency	(7) Monitoring: Who	(8) Corrective Action(s)	(9) Records	(10) Verification
Receiving - frozen tuna	Scombrotoxin formation	• Less than 50 ppm histamine in all fish in the sample	• Fish flesh for histamine content	• Histamine analysis of 1 fish per ton if fish are 20 lbs. or more each and 2 fish per ton if fish are less than 20 lbs. each fish in each incoming lot	• Every lot	• Quality assuarance staff	• Subdivide lot and re-examine portions of the lot for histamine. Reject portion of the lot if any fish in the portion is 50 ppm or greater	• Reports of analysis • Quality Assuarance Record	• 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 analysis	• 118 fish in every lot	• Quality assuarance staff	• Reject the lot		
Thawing	Scombrotoxin formation	• For fish that have been frozen for 24 weeks or more: no more than 12 hours cumulative time for thawing and butchering	• Length of frozen storage	• Information from harvest or transport vessel	• Every lot received	• Receiving supervisor	• Make adjustments to the thawing process	• Receiving record	• Review monitoring, corrective action and verification records within one week of preparation
			• Time of product exposure to unrefrigerated conditions during thawing	• Visual observation of marked product	• Start marked product at start of every thaw process	• Quality assuarance staff	• Analyze representative sample of lot for histamine. Divert to non-food use if any unit is 50 ppm or greater	• Processing record	
		• For fish that have been frozen for less than 24 weeks: no more than 4 hours cumulative time for thawing and butchering	• Time of product exposure to unrefrigerated conditions during thawing	• Visual observation of marked product	• Start marked product at start of every thaw process	• Quality assuarance staff	• Same	• Processing record	• Same

TABLE #7-3, 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			
Butchering	Scombrotoxin formation	• For fish that have been frozen for 24 weeks or more: no more than 12 hours cumulative time for thawing and butchering	• Length of frozen storage • Time of product exposure to unrefrigerated conditions during butchering	• Information from harvest or transport vessel • Visual observation of marked product	• Every lot received • Start marked product at start of every thaw process	• Receiving supervisor • Quality assurance staff	• Move product to cooler and hold • Analyze representative sample of lot for histamine. Divert to non-food use if any unit is 50 ppm or greater	• Receiving record • Processing record	• Review monitoring and corrective action records within one week of preparation
		• For fish that have been frozen for less than 24 weeks: no more than 4 hours cumulative time for thawing and butchering	• Time of product exposure to unrefrigerated conditions during butchering	• Visual observation of marked product	• Start marked product at start of every thaw process	• Quality assurance staff	• Same	• Processing record	• Same