Hazard Analysis Worksheet

STEP #10: ***Understand the potential hazard.***

Clostridium botulinum toxin formation can result in consumer illness and death. This chapter covers the potential for *C. botulinum* growth and toxin formation as a result of time/temperature abuse during processing, storage and distribution. The growth of other pathogens and the formation of other toxins as a result of time/temperature abuse during processing are covered in Chapters 7 (histamine formation), 12 (pathogen growth during processing other than *C. botulinum*), and 15 (*Staphylococcus aureus* toxin formation in hydrated batter mixes). Additionally, the prevention of *C. botulinum* toxin development during storage and distribution of the finished product by drying is covered in Chapter 14. The prevention of *C. botulinum* toxin development during storage and distribution of the finished product by pasteurization is covered in Chapter 17.

C. botulinum produces a potent toxin when it grows which can cause death by preventing breathing. It is one of the most poisonous naturally occurring substances known. The toxin can be destroyed by heat (e.g. boiling for 10 minutes).

There are two major groups of *C. botulinum*, the proteolytic group (i.e. those that break down proteins) and the nonproteolytic group (i.e. those that do not break down proteins). The proteolytic group includes *C. botulinum* type A and some of types B and F. The nonproteolytic group includes *C. botulinum* type E and some of types B and F.

C. botulinum is able to produce spores. In this state the pathogen is very resistant to heat. The spores of the proteolytic group are much more resistant to heat than are those of the nonproteolytic group. The vegetative cells of all types are easily killed by heat.

Temperature abuse occurs when product is exposed to temperatures favorable for *C. botulinum* growth for sufficient time to result in toxin formation. Table #A-1 (Appendix 4) provides guidance about the conditions under which *C. botulinum* and other pathogens are able to grow.

Packaging conditions that exclude oxygen (e.g. vacuum packaging) favor the growth of *C. botulinum*, because oxygen is toxic to the pathogen. Vacuum packaging inhibits the growth of many spoilage bacteria, which increases the shelf life of the product. The safety concern with these products is the increased potential for the formation of *C. botulinum* toxin before spoilage makes the product unacceptable to consumers. Both smoked and raw products in vacuum packaging and other reduced oxygen packaging require strict refrigeration (or frozen storage conditions) throughout distribution.

C. botulinum forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth of *C. botulinum* type E and nonproteolytic type B and F is 38˚F (3.0˚C). For type A and proteolytic types B and F, the minimum temperature for growth is 50˚F (10˚C). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. Processors should expect that at some point during storage, distribution, display or consumer handling of refrigerated foods, proper refrigeration temperatures will not be maintained (especially for the nonproteolytic group). Surveys of retail display cases indicate that temperatures of 45-50˚F (7-10˚C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50˚F (10˚C).

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• Sources of *C. botulinum*

C. botulinum can enter the process on raw materials. The spores of *C. botulinum* are very common in nature. They have been found in the gills and viscera of fin fish, crabs, and shellfish. *C. botulinum* type E is the most common form found in fresh water and marine environments. Types A and B are generally found on land, but may also be occasionally found in water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.

• Control of *C. botulinum*

There are a number of strategies to control *C. botulinum* in fishery products. They include:

• Heating the finished product sufficiently by retorting to destroy the spores of *C. botulinum* types A,B,E, and F (e.g. canned fish) (covered by the low acid canned foods regulations, 21 CFR 113). Note: these controls are not required to be included in your HACCP plan;

• 1) First, heating the finished product sufficiently by pasteurization to destroy the spores of *C. botulinum* type E and nonproteolytic type B and F (covered in Chapter 17); and then 2) controlling the growth of the surviving *C. botulinum* type A and proteolytic type B and F in the finished product with refrigerated storage (e.g. pasteurized crabmeat) (covered in this chapter);

• Controlling the level of acidity (pH) in the finished product sufficient to prevent the growth of *C. botulinum* types A,B,E, and F (e.g. shelf-stable acidified products) (covered by the acidified foods regulations, 21 CFR 114). Note: these controls are not required to be included in your HACCP plan;

• Controlling the amount of moisture that is available in the product (water activity) sufficient to prevent the growth of *C. botulinum* types A,B,E, and F (e.g. shelf-stable dried products) (covered by Chapter 14);

• 1) First, controlling the level of acidity (pH), salt, moisture (water activity), or some combination of these barriers, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic type B and F; and then 2) controlling the growth of *C. botulinum* type A and proteolytic type B and F in the finished product with refrigerated storage (e.g. refrigerated acidified ["pickled"] products) (covered in this chapter);

• 1) First, controlling the amount of salt or preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as heat damage and competitive bacteria, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic type B and F; and then 2) controlling the growth of *C. botulinum* type A and proteolytic type B and F in the finished product with refrigerated storage (e.g. salted, smoked, or smoke-flavored fish) (covered in this chapter);

• Managing the amount of time that food is exposed to temperatures that are favorable for *C. botulinum* growth and toxin formation during processing and storage (covered in this chapter).

Because spores are known to be present in the viscera of fish, any product that will be preserved using salt, drying, pickling, or fermentation must be eviscerated prior to processing (see Compliance Policy Guide sec. 540.650). Without evisceration, toxin formation is possible during the process. Small fish, less than 5 inches in length (e.g. anchovies and herring sprats), that are processed in a manner that prevents toxin formation, and that reach a water phase salt content of 10 percent, a water activity of below 0.85 (Note: this value is based on the minimum water activity for growth of *S. aureus*), or a pH of 4.6 or less are exempt from the evisceration requirement.

Processors of these types of products should also consider the possibility of *Staphylococcus aureus* growth and toxin formation during processing. This potential hazard is covered in Chapter 12.

• Control in salted, smoked, and smoke-flavored fish

Achieving the proper concentration of salt and or nitrite in the flesh of salted, smoked, and smoke-flavored fish is necessary to prevent the formation of toxin by *C. botulinum* type E and nonproteolytic type B and F during storage and distribution. In salted fish, the salt concentration alone is responsible for this inhibition. In smoked and smoke-flavored fish, salt works along with smoke and any nitrites that are added to prevent toxin formation by *C. botulinum* type E and nonproteolytic B and F (Note: nitrites may only be used in salmon, sable, shad, chubs, and tuna - FDA Compliance Policy Guide sections 540.500 and 540.200).

In hot-smoked products, heat damage to the spores of *C. botulinum* type E and nonproteolytic type B and F also helps prevent toxin formation. In these products control of the heating process is critical to the safety of the finished product. It is important to note, however, that this same heating process also reduces the numbers of naturally occurring spoilage organisms. The spoilage organisms would otherwise have competed with, and inhibited the growth of, *C. botulinum*.

In cold-smoked fish, it is important that the product does not receive so much heat that the number of spoilage organisms are significantly reduced. This is true because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and nonproteolytic type B and F. This inhibition is important in cold-smoked fish because the heat applied during this process is not adequate to weaken the *C. botulinum* spores. Control of the temperature during the cold-smoking process is, therefore, critical to the safety of the finished product.

The interplay of these inhibitory effects (salt, temperature, smoke, nitrite) is complex. Control of the brining or dry salting process is clearly critical to ensure that there is sufficient salt in the finished product. However, preventing *C. botulinum* type E (and nonproteolytic type B and F) toxin production is made even more complex by the fact that adequate salt levels are not usually achieved during brining.

Proper drying is also critical in order to achieve the finished product water phase salt level (the concentration of salt in the water portion of the fish flesh) needed to inhibit the growth and toxin formation of *C. botulinum*.

Processors should ordinarily restrict brining, dry salting, and smoking loads to single species and to fish of approximately uniform size. This minimizes the complexity of controlling the operation.

Salt levels alone in some salted products may be adequate to prevent toxin formation by *C. botulinum* type A and proteolytic type B and F. However, even the combination of inhibitory effects that are present in smoked and smoke-flavored fish are not adequate to prevent the growth of type A and proteolytic B and F. Strict refrigeration control during storage and distribution must be maintained to prevent the growth of *C. botulinum* type A and proteolytic type B and F in these products.

• Control in "pickled" fish and similar products

In "pickled" fish and similar products that have not been preserved sufficient for them to be shelf-stable, growth and toxin formation by *C. botulinum* type E and nonproteolytic type B and F is controlled by either:

• Adding sufficient salt to produce a water phase salt level (the concentration of salt in the water-portion of the fish flesh) in the loin muscle of at least 5 percent;

• Adding sufficient acid to reduce the acidity (pH) in the loin muscle to 5.0 or below;

• Reducing the amount of moisture that is available for growth (water activity) in the loin muscle to 0.97 or below (e.g., by adding salt or other substances that "bind" the available water); or

• Making a combination of salt, pH, and/or water activity adjustments that, when combined, prevent the growth of *C. botulinum* type E and nonproteolytic type B and F (to be established by a scientific study).

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Much like smoked products, in some of these products the interplay of these inhibitory effects (salt, water activity, and pH) can be complex. Control of the brining, pickling, or formulation steps is, therefore, critical to ensure that there are sufficient barriers in the finished product to prevent the growth and toxin formation of *C. botulinum* type E and nonproteolytic type B and F during storage and distribution.

Processors should ordinarily restrict brining and pickling loads to single species and to fish of approximately uniform size. This minimizes the complexity of controlling the operation.

The above discussed controls are not sufficient to prevent the growth of *C. botulinum* type A and proteolytic B and F. Strict refrigeration control during storage and distribution must, therefore, be maintained to prevent the growth of this group, unless one of the following conditions is also met:

• Sufficient salt is added to produce a water phase salt level in the loin muscle of at least 10 percent;

• Sufficient acid is added to reduce the pH in the loin muscle to 4.6 or below; or,

• The water activity in the loin muscle is reduced to 0.85 or below (Note: this value is based on the minimum water activity for growth of *S. aureus*) (e.g., by adding salt or other substances that "bind" the available water).

• Control during storage

As previously stated, many salted, smoked, smoke-flavored, "pickled," and similar fishery products are not shelf-stable. The same is true for pasteurized fishery products (e.g. pasteurized crabmeat) for which the control of *C. botulinum* type E and nonproteolytic type B and F is discussed in Chapter 17. For all of these products, the control of *C. botulinum* type A and proteolytic B and F in the finished product during storage comes from refrigeration. Refrigeration is also a highly desirable secondary barrier in these products for the control of *C. botulinum* type E and nonproteolytic type B and F. For these reasons, they should be stored at temperatures at or below 50˚F (10˚C), or properly iced.

STEP #11: ***Determine if this potential hazard is significant.***

At each processing step, determine whether "*C. botulinum* toxin formation" is a significant hazard. The criteria are:

1. Is it reasonably likely that *C. botulinum* will grow and produce toxin at this processing step?

Table #A-1 (Appendix 4) provides guidance on some conditions in food that limit the growth of *C. botulinum*. Remember that 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 during processing. 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 the production of *C. botulinum* toxin, 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.

Three factors that make such toxin formation reasonably likely are:

• Vacuum packaging or modified atmosphere packaging. Because most of these packaging methods exclude or reduce the amount of oxygen in the package, conditions may be favorable for *C. botulinum* growth and toxin formation;

• Packaging in hermetically sealed containers (e.g. double seamed cans, glass jars with sealed lids, heat sealed plastic containers) or packing in oil. These and similar processing/packaging techniques prevent the entry of oxygen into the container. Any oxygen present at the time of packaging may be rapidly depleted by the activity of spoilage bacteria, resulting in a reduced oxygen environment that is favorable for *C. botulinum* growth and toxin formation.

• Prior moderate heat treatment that was not sufficient to eliminate the spores, combined with the application of salt at less than 10% (e.g. hot-smoked fish, regardless of packaging). With this type of processing: 1) the spores of *C. botulinum* are encouraged to germinate and produce toxin by the "heat shock;" 2) the spoilage bacteria that would normally compete with *C. botulinum* are eliminated or reduced in numbers by the heat; and 3) any surviving spoilage bacteria may be inhibited by the salt.

Table #A-2 (Appendix 4) provides guidance on the length of time at which product can be held in several temperature ranges before *C. botulinum* toxin formation is likely to occur. If, in the absence of controls, the cumulative time at these temperatures could exceed the times listed in the table you should consider it reasonably likely that *C. botulinum* will grow and produce toxin during the process, if one of the 3 previously described factors applies to the product at those steps.

You should also consider the potential for *C. botulinum* toxin formation during finished product distribution. If one of the three above listed conditions applies to the finished product, you should consider it reasonably likely that *C. botulinum* will grow and produce toxin during finished product distribution.

2.Can the growth and/or toxin production of *C. botulinum,* which is 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.)

"*C. botulinum* toxin formation" should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if its reasonably likely to occur.

Step #10 discusses a number of *C. botulinum* control strategies. This chapter covers control of *C. botulinum* growth and toxin production that occurs as a result of time/temperature abuse during processing, storage, and distribution.

Preventive measures for *C. botulinum* toxin formation during processing can include:

- controlling refrigeration temperatures (i.e. below 38˚F [3.3˚C]);
- proper icing;
- controlling the amount of time that the product is exposed to temperatures that would permit *C. botulinum* toxin formation;
- rapidly cooling the fish.

Preventive measures for *C. botulinum* toxin formation during distribution and storage can include:

• Heating the finished product sufficiently by retorting to destroy the spores of *C. botulinum* types A,B,E, and F (e.g. canned fish) (covered by the low acid canned foods regulations, 21 CFR 113). Note: these controls are not required to be included in your HACCP plan;

• 1) First, heating the finished product sufficiently by pasteurization to destroy the spores of *C. botulinum* type E and nonproteolytic type B and F (covered in Chapter 17); and then 2) controlling the growth of the surviving *C. botulinum* type A and proteolytic type B and F in the finished product with refrigerated storage (e.g. pasteurized crabmeat) (covered in this chapter);

• Controlling the level of acidity (pH) in the finished product sufficient to prevent the growth of *C. botulinum* types A,B,E, and F (e.g. shelf-stable acidified products) (covered by the acidified foods regulations, 21 CFR 114). Note: these controls are not required to be included in your HACCP plan;

• Controlling the amount of moisture that is available in the product (water activity) sufficient to prevent the growth of *C. botulinum* types A,B,E, and F (e.g. shelf-stable dried products) (covered by Chapter 14);

• 1) First, controlling the level of acidity (pH), salt, moisture (water activity), or some combination of these barriers, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic type B and F; and then 2) controlling the growth of *C. botulinum* type A and proteolytic type B and F in the finished product with refrigerated storage (e.g. refrigerated

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acidified ["pickled"] products) (covered in this chapter);

• 1) First, controlling the amount of salt or preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as heat damage and competitive bacteria, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic type B and F; and then 2) controlling the growth of *C. botulinum* type A and proteolytic type B and F in the finished product with refrigerated storage (e.g. salted, smoked, or smoke-flavored fish) (covered in this chapter).

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

Preventive measures of the type just described should be available to most of the at risk products described above (i.e. vacuum packaged fish, modified atmosphere packaged fish, fish packaged in hermetically sealed containers, fish packed in oil, hot-smoked fish, regardless of packaging). Notable products for which these preventive measures are not available include: vacuum packaged raw, unpreserved fish, sous vide fishery products, and heat-and-fill fishery products. If you intend to vacuum package, or use modified atmosphere packaging or hermetically sealed packaging for these products or pack them in oil or a similar oxygen excluding media, you will need to evaluate the effectiveness of other preventive measures, either singularly, or in combination. Such evaluation will usually necessitate the performance of inoculated pack studies under moderate abuse conditions. An example of another preventive measure to consider is strict temperature controls throughout distribution and retail sale, such as the use of recorder thermometer charts or digital time/temperature data loggers during distribution and retail storage and sales, or time/temperature integrators on individual packages.

If the answer to either question 1 or 2 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" or where noted above.

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 and method of distribution and storage

In determining whether a hazard is significant you should also consider the intended use and method of distribution and storage of the product, which you developed in Step #4. Due to the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the significance of the hazard will be affected by the intended use of your product.

However, if your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration"), then formation of *C. botulinum* toxin may not be a significant hazard during storage and distribution. You would still, however, have to evaluate the likelihood of *C. botulinum* toxin formation during processing.

STEP #12: ***Identify the critical control points (CCP).***

For each processing step where "*C. botulinum* toxin 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 *C. botulinum* toxin formation:

1. Is there an acidification step (equilibrium pH of 4.6 or below), a drying step (final water activity of 0.85 or below), a pasteurization step (target organism *C. botulinum* type E and nonproteolytic type B and F), or a retorting step (commercial sterility) in the process?

   a. If there is, you may in most cases identify the acidification step, drying step, pasteurization step, or retorting step as the CCP for this hazard. Other processing steps where you have identified "*C. botulinum* toxin formation" as a significant hazard will then not require control and will not need to be identified as CCPs for the hazard. One exception is in the case of products pasteurized to kill *C. botulinum* type E and nonproteolytic type B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic type B and F (e.g. pasteurized crabmeat). These products require control of temperature during finished product storage and distribution. Another exception is when there is the potential for sufficient time/temperature abuse during processing to result in toxin formation (e.g. during cooling after hot smoking). In this case, you should also identify those steps where significant time/temperature abuse is reasonably likely as CCPs for the hazard. Such control is outlined in this chapter, beginning with Step #14.

Guidance for these *C. botulinum* toxin control strategies is contained in the following locations:

- Chapters 17 and 18, for control of pasteurization;
- Chapter 14, for control of drying;
- Acidified foods regulations, 21 CFR 114, for control of acidification;
- Low acid canned foods regulations, 21 CFR 113, for control of retorting.

Note: acidification and retorting controls required by 21 CFR 113 and 114 need not be included in your HACCP plan.

   b. If there is no acidification step, drying step, pasteurization step, or retorting step in the process, then decide which of the following categories best describes your product:
      - salted, smoked, or smoke-flavored fish;
      - "pickled" fish and similar products;
      - other products for which *C. botulinum* toxin formation is a significant hazard.

If your product fits into the third category (other products), you will have to establish other preventive measures, either singularly, or in combination that are effective in controlling the hazard, and develop a HACCP plan accordingly.

If your product fits into the first category (salted, smoked, or smoke-flavored fish), you should follow the guidance contained in the rest of this chapter contained under the heading "Control Strategy Example 1 – Salting/smoking."

If your product fits into the second category ("pickled" fish), you should follow the guidance in the rest of this chapter contained under the heading "Control Strategy Example 2 - Pickling."

• Control Strategy Example 1 – Salting/smoking

The following questions, apply to salted, smoked, and smoke-flavored fish:

1. Is the temperature of the heating/smoking process important to the safety of the product?

For both cold-smoked and hot-smoked fish products the temperature of heating/smoking is critical. The heating/smoking step for hot-smoked fish must be sufficient to damage the spores and make them more susceptible to inhibition by salt. The smoking step for cold-smoked fish must not be so severe that it kills the natural spoilage bacteria. These bacteria are necessary so that the product will spoil before toxin production occurs. It is likely that they will also produce acid, which will further inhibit *C. botulinum* growth and toxin formation.

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For these products you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the heating/smoking step.

2. Is the water phase salt level and, when permitted, the nitrite level, important to the safety of the product?

For all products in this category the water phase salt level is critical to the safety of the product. Nitrite, when permitted, allows a lower level of salt to be used. Salt, and nitrite are the principal inhibitors to *C. botulinum* type E and nonproteolytic type B and F toxin formation in these products. The water phase salt level needed to inhibit toxin formation is partially achieved during brining or dry salting, and partially achieved during drying. Control must be exercised over both operations.

You should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the brining or dry salting step and the drying step.

3. Is the finished product storage temperature important to the safety of the product?

Unless salting results in a water phase salt level of 10% or higher, storage and distribution temperature will be critical to ensure the safety of the product. Toxin formation by *C. botulinum* type A and proteolytic B and F is not inhibited by salt levels below 10%, nor by the combination of inhibitors present in most smoked or smoke-flavored fish. Finished product storage temperature must be controlled.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the finished product storage step.

In some cases salted, smoked, or smoke-flavored fish are received as ingredients for assembly into another product, such as a salmon pate. In other cases, they are received simply for storage and further distribution (e.g. by a warehouse). In these cases, the receiving and storage steps may also require time/temperature controls, and should be designated as CCPs.

4. Is there the potential for sufficient time/temperature abuse for toxin formation during processing?

If you identified this hazard as significant at a step because of the potential for cumulative time/temperature abuse during processing that could result in *C. botulinum* toxin formation, control should be exercised at that step to prevent such abuse. In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for that processing step(s).

The above described control approach is referred to as "Control Strategy Example 1" in Steps #14-18. 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.

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

• Control Strategy Example 2 – Pickling

The following questions apply to "pickled" fish and similar products:

1. Is the water phase salt level, water activity, and/or pH level important to the safety of the product?

For all products in this category the water phase salt level, water activity, and/or pH level is critical to the safety of the product, because they are the principle inhibitors to *C. botulinum* type E and nonproteolytic type B and F growth and toxin formation. The levels of these inhibitors needed to inhibit toxin formation are achieved during the pickling, brining, or formulation step. Control must be exercise over the relevant step.

You should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pickling, brining, or formulation step, as appropriate.

2. Is the finished product storage temperature important to the safety of the product?

Unless pickling, brining, or formulation results in a water phase salt level of at least 10 percent, a pH of 4.6 or below, or a water activity of 0.85 or below (Note: this value is based on the minimum water activity for growth of *S. aureus*), storage and distribution temperature will be critical to ensure the safety of the product.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the finished product storage step.

In some cases "pickled" fish or similar products are received as ingredients for assembly into another product, such as receipt of bulk "pickled" herring for repackaging into retail-size containers. In other cases, they are received simply for storage and further distribution (e.g. by a warehouse). In these cases, the receiving and storage steps may also require time/temperature controls, and should be designated as CCPs.

3. Is there the potential for sufficient time/temperature abuse for toxin formation during processing?

If you identified this hazard as significant at a step because of the potential for cumulative time/temperature abuse during processing that could result in *C. botulinum* toxin formation, control should be exercised at that step to prevent such abuse. In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for that processing step(s).

The above described control approach is referred to as Control Strategy Example 2" in Steps #14-18. 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.

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

STEP #14: ***Set the critical limits (CL).***

For each processing step where "*C. botulinum* toxin 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 is 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 - Salting/smoking

For controlling toxin formation by cold smoking:

CRITICAL LIMIT: The smoker temperature must not exceed 90˚F (32.2˚C).

For controlling toxin formation by hot smoking:

CRITICAL LIMIT: The internal temperature of the fish must be maintained at or above 145˚F (62.8˚C) throughout the fish for at least 30 minutes.

For controlling toxin formation by brining, dry salting, and/or drying:

CRITICAL LIMIT: The minimum or maximum values for the critical factors of the brining/dry salting, and/or drying processes established by a scientific study. The critical factors are those that are necessary to assure that the finished product has:

- For air packaged smoked fish or smoked-flavored fish, not less than 2.5 percent water phase salt in the loin muscle;

OR

- For vacuum or modified atmosphere packaged smoked fish or smoke-flavored fish, not less than 3.5 percent water phase salt in the loin muscle, or, where permitted, the combination of 3.0 percent water phase salt in the loin muscle and not less than 100 ppm nitrite;

OR

- For salted fish, not less than 10 percent water phase salt in the loin muscle.

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The critical factors may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; drier loading.

• Control Strategy Example 2 - Pickling

For controlling toxin formation by pickling, brining, or formulation:

CRITICAL LIMIT: The minimum or maximum values for the critical factors of the pickling, brining, or formulation process established by a scientific study. The critical factors are those that are necessary to assure that the finished product has:

- A water phase salt level of at least 5 percent in the loin muscle;

OR

- A pH of 5.0 or below in the loin muscle;

OR

- A water activity of 0.97 or below in the loin muscle;

OR

- A combination of water phase salt, pH, and/or water activity in the loin muscle that, when combined, have been demonstrated to prevent the growth of *C. botulinum* type E and nonproteolytic type B and F.

The critical factors may include: brine strength; acid strength; brine/acid to fish ratio; brining/pickling time; brining/pickling temperature; thickness, texture, fat content, quality, and species of fish.

• Control Strategy Examples 1 & 2

For controlling toxin formation during in-process and finished product storage:

CRITICAL LIMIT: The product must not be exposed to temperatures above 50˚F (10˚C), which may be assured by:

- A maximum cooler temperature of 50˚F (10˚C);

OR

- The presence of sufficient cooling media (e.g. adequate ice to completely surround the product).

For controlling toxin formation during processing:

CRITICAL LIMIT: The product must not be exposed to temperatures above 50˚F (10˚C) for more than 12 hours nor to temperatures above 70˚F (21˚C) for more than 4 hours, excluding time above 140˚F (60˚C).

For controlling toxin formation at receipt of "pickled," smoked, smoke-flavored, or salted fish for storage or further processing:

CRITICAL LIMIT: The product must not be exposed during transportation to temperatures above 50˚F (10˚C), which may be assured by:

- A maximum refrigerated container temperature of 50˚F (10˚C) throughout transit;

OR

- The presence of sufficient cooling media (e.g. adequate ice to completely surround the product) upon receipt.

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

STEP #15: ***Establish monitoring procedures.***

For each processing step where "*C. botulinum* toxin 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.

What Will Be Monitored?

• Control Strategy Example 1 - Salting/smoking

For controlling toxin formation by cold smoking:

WHAT: The smoker temperature.

For controlling toxin formation by hot smoking:

WHAT: The internal temperature at the thickest portion of three of the largest fish in the smoking chamber.

For controlling toxin formation by brining, dry salting, and/or drying:

WHAT: The critical aspects of the established brining, dry salting, and/or drying processes. These may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; drier loading.
OR
The water phase salt and, where appropriate, nitrite level of the finished product.

• Control Strategy Example 2 - Pickling

For controlling toxin formation by pickling, brining, or formulation:

WHAT: The critical aspects of the established pickling, brining, or formulation process. These may include: brine/acid strength; brine/acid to fish ratio; brining/pickling time; brine/acid temperature; thickness, texture, fat content, quality, and species of fish;
OR
The water phase salt, pH, and/or water activity of the finished product.

• Control Strategy Examples 1 & 2

For controlling toxin formation during in-process and finished product storage:

WHAT: The temperature of the cooler;
OR
The quantity of ice or chemical cooling media.

For controlling toxin formation during processing:

WHAT: The length of time of exposure of the product to unrefrigerated conditions, and either the internal temperature of the product (for product cooling) or the ambient temperature (for processing of previously chilled product);
OR
The length of time of exposure of the product to unrefrigerated conditions (for processing of previously chilled product where a temperature greater than 70˚F [21˚C] is assumed or where a study demonstrates that under ordinary conditions product does not exceed 70˚F [21˚C] when exposed for the length of time specified by the critical limit [not to exceed 4 hours]);
OR
The internal temperature of the product (where temperatures are held below 50˚F [10˚C] or above 140˚F [60˚C]);
OR
The ambient air temperature (for processing of previously chilled product where the ambient air temperature is 50˚F [10˚C] or below).

Continued

For controlling toxin formation at receipt of "pickled," smoked, smoke-flavored, or salted fish for storage or further processing:

WHAT: The internal temperature of the fish;
OR
The temperature of the truck or other carrier;
OR
The quantity of ice or chemical cooling media.

How Will Monitoring Be Done?

• Control Strategy Example 1 - Salting/smoking

For controlling toxin formation by cold smoking:

HOW: Digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Maximum indicating thermometer;
OR
High temperature alarm.

For controlling toxin formation by hot smoking:

HOW: Digital time/temperature data logger with three probes.

For controlling toxin formation by brining. dry salting, and/or drying:

HOW: Monitor the drying time and the input/output air temperature (as specified by the study) with a temperature recording device or digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the input/output air temperature;
AND
Monitor brine strength with a salinometer;
AND
Monitor the brine temperature with a dial or digital thermometer;
AND
Monitor all other critical factors specified by the study with equipment appropriate for the measurement;
OR
Collect a representative sample of finished product and conduct water phase salt analysis.

• Control Strategy Example 2 – Pickling

For controlling toxin formation by pickling, brining, or formulation:

HOW: Monitor brine strength with a salinometer;
AND
Monitor acid strength with a pH meter or by titration;
AND
Monitor brine/acid temperature with a dial or digital thermometer;
AND
Monitor all other critical factors specified by the study with equipment appropriate for the measurement;
OR
Collect a representative sample of finished product and conduct water phase salt, pH, and/or water activity analysis.

• Control Strategy Examples 1 & 2

For controlling toxin formation during in-process and finished product storage:

HOW: Digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Maximum indicating thermometer;
OR
High temperature alarm;
OR
Visual observation for ice or chemical cooling media.

For controlling toxin formation during processing:

HOW: Dial or digital thermometer for product or ambient air temperature;
AND/OR
Visual observation of length of exposure to unrefrigerated conditions.

For controlling toxin formation at receipt of "pickled," smoked, smoke-flavored, or salted fish for storage or further processing:

HOW: Time/temperature integrator for product temperature monitoring;
OR
Digital time/temperature data logger for product or ambient air temperature monitoring;
OR
Recorder thermometer chart for ambient air temperature monitoring;
OR
Visual observation of the quantity of ice or other chemical cooling media.

How Often Will Monitoring Be Done (Frequency)?

• Control Strategy Example 1 - Salting/smoking

For controlling toxin formation by cold smoking:

FREQUENCY: Continuous monitoring, with visual check of the monitoring instrument at least once per batch.

For controlling toxin formation by hot smoking:

FREQUENCY: Continuous monitoring, with visual check of the monitoring instrument at least once per batch.

For controlling toxin formation by brining, dry salting, and/or drying:

FREQUENCY: Temperature requirements of the drying process should be monitored continuously;
AND
Time requirements of the drying process should be monitored for each batch;
AND
Monitor brine strength at least at the start of the brining process;
AND
Monitor the brine temperature at the start of the brining process and at least every two hours thereafter;
AND
Monitor the brine to fish ratio at the start of the brining process;
AND
Monitor all other critical factors specified by the study as often as necessary to maintain control.
OR
Water phase salt should be determined for each lot or batch of finished product.

• Control Strategy Example 2 - Pickling

For controlling toxin formation by pickling, brining, or formulation:

FREQUENCY: Monitor brine/acid strength at the start of the brining/pickling/formulation process;
AND
Monitor the brine/acid temperature at the start of the brining/pickling formulation process and at least every two hours thereafter;
AND
Monitor the brine/acid to fish ratio at the start of the brining/pickling/formulation process;
AND
Monitor all other critical factors specified by the study as often as necessary to maintain control;
OR
Water phase salt, pH, and/or water activity analysis should be determined for each batch of finished product.

• Control Strategy Examples 1 & 2

For controlling toxin formation during in-process and finished product storage:

FREQUENCY: Continuous monitoring, with visual check of the monitoring instrument at least once per day.

For controlling toxin formation during processing:

FREQUENCY: At least every two hours;
OR
Each batch.

Continued

For controlling toxin formation at receipt of "pickled," smoked, smoke-flavored, or salted fish for storage or further processing:

FREQUENCY: Each shipment.

Who Will Perform the Monitoring?

• Control Strategy Examples 1 & 2

WHO: With recorder thermometer charts, time/temperature integrators, high temperature alarms, maximum indicating thermometers, and digital time/temperature 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 (at least once at the end of each heating cycle in the case of control during heating) in order to ensure that the critical limits have consistently been met. These checks, as well as dial thermometer checks, salinometer checks, pH meter checks, titrations 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, the monitoring procedure, and the critical limits.

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 "*C. botulinum* toxin 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 - Salting/smoking

For controlling toxin formation by cold smoking:

CORRECTIVE ACTION: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:
- Make repairs or adjustments to the smoking/drying chamber;

OR
- Move some or all of the product to another smoking/drying chamber;

AND

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

OR
- Hold the product until its safety can be evaluated;

OR
- Divert the product to a use in which the critical limit is not applicable (e.g. low acid canned food [LACF] or frozen product);

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

For controlling toxin formation by hot smoking:

CORRECTIVE ACTION: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:
- Make repairs or adjustments to the heating chamber;

OR
- Move some or all of the product to another heating chamber;

AND

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

OR
- Hold the product until its safety can be evaluated;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. LACF or frozen product);

OR

- Divert the product to a non-food use.

For controlling toxin formation by brining, dry salting, and/or drying:

CORRECTIVE ACTION: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Adjust the brine and/or nitrite concentration;

OR

- Adjust the air velocity or input air temperature to the drying chamber;

OR

- Extend the drying process to compensate for a reduced air velocity or temperature or elevated humidity;

OR

Adjust the brine strength or brine to fish ratio;

OR

- Extend the brining time to compensate for an improper brine temperature;

AND

Take one of the following actions to the product involved when there has been a failure to maintain specified critical factors of the brining, dry salting or drying process:

- Destroy the product;

OR

- Hold the product until it can be evaluated based on its water phase salt and/or nitrate level;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. LACF or frozen product);

OR

- Divert the product to a non-food use.

AND

Take one of the following actions to the product involved when finished product testing shows that the water phase salt level and/or nitrite level is below the critical limit:

- Destroy the product

OR

- Divert the product to a use in which the critical limit is not applicable because *C. botulinum* growth in the finished product will be controlled by some other means (e.g. divert to a low acid canned food operation);

OR

- Divert to a non-food use.

• Control Strategy Example 2 - Pickling

For controlling toxin formation by pickling, brining, or formulation:

CORRECTIVE ACTION: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Adjust the brine/acid strength or brine/acid to fish ratio;

OR

- Extend the brining/pickling time to compensate for an improper brine/acid temperature;

AND

Take one of the following actions to the product involved when there has been a failure to maintain the specified critical factors of the pickling, brining, or formulation process:

- Destroy the product;

OR

- Hold the product until it can be evaluated based on its water phase salt, pH, and/or water activity level;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. packaging that is not hermetically sealed, or frozen product);

OR

- Divert the product to a non-food use.

AND

Continued

Take one of the following actions to the product involved when finished product testing shows that water phase salt is below 5 percent, or the pH is above 5.0, or the water activity is above 0.97, or the intended combination of water phase salt, pH, and/or water activity has not been achieved, as appropriate:

- Destroy the product;

OR

- Divert the product to a use in which the critical limit is not applicable because *C. botulinum* growth in the finished product will be controlled by some other means (e.g. divert to a low acid canned food operation);

OR

- Reprocess the product (if reprocessing does not jeopardize the safety of the product);

OR

- Divert to a non-food use.

• Control Strategy Examples 1 & 2

For controlling toxin formation during in-process and finished product storage:

CORRECTIVE ACTION: Take one or several of the following actions as necessary to regain control over the operation after a CL deviation:

- Make repairs or adjustments to the cooler;

OR

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

OR

- Freeze the product;

AND

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

- Destroy the product;

OR

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

OR

- Divert the product to a non-food use.

For controlling toxin formation during processing:

CORRECTIVE ACTION: Take one or several of the following actions as necessary to regain control over the operation after a CL deviation:

- Ice the product;

OR

- Move the product to a cooler;

OR

- Freeze the product;

AND

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

- Destroy the product;

OR

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

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. LACF or frozen product);

OR

- Divert to a non-food use.

For controlling toxin formation at receipt of "pickled," smoked, smoke-flavored, or salted fish for storage or further processing:

CORRECTIVE ACTION: Reject products that do not meet the time/temperature or adequacy of ice or other cooling media critical limit at receiving;

OR

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

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

STEP #17: ***Establish a recordkeeping system.***

For each processing step where "*C. botulinum* toxin 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 record-keeping system for the control strategy examples discussed in Step #12.

• Control Strategy Example 1 - Salting/smoking

For controlling toxin formation by cold smoking:

RECORDS: Printout from digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Record showing the results of the maximum indicating thermometer checks;
OR
Record showing the results of the high temperature alarm checks.

For controlling toxin formation by hot smoking:

RECORDS: Printout from digital time/temperature data logger;
AND
Smoking log showing the time that the product reached 145˚F (62.8˚C) and the time that the heating process ended.

For controlling toxin formation by brining, dry salting, and/or drying:

RECORDS: Temperature recorder chart or data logger printout for drier input/output air temperature;
AND
Appropriate records (e.g. processing record showing the results of the brine strength and temperature, brine to fish ratio, size and species of fish, time of brining) as necessary to document the monitoring of the critical factors of the brining, dry salting, and/or drying process, as established by a study;
OR
Results of the finished product water phase salt determination.

• Control Strategy Example 2 - Pickling

For controlling toxin formation by pickling, brining, or formulation:

RECORDS: Appropriate records (e.g. processing record showing the results of the brine/acid strength and temperature, brine/acid to fish ratio, size and species of fish, time of brining/pickling) as necessary to document the monitoring of the critical factors of the brining/pickling process, as established by a study;
OR
Results of the finished product water phase salt, pH, or water activity determinations.

• Control Strategy Examples 1 & 2

For controlling toxin formation during in-process and finished product storage:

RECORDS: 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.

For controlling toxin formation during processing:

RECORDS: Processing records showing the results of time and/or temperature checks;
OR
Printout from digital time/temperature data logger.

Continued

For controlling toxin formation at receipt of "pickled," smoked, smoke-flavored, or salted fish for storage or further processing:

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.

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 "*C. botulinum* toxin 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 C. botulinum toxin production; 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 - Salting/smoking

VERIFICATION: Review monitoring, corrective action, and verification records within one week of preparation;
AND
Process establishment (except where finished product water phase salt analysis is the monitoring procedure): The adequacy of the brining/dry salting and/or drying process should be established by a scientific study. It should be designed to ensure a water phase salt level in the loin muscle of: 2.5 percent for air packaged smoked or smoke-flavored fish; 3.5 percent or 3.0 percent with not less than 100 ppm nitrite for vacuum or modified atmosphere packaged smoked fish or smoke-flavored fish; or 10 percent for salted fish. Expert knowledge of salting and/or drying processes is required to establish such a process. Such knowledge can be obtained by education or experience or both. Establishment of brining/dry salting and drying processes requires access to adequate facilities and the application of recognized methods. The drying equipment must be designed, operated and maintained to deliver the established drying process to every unit of product. In some instances, brining/dry salting and/or drying studies will be required to establish minimum processes. In other instances, existing literature, which establish minimum processes or adequacy of equipment, are available. Characteristics of the process, product, and/or equipment that affect the ability of the established minimum salting and/or drying process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;
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 digital time/temperature data loggers or recorder thermometers are used for monitoring of transport conditions at receiving, check for accuracy against a known accurate thermometer (NIST-traceable) at time of receipt;
AND
When dial thermometers or maximum indicating 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);
AND
Other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;
AND

Finished product sampling and analysis to determine water phase salt at least once every three months (except where such testing is performed as part of monitoring).

• Control Strategy Example 2 - Pickling

VERIFICATION: Review monitoring, corrective action, and verification records within one week of preparation;
AND
Process establishment (except where finished product water phase salt, pH, or water activity analysis is the monitoring procedure): The adequacy of the pickling/brining/formulation process should be established by a scientific study. It should be designed to ensure: a water phase salt level in the loin muscle of at least 5 percent; a pH in the loin muscle of 5.0 or below; a water activity in the loin muscle of 0.97 or below; or a combination of salt, pH, and/or water activity in the loin muscle that, when combined, prevent the growth of *C. botulinum* type E and nonproteolytic type B and F (established by scientific study). Expert knowledge of pickling/brining/formulation processes is required to establish such a process. Such knowledge can be obtained by education or experience or both. Establishment of pickling/brining/formulation processes requires access to adequate facilities and the application of recognized methods. In some instances, pickling/brining/formulation studies will be required to establish minimum processes. In other instances, existing literature, which establish minimum processes, are available. Characteristics of the process and/or product that affect the ability of the established minimum pickling/brining/formulation process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;
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 digital time/temperature data loggers or recorder thermometers are used for monitoring of transport conditions at receiving, check for accuracy against a known accurate thermometer (NIST-traceable) at time of receipt;
AND
When dial thermometers or maximum indicating 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);
AND
Daily calibration of pH meters;
AND
Other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;
AND
Finished product sampling and analysis to determine water phase salt, pH, or water activity level, as appropriate, at least once every three months (except where such testing is performed as part of monitoring).

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

TABLE #13-1

Control Strategy Example 1 – Salting/smoking

This table is a an example of a portion of a HACCP plan relating to the control of *C. botulinum* toxin formation for a processor of vacuum packaged hot-smoked salmon, using Control Strategy Example 1 - Salting/smoking. It is provided for illustrative purposes only. *C. botulinum* toxin 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. aquaculture drugs, chemical contaminants, parasites, growth of other pathogens, survival of other pathogens through the cook step, and metal fragments).

(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			
Brining	• *C. botulinum* toxin formation in finished product	• Minimum brining time 6 hours	• Length of brining process	• Visual	• Start and end of brining process	• Brine room employee	• Extend brining process	• Production record	• Documentation of brining/ drying process establishment
		• Minimum salt concentration of brine at start of brining 60° salimeter	• Salt concentration of brine	• Salimeter	• Start of brining process	• Brine room employee	• Add salt	• Production record	• Review monitoring, corrective action, and verification records within one week of preparation
		• Minimum ratio of brine:fish 2:1	• Weight of brine (as determined by volume)	• Visual to mark on tank	• Start of brining process	• Brine room employee	• Add brine	• Production record	
			• Weight of fish	• Scale	• Each batch	• Brine room employee	• Remove some fish and reweigh	• Production record	• Monthly calibration of scale
		• Maximum fish thickness 1 1/2" (Note: Above CLs are designed to produce a minimum water phase salt level in the loin muscle of 3.5%)	• Fish thickness	• Caliper	• Each batch (10 fish)	• Brine room employee	• Hold and evaluate based on finished product water phase salt analysis	• Production record	• Quarterly water phase salt analysis

Note: The critical limits in this example are for illustrative purposes only, and are not related to any recommended process.

TABLE #13-1, 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			
Smoking/drying/ heating	• *C. botulinum* toxin formation in finished product	• Minimum time open vent 2 hours • Internal temperature of fish held at or above 145˚F for at least 30 minutes	• Time of open vent • Internal temperature of fish	• Visual • Digital data logger with probes in 3 of thickest fish in cold spot of oven	• Each batch • Continuous with visual at end of batch	• Smoker employee • Smoker employee	• Extend drying process, and • Hold and evaluate • Extend heating process, and • Hold and evaluate	• Production record • Data logger printout	• Documentation of brining/ drying process establishment • Review monitoring, corrective action, and verification records within one week of preparation • Daily calibration of data logger • Quarterly water phase salt analysis
Cooling after hot smoking	• *C. botulinum* toxin formation	• No more than 4 hours between end of smoking process and placement of racks under refrigeration	• Length of time between end of smoking process and placement of racks under refrigeration	• Visual observation of end of smoking process and time of placement in cooler	• Each batch	• Smoker employee	• Place product in cooler, and • Hold and evaluate based on time/ temperature of exposure	• Production record	• Review monitoring and corrective action records within one week of preparation

Note: The critical limits in this example are for illustrative purposes only, and are not related to any recommended process.

TABLE #13-1, 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			
Smoked fish storage cooler	• *C. botulinum* toxin formation	• Maximum cooler temperature 50˚F	• Cooler air temperature	• Digital data logger	• Continuous, with visual once per day	• Production employee	• Adjust or repair cooler, and • Hold and evaluate based on time/ temperature of exposure	• Digital logger printout	• Review monitoring, corrective action, and verification records within one week of preparation • Daily check of data logger accuracy
Finished product storage	• *C. botulinum* toxin formation during finished product storage	• Maximum cooler temperature 50˚F	• Cooler air temperature	• Digital data logger	• Continuous, with visual once per day	• Production employee	• Adjust or repair cooler, and • Hold and evaluate based on time/ temperature of exposure	• Data logger printout	• Review monitoring, corrective action, and verification records within one week of preparation • Daily check of data logger accuracy

Note: The critical limits in this example are for illustrative purposes only, and are not related to any recommended process.

TABLE #13-2

Control Strategy Example 2 – Pickling

This table is an example of a portion of a HACCP plan relating to the control of *Clostridium botulinum* for a processor of pickled herring, using Control Strategy Example 2 - Pickling. It is provided for illustrative purposes only. *C. botulinum* toxin 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. histamine, chemical contaminants, parasites, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Pickling	*C. botulinum* toxin formation in finished product	Maximum finished product pH in the loin muscle of 5.0	Finished product pH in the loin muscle	Collect sample of product from each pickling tank at the end of each pickling cycle and analyze for pH using a pH meter	Each pickling tank, each cycle	QC personnel	Continue pickling process until pH meets the CL	Analytical results	• Daily calibration of pH meter • Review monitoring, corrective action, and verification records within one week of preparation
Finished product storage	*C. botulinum* toxin formation during finished product storage	Maximum cooler temperature 50˚F	Cooler air temperature	High temperature alarm	Continuous, with visual check of operation once per day	Production employee	• Adjust or repair cooler, and • Hold and evaluate based on time/ temperature of exposure	Production record with daily alarm check	• Daily accuracy check of high temperature alarm • Review monitoring, corrective action, and verification records within one week of preparation

Notes: