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 formation during storage and distribution of the finished product by drying is covered in Chapter 14. The prevention of *C. botulinum* toxin formation during storage and distribution of the finished product by specialized cooking and hot filling procedures is covered in Chapter 16. The prevention of *C. botulinum* toxin development during storage and distribution of the finished product by pasteurization in the finished product container is covered in Chapter 17.

When *C. botulinum* grows it can produce a potent toxin, 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), but processors cannot rely on this as a means of control.

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.

The vegetative cells of all types are easily killed by heat. *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. Table A-4 (Appendix 4) provides guidance about the conditions under which the spores of the most heat resistant form of nonproteolytic *C. botulinum*, type B, are killed. However, there are some indications that substances that may be naturally present in some products, such as lysozyme, may enable nonproteolytic *C. botulinum* to more easily recover after heat damage, resulting in the need for a considerably more aggressive process to ensure destruction.

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 reduce the amount of oxygen present in the package (e.g. vacuum packaging) extend the shelf life of product by inhibiting the growth of aerobic spoilage bacteria. 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.

C. botulinum forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F is 38˚F (3.3˚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,

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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).

In reduced oxygen packaged products in which the spores of nonproteolytic *C. botulinum* are inhibited or destroyed (e.g., smoked fish, pasteurized crabmeat, pasteurized surimi), normal refrigeration temperatures of 40˚F (4.4˚C) are appropriate because they will limit the growth of proteolytic *C. botulinum* and other pathogens that may be present. Even in products where nonproteolytic *C. botulinum* is the target organism for the pasteurization process and vegetative pathogens, such as *Listeria monocytogenes,* are not likely to be present (e.g. pasteurized crabmeat, pasteurized surimi), a storage temperature of 40˚F (4.4˚C) is still appropriate because of the potential survival through the pasteurization process and recovery of spores of nonproteolytic *C. botulinum* aided by naturally occurring substances, such as lysozyme. In this case refrigeration serves as a prudent second barrier.

In reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of nonproteolytic *C. botulinum* and the spores have not been destroyed (e.g. vacuum packaged raw fish, unpasteurized crayfish meat), the temperature must be maintained at 38˚F (3.3˚C) or below from packing to consumption. Ordinarily processors can ensure that temperatures are maintained at or below 38˚F (3.3˚C) while the product is in their control. However, current distribution channels do not ensure the maintenance of these temperatures after the product leaves their control. The use of time temperature integrators on each consumer package may be an appropriate means of enabling temperature control throughout distribution. Alternatively, products of this type may be safely marketed frozen, with appropriate labeling. For some products, control of *C. botulinum* can be achieved by breaking the vacuum seal before the product leaves the processor's control.

• 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.

• Reduced oxygen packaging

There are a number of conditions that can result in the creation of a reduced oxygen packaging environment. They include:

• Vacuum packaging or modified or controlled atmosphere packaging. These packaging methods directly reduce the amount of oxygen in the package;

• Packaging in hermetically sealed containers (e.g. double seamed cans, glass jars with sealed lids, heat sealed plastic containers), or packing in deep containers from which the air is expressed (e.g. caviar in large 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 the formation of a reduced oxygen environment.

Packaging that provides an oxygen transmission rate of 10,000 cc/m^2/24hrs (e.g. 1.5 mil polyethylene) can be regarded as an oxygen-permeable packaging material for fishery products. This can be compared to an oxygen-impermeable package which might have an oxygen transmission rate as low as or lower than 100 cc/m^2/24hr (e.g. 2 mil polyester). An oxygen permeable package should provide sufficient exchange of oxygen to allow aerobic spoilage organisms to grow and spoil the product before toxin is produced under moderate abuse temperatures. However, use of an oxygen permeable package will not compensate for the restriction to oxygen exchange created by practices such as packing in oil or in deep containers from which the air is expressed.

• Control of *C. botulinum* in the finished product

There are a number of strategies to prevent *C. botulinum* toxin formation during storage and distribution of finished fishery products. They include:

For products that do not require refrigeration (i.e. shelf-stable products):

• Heating the finished product in its final container 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;

• Controlling the level of acidity (pH) in the finished product sufficient to prevent the growth of *C. botulinum* types A,B,E, and F (4.6 or below) (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 and other pathogens that may be present in the product (i.e. 0.85 or below) (e.g. shelf-stable dried products) (covered by Chapter 14);

• Controlling the amount of salt in the product sufficient to prevent the growth of *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (i.e. 20% salt or more)(e.g. shelf-stable salted products)(covered in this chapter).

For products that require refrigeration:

• Heating the finished product in its final container sufficiently by pasteurization to destroy the spores of *C. botulinum* type E and nonproteolytic types B and F (covered in Chapter 17); and then controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F in the finished product with refrigerated storage (e.g. pasteurized crabmeat, some pasteurized surimi-based products) (covered in this chapter and Chapter 12);

• Heating the product sufficiently to destroy the spores of *C. botulinum* type E and nonproteolytic types B and F (covered in Chapter 16); and then minimizing the risk of recontamination by hot filling the product into the final container in a continuous filling system (covered in Chapter 18); and then controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (covered in this chapter and Chapter 12);

• Controlling the amount of moisture that is available in the product (water activity) sufficient to inhibit the growth of *C. botulinum* type E and nonproteolytic types B and F by drying (covered in Chapter 14); and then controlling the growth of *C. botulinum* type A, and proteolytic types B and F, and other pathogens that may be present in the finished product through refrigerated storage (covered in this chapter and Chapter 12);

• Controlling the level of acidity (pH), salt, moisture (water activity), or some combination of these barriers, in the finished product sufficiently to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F by formulation (i.e. pH 5 or below; salt 5% or more; or water activity below 0.97) (covered in this chapter); and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g. refrigerated acidified ["pickled"] products) (covered in this chapter and Chapter 12);

• Controlling the amount of salt and preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as smoke, heat damage and competitive bacteria, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (covered in this chapter); and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g. salted, smoked, or smoke-flavored fish) (covered in this chapter and Chapter 12);

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• Controlling the amount of salt in the finished product, in combination with heat damage from pasteurization in the finished product container, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (covered in this chapter); and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g. some pasteurized surimi-based products) (covered in this chapter and Chapter 12);

• Control of *C. botulinum* during processing and storage

There are a number of strategies to prevent *C. botulinum* toxin formation during the processing and storage of fishery products. They include:

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

Note: The guidance in this chapter emphasizes preventive measures for the control of *C. botulinum* in products that are contained in reduced oxygen packaging. As was previously described, this is because such an environment extends the shelf life of the product in a way that favors *C. botulinum* growth and toxin formation over aerobic spoilage. It is also possible for *C. botulinum* to grow and produce toxin in unpackaged or aerobically packaged product. This is because of the development within the product of microenvironments that support its growth. However, toxin formation under these circumstances requires the type of severe temperature abuse that is not reasonably likely to occur in most food processing environments. Nonetheless, the Good Manufacturing Practice Regulations, 21 CFR 110, require refrigeration of foods that support the growth of pathogenic microorganisms. In addition Chapter 12 provides recommendations for storage controls for pathogens other than *C. botulinum*.

• Evisceration of fish before processing. Because spores are known to be present in the viscera of fish, any product that will be preserved by salting, 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 even with strict control of temperature. Evisceration must be thorough and performed to minimize contamination of the fish flesh. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. 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 in refrigerated products, or 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, in shelf-stable products are exempt from the evisceration requirement.

Examples of *C. botulinum* Control in Specific Products:

• Control in refrigerated, reduced oxygen packaged smoked and smoke-flavored fish

Achieving the proper concentration of salt and nitrite in the flesh of refrigerated, reduced oxygen packaged smoked and smoke-flavored fish is necessary to prevent the formation of toxin by *C. botulinum* type E and nonproteolytic types B and F during storage and distribution. Salt works along with smoke and any nitrites that are added to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types 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 types 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 because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and nonproteolytic types 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 to ensure survival of the spoilage organisms is, therefore, critical to the safety of the finished product.

The interplay of these inhibitory effects (i.e. 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 toxin formation by *C. botulinum* type E and nonproteolytic types B and F 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 (i.e. the concentration of salt in the water portion of the fish flesh) needed to inhibit the growth and toxin formation of *C. botulinum*.

The above described control procedures are covered in this chapter.

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

The combination of inhibitory effects that are present in smoked and smoke-flavored fish are not adequate to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e. at or below 40˚F [4.4˚C]) during storage and distribution must be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in these products (covered in this chapter and Chapter 12).

• Control in refrigerated, reduced oxygen packaged, pasteurized fishery products

Refrigerated, reduced oxygen packaged, pasteurized products fall into two categories: 1) those which are pasteurized in the final container); and 2) those which are pasteurized in a kettle (i.e. cooked) and then hot filled into the final container (e.g."heat and fill" soups and sauces). In both cases, ordinarily the heating process must be sufficient to destroy the spores of *C. botulinum* type E and nonproteolytic types B and F. In neither case is it likely that the heating process will be sufficient to destroy the spores of *C. botulinum* type A and proteolytic types B and F. Therefore, strict refrigeration control (i.e. at or below 40˚F [4.4˚C]) must be maintained during storage and distribution to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F, and because of the potential survival through the pasteurization process and recovery of spores of nonproteolytic *C. botulinum* aided by naturally occurring substances, such as lysozyme. In the case of the lysozyme effect, refrigeration serves as a prudent second barrier.

In the second category of products, filling the product into the final container while it is still hot in a continuous filling system (i.e. "hot filling") is also critical to the safety of the finished product, because it minimizes the risk of recontamination of the product with pathogens, including *C. botulinum* type E and nonproteolytic types B and F. This strategy applies to products such as soups and sauces that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It does not apply to products such as crabmeat, lobster meat, or crayfish meat, or other products that are handled between cooking and filling. Control of hot filling is covered in Chapter 18. Chapter 18 also covers other controls that may be necessary to prevent recontamination, including controlling container sealing and controlling contamination of container cooling water. These controls may be critical to the safety of both categories of products.

Examples of properly pasteurized products are: blue crabmeat pasteurized to a cumulative lethality of $F_{185^{\circ}F}$ ($F_{85^{\circ}C}$) = 31 min., z=16˚F (9˚C); surimi-based products, soups, or sauces pasteurized at an internal temperature of 194˚F (90˚C) for at least 10 minutes.

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In some pasteurized surimi-based products, salt in combination with a milder pasteurization process in the finished product container work to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F. Control of the formulation process is clearly critical in these products to ensure that there is sufficient salt in the finished product. The formulation controls discussed in this chapter for the production of "pickled" fishery products are also suitable for the control of surimi-based product formulation. Control of the in-container pasteurization process is also critical. An example of a properly pasteurized surimi-based product in which 2.5% salt is present is one that has been pasteurized at an internal temperature of 185˚F (85˚C) for at least 15 minutes. This process may not be suitable for other types of products, because of the unique formulation and processing involved in the manufacture of surimi-based products.

In-container pasteurization is covered in Chapter 17. Cooking is covered in Chapter 16. Control of refrigerated storage is covered in this chapter and in Chapter 12.

• Control in refrigerated, reduced oxygen packaged "pickled" fish, caviar, and similar products

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

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

- Adding sufficient acid to reduce the acidity (pH) to 5.0 or below;

- Reducing the amount of moisture that is available for growth (water activity) to below 0.97 (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 types B and F (to be established by a scientific study).

Much like smoked products, in some of these products the interplay of these inhibitory effects (i.e. 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. These control procedures are covered in this chapter.

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

The above discussed controls are not sufficient to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e. at or below 40˚F [4.4˚C]) during storage and distribution must, therefore, be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F, and other pathogens that may be present in these products (covered in this chapter).

• Control in refrigerated, reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products

For refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g. vacuum packaged fresh fish fillets) and unpasteurized, cooked fishery products (e.g. vacuum packaged, unpasteurized crabmeat, lobstermeat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and nonproteolytic types B and F during finished product storage and distribution is refrigeration. These types of *C. botulinum* will grow at temperatures as low as 38˚F (3.3C). As was previously stated, maintenance of temperatures at or below 38˚F (3.3˚C) after the product leaves the processor's control cannot normally be ensured. Time temperature integrators on each consumer package may be an appropriate means of providing such control. If you intend to use a reduced oxygen packaging technique for these products and you intend to market the products refrigerated without time temperature integrators on each consumer package, 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. A suitable protocol for the performance of such studies is contained in a 1992 publication by the National Advisory Committee on Microbiological Criteria for Foods, "Vacuum or modified atmosphere packaging for refrigerated, raw fishery products.

- Control in frozen, reduced oxygen packaged fishery products

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 immediately before use"), then formation of *C. botulinum* toxin may not be a significant hazard.

- Control in unrefrigerated (shelf-stable), reduced oxygen packaged fishery products

Examples of shelf-stable, reduced oxygen packaged fishery products are dried fish, acidified fish, canned fish and salted fish. Because these products are marketed without refrigeration, either: 1) the spores of *Clostridium botulinum* types A,B, E and F must be destroyed after the product is placed in the finished product container (covered by the low acid canned foods regulations, 21 CFR 113); or 2) a barrier, or combination of barriers, must be in place that will prevent growth and toxin formation by *Clostridium botulinum* types A,B, E and F, and other pathogens that may be present in the product. Suitable barriers include:

- Sufficient salt is added to produce a water phase salt level (the concentration of salt in the water-portion of the fish flesh) of at least 20 percent (Note: this value is based on the maximum salt level for growth of *S. aureus*.) (covered in this chapter)

- Sufficient salt is added to reduce the water activity to 0.85 or below (covered in this chapter);

- Sufficient acid is added to reduce the pH to 4.6 or below (covered by the acidified foods regulations, 21 CFR 114);

- The product is dried sufficiently to reduce the water activity to 0.85 or below (Note: this value is based on the minimum water activity for growth and toxin formation of *S. aureus,*)(covered in Chapter 14).

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 during finished product storage and distribution?

The factors that make *C. botulinum* toxin formation during finished product storage and distribution reasonably likely are those that may result in the formation of a reduced oxygen packaging environment. These are discussed in Step #10, under the heading, "Reduced oxygen packaging."

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 also 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 it is reasonably likely to occur.

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

- controlling refrigeration temperatures;
- 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.

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Preventive measures for *C. botulinum* toxin formation during finished product distribution and storage are discussed in Step #10, under the heading, "Control of *C. botulinum* in the finished product."

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, fish packed in deep containers in which the air is expressed). Notable products for which these preventive measures are not available include: refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g. vacuum packaged, fresh fish fillets) and reduced oxygen packaged, unpasteurized, cooked fishery products (e.g. vacuum packaged, unpasteurized crabmeat, lobstermeat, or crayfish meat). For these products, the sole barrier to toxin formation by *C. botulinum* type E and nonproteolytic types B and F during finished product storage and distribution is refrigeration. These types of *C. botulinum* will grow at temperatures as low as 38˚F (3.3C). As was previously stated, maintenance of temperatures at or below 38˚F (3.3˚C) after the product leaves the processor's control cannot normally be ensured. Time temperature integrators on each consumer package may be an appropriate means of providing such control. If you intend to use a reduced oxygen packaging technique for these products and you intend to market the products refrigerated without time temperature integrators on each consumer package, 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.

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 immediately before use"), then formation of *C. botulinum* toxin may not be a significant hazard.

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 #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for *C. botulinum* toxin formation:

1. Is there an acidification step (equilibrium pH of 4.6 or below), a drying step or an in-package pasteurization step (target organism *C. botulinum* type E and nonproteolytic types B and F) a combination of cook and hot-fill steps (target organism *C. botulinum* type E and nonproteolytic types 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, cook and hot-fill steps or retorting step as

the CCP(s) 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. However, the following products require control of temperature during finished product storage and distribution: products pasteurized in the final container to kill *C. botulinum* type E and nonproteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present (e.g. pasteurized crabmeat, pasteurized surimi); 2) products cooked to kill *C. botulinum* type E and nonproteolytic types B and F, and then hot filled into the final container, and then refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F, and other pathogens that may be present; and 3) products dried to control the growth of *C. botulinum* type E and nonproteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present. In these cases, you should also identify the finished product storage step as a CCP for the hazard. Such control is covered in this chapter and in Chapter 12. Additionally, some pasteurized surimi-based products rely on a combination of salt and a relatively mild pasteurization process in the finished product container for the control of *C. botulinum* type E and nonproteolytic types B and F. In these products, you should also identify the formulation step as a CCP for the hazard. Such control is covered in this chapter under Control Strategy Example 2 – "Pickling."

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

- Chapters 16 and 18, for control of cooking and hot-filling;
- 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, cooking and hot-filling, or retorting step(s) in the process, then decide which of the following categories best describes your product:
   - smoked or smoke-flavored fish;
   - "pickled" fish, salted 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 (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

Continued

produce acid, which will further inhibit *C. botulinum* growth and toxin formation.

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 types 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?

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. *B. cereus* can grow and form toxin at salt concentrations as high as 18%. Therefore, in these products, 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 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.

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 (and to some pasteurized surimi-based products that rely on a combination of salt and a relatively mild pasteurization process in the finished product container for the control of *C. botulinum* type E and nonproteolytic types B and F):

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 growth and toxin formation by *C. botulinum* type E and nonproteolytic type B and F. The levels of these inhibitors needed to inhibit toxin formation are achieved during the pickling, brining, or formulation step. Control must be exercised 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 20% (Note: this value is based on the maximum salt concentration for growth of *S. aureus*), 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.

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 - 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 refrigerated, reduced oxygen packaged (e.g. vacuum or modified atmosphere packaged) smoked fish or smoke-flavored fish, not less than 3.5 percent water phase salt, or, where permitted, the combination of 3.0 percent water phase salt and not less than 100 ppm nitrite.

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:

Continued

For refrigerated, reduced oxygen packaged fishery products:

- A water phase salt level of at least 5 percent;

OR

- A pH of 5.0 or below;

OR

- A water activity of below 0.97;

OR

- a water phase salt level of at least 2.5% in surimi-based products, when combined with a pasteurization process in the finished product container of 185˚F (85˚C) for at least 15 minutes (covered in Chapter 17);

OR

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

For unrefrigerated (shelf-stable), reduced oxygen packaged products:

- A water phase salt level of at least 20 percent (based on the maximum salt level for growth of *S. aureus*;

OR

- A pH of 4.6 or below;

OR

- A water activity of 0.85 or below (based on the minimum water activity for growth and toxin formation of *S. aureus*).

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 refrigerated (not frozen) finished product storage:

Critical Limit: The product must not be exposed to a combination of times and temperatures that will allow growth or toxin formation by *C. botulinum* or other pathogens that may be present in the product. Refer to the guidance for the control of pathogens other than *C. botulinum* provided in the critical limits section (Step #14) of Chapter 12, which is also adequate for the control of *C. botulinum*.

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

Critical Limit: The product must not be exposed to a combination of times and temperatures that will allow growth or toxin formation by *C. botulinum* or other pathogens that may be present in the product. Refer to the guidance for the control of pathogens other than *C. botulinum* provided in the critical limits section (Step #14) of Chapter 12, which is also adequate for the control of *C. botulinum*.

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 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 - 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 refrigerated (not frozen) finished product storage:

What: The temperature of the cooler;
OR
The adequacy of ice or other cooling media.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

What: The internal temperature of the fish throughout transportation;
OR
The temperature of the truck or other carrier throughout transportation;
OR
For fishery products with a transit time of four hours or less: The internal temperature of a representative number of containers in the lot at time of delivery;
OR
The adequacy of ice or other cooling media at time of delivery.

How Will Monitoring Be Done?

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

How: Use a digital time/temperature data logger;
OR
Use a recorder thermometer;
OR
Use a maximum indicating thermometer;
OR
Use a high temperature alarm.

Continued

For controlling toxin formation by hot smoking:

How: Use a 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, and, when appropriate, nitrate 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 refrigerated (not frozen) finished product storage:

How: Use a digital time/temperature data logger;
OR
Use a recorder thermometer;
OR
Use a high temperature alarm with 24-hour monitoring;
OR
Make visual observations of the adequacy of ice or other cooling media in a sufficient number of containers to represent all of the product.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

How: Use a time/temperature integrator for product internal temperature monitoring during transit;
OR
Use a digital time/temperature data logger for product internal temperature or ambient air temperature monitoring during transit;
OR
Use a recorder thermometer for ambient air temperature monitoring during transit;
OR
Use a maximum indicating thermometer for ambient air temperature monitoring during transit;
OR
Use a dial or digital thermometer for internal product temperature monitoring at receipt;
OR
Make visual observations of the adequacy of ice or other cooling media in a sufficient number of containers to represent all of the product.

How Often Will Monitoring Be Done (Frequency)?

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

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

For controlling toxin formation by hot smoking:

Frequency: Continuous monitoring by the instrument itself, 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 by the instrument itself, with visual check of the monitoring instrument at least once per batch;
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 and, when appropriate, nitrite 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 refrigerated (not frozen) finished product storage:

Frequency: Continuous monitoring by the instrument itself, with visual check of the monitoring instrument at least once per day;
OR
For ice or other cooling media, check at least twice per day, or immediately prior to shipment.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

Frequency: Each shipment.

Continued

Who Will Perform the Monitoring?

• CONTROL STRATEGY EXAMPLES 1 & 2

Who: With recorder thermometers, 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 per batch, as appropriate) 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 - 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. packaging that is not hermetically sealed, or 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. packaging that is not hermetically sealed, or 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. packaging that is not hermetically sealed, or 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 (e.g. packaging that is not hermetically sealed, or LACF or frozen product);

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 LACF or frozen product);

OR

- Divert the product to a non-food use.

Continued

AND

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 0.97 or above, 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. packaging that is not hermetically sealed, or LACF or frozen product);

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 refrigerated (not frozen) 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:

- Add ice to the affected product

OR

- Make repairs or adjustments to the malfunctioning cooler;

OR

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

OR

- 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 at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored 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.

AND

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

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

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

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "*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 recordkeeping system for the control strategy examples discussed in Step #12.

• CONTROL STRATEGY EXAMPLE 1 - 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, and, when appropriate, nitrite 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 refrigerated (not frozen) finished product storage:

Records: Printout from digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Storage record showing the results of the high temperature alarm checks.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored 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 maximum indicating thermometer checks;
OR
The results of internal product temperature monitoring at receipt;
AND
The date and time of departure and arrival of the vehicle;
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.

Continued

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 - 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 and, where appropriate, nitrite 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 consistently achieve a water phase salt level of: 3.5 percent or 3.0 percent with not less than 100 ppm nitrite for refrigerated, reduced oxygen packaged (e.g. vacuum or modified atmosphere packaged) smoked fish or smoke-flavored 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). Verification should be conducted on new suppliers' vehicles and at least quarterly for each supplier thereafter. Additional verifications may be warranted based on observations at receipt (e.g. refrigeration units appear to be in poor repair, or readings appear to be erroneous);

AND

When dial or digital 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 and, where appropriate, nitrite analysis 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. For refrigerated, reduced oxygen packaged products it should be designed to consistently achieve: a water phase salt level of at least 5 percent; a pH of 5.0 or below; a water activity of below 0.97; a water phase salt level of at least 2.5% in surimi-based products, when combined with a pasteurization process in the finished product container of 185˚F (85˚C) for at least 15 minutes; or, a combination of salt, pH, and/or water activity that, when combined, prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (established by scientific study). For unrefrigerated (shelf-stable), reduced oxygen packaged products, it should be designed to consistently achieve: a water phase salt level of at least 20% (based on the maximum water phase salt level for growth of *S. aureus*); a pH of 4.6 or below; or a water activity of 0.85 or below (based on the minimum water activity for growth of *S. aureus*. 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 accurat 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). Verification should be conducted on new suppliers' vehicles and at least quarterly for each supplier thereafter. Additional verifications may be warranted based on observations at receipt (e.g. refrigeration units appear to be in poor repair, or readings appear to be erroneous);

AND

When visual checks of ice or cooling media are used to monitor the adequacy of coolant, periodically measure internal temperatures of the product to ensure that the ice or cooling media is sufficient to maintain product temperatures at or below 40˚F (4.4˚C);

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 against standard buffers;

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.

Continued

TABLE #13-1

Control Strategy Example 1 – Smoking

This table is 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 - 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	• Salinometer	• 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: 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: What	(5) Monitoring: How	(6) Monitoring: Frequency	(7) Monitoring: Who	(8) Corrective Action(s)	(9) Records	(10) Verification
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 and time at that temperature	• 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 • Make repairs or adjustments to the smoking chamber, and • Hold and evaluate	• Production record • Data logger printout • Smoking log	• 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
Finished product storage	• *C. botulinum* toxin formation during finished product storage	• Maximum cooler temperature 40˚F (based on growth of vegetative pathogens)	• 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 40°F (based on growth of vegetative pathogens)	Cooler air temperature	High temperature alarm with 24-hour monitoring	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