CHAPTER 14: **Pathogenic Bacteria Growth and Toxin Formation as a Result of Inadequate Drying**

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UNDERSTAND THE POTENTIAL HAZARD.

Pathogenic bacteria growth and toxin formation in the finished product as a result of inadequate drying of fishery products can cause consumer illness. The primary pathogens of concern are *Staphylococcus aureus* (*S. aureus*) and *Clostridium botulinum* (*C. botulinum*). See Appendix 7 for a description of the public health impacts of these pathogens.

- **Control by Drying**

Dried products are usually considered shelf stable and are, therefore, often stored and distributed unrefrigerated. Examples of shelf-stable dried fish products are salmon jerky, octopus chips, dried shrimp, stock fish, and shark cartilage. The characteristic of dried foods that makes them shelf stable is their low water activity (A_w). Water activity is the measure of the amount of water in a food that is available for the growth of microorganisms, including pathogenic bacteria. A water activity of 0.85 or below will prevent the growth and toxin production of all pathogenic bacteria, including *S. aureus* and *C. botulinum*, and is critical for the safety of a shelf-stable dried product. *S. aureus* grows at a lower water activity than other pathogenic bacteria, and should, therefore, be considered the target pathogen for drying for shelf-stable products.

You should select a packaging material that will prevent rehydration of the product under the expected conditions of storage and distribution. Additionally, finished product package closures should be free of gross defects that could expose the product to moisture during storage and distribution. Chapter 18 provides guidance on control of container closures.

Some dried products that are reduced oxygen packaged (e.g., vacuum packaged, modified atmosphere packaged) are dried only enough to control growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F (i.e., types that will not form toxin with a water activity of below 0.97). These dried products are then refrigerated to control growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and by other pathogenic bacteria that may be present in the product, including *S. aureus*. The products might have the appearance of a fully dried product. Therefore, their packaging should include "keep refrigerated" labeling to ensure that temperature controls are applied throughout distribution.

Distributing partially dried, reduced oxygen packaged products frozen also could be used to control these pathogens. However, labeling with "keep frozen" instructions would then be important to ensure food safety. More information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

This chapter does not cover the growth of pathogenic bacteria, including *S. aureus*, which may occur as a result of time and temperature

abuse during processing, including before or during the drying process. That hazard is covered in Chapter 12. It also does not cover the control of *C. botulinum* type A and proteolytic types B and F and that of other pathogenic bacteria that may be present, including *S. aureus,* during refrigerated storage of reduced oxygen packaged, partially dried products. That hazard is covered in Chapters 12 and 13, respectively.

Controlling pathogenic bacteria growth and toxin formation by drying is best accomplished by:

- Scientifically establishing a drying process that reduces the water activity to 0.85 or below if the product will be stored and distributed unrefrigerated (shelf stable). Note that a heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms, for example, mold;
- Scientifically establishing a drying process that reduces the water activity to below 0.97 if the product will be stored refrigerated (not frozen) in reduced oxygen packaging;
- Designing and operating the drying equipment so that every unit of a product receives at least the established minimum process;
- Packaging the finished product in a container that will prevent rehydration.

The drying operation used in the production of smoked or smoke-flavored fish is not designed to result in a finished product water activity of 0.85 or below. The controls for these products are described in Chapter 13.

Because spores of *C. botulinum* are known to be present in the viscera of fish, any product that will be preserved by salting, drying, pickling, or fermentation should be eviscerated prior to processing (see the "Compliance Policy Guide," Sec. 540.650). Without evisceration, toxin formation is possible during the process even with strict control of temperature. Evisceration should 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, that are processed in a manner that eliminates preformed toxin and prevents toxin formation and that reach (1) a water phase salt content of 10%, a value based on the control of *C. botulinum* type A and proteolytic types B and F, in refrigerated products; or (2) a water activity of 0.85 or below (note that this is a value based on the minimum water activity for toxin production by *S. aureus*, in shelf-stable products); or (3) a pH (acidity) level of 4.6 or less in shelf-stable products are not subject to the evisceration recommendation.

- **Strategies for controlling pathogenic bacteria growth**

Pathogens can enter the process on raw materials. They can also be introduced into foods during processing, from the air, unclean hands, insanitary utensils and equipment, contaminated water, and sewage. There are a number of strategies for the control of pathogenic bacteria in fish and fishery products. They include:

- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the pH in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 12);

- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or by retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (called the Low-Acid Canned Foods Regulation in this guidance document));
- Killing pathogenic bacteria by processes that retain raw product characteristics (covered in Chapter 17).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogenic bacteria growth and toxin formation as a result of inadequate drying is a significant hazard at a processing step:

1. For shelf-stable, dried products, is it reasonably likely that *S. aureus* will grow and form toxin in the finished product if the product is inadequately dried?

   Table A-1 (Appendix 4) provides information on the conditions under which *S. aureus* will grow. If your food that is not distributed refrigerated or frozen and meets these conditions (i.e., in Table A-1) before drying, then drying will usually be important to the safety of the product, because it provides the barrier to *S. aureus* growth and toxin formation. Under ordinary circumstances, it would be reasonably likely that *S. aureus* will grow and form toxin in such products during finished product storage and distribution if drying is not properly performed. Note that drying to control toxin formation by *S. aureus* will also control toxin formation by *C. botulinum* in these products.

2. For shelf-stable, dried products, can *S. aureus* toxin formation that is reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria growth and toxin formation as a result of inadequate drying should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard of *S. aureus* toxin formation (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measure that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying are:

   - Proper design and control of the drying process (covered in this chapter);

3. For refrigerated or frozen, partially dried (i.e., not shelf stable) products, is it reasonably likely that *C. botulinum* type E and nonproteolytic types B and F will grow and form toxin in the finished product if the product is inadequately dried?

   Table A-1 (Appendix 4) provides information on the conditions under which *C. botulinum* type E and non-proteolytic types B and F will grow. Because of the need to prevent rehydration of dried products, these products generally will be contained in a reduced oxygen package. If your refrigerated (not frozen), reduced oxygen packaged food meets these conditions (i.e., Table A-1) before drying, then drying will usually be important to the safety of the product, because it provides the barrier to growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. Note that refrigeration will control toxin formation by *S. aureus* and *C. botulinum* type A and non-proteolytic types B and F in these products. Under ordinary

circumstances, it would be reasonably likely that *C. botulinum* type E and non-proteolytic types B and F will grow and form toxin in such products during finished product storage and distribution if drying is not properly performed. In addition, controlling labeling (e.g., "keep refrigerated" labeling) to ensure that the product is held refrigerated throughout distribution may be important to the safety of the product, because the product may appear to retailers, consumers, and end users to be shelf stable.

However, if your dried, reduced oxygen packaged product is distributed frozen, then freezing may provide the barrier to growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F, rather than drying. In this case, labeling to ensure that the product is distributed frozen may be important to the safety of the product. Chapter 13 provides guidance on labeling controls to ensure that frozen product that supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

4. For refrigerated or frozen, partially dried, reduced oxygen packaged dried products, can growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria growth and toxin formation as a result of inadequate drying should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measures that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying for refrigerated or frozen, partially dried, reduced oxygen packaged products are:

   - Proper design and control of the drying process (covered in this chapter);
   - Refrigeration (covered in Chapter 12) and labeling to ensure that the product is held refrigerated throughout distribution (covered in this chapter);
   - Freezing (Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen).

- **Intended use**

Because of the highly stable nature of *S. aureus* toxin and the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the intended use will affect the significance of the hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for pathogenic bacteria growth and toxin formation as a result of inadequate drying:

1. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because drying (rather than, or in addition to, refrigeration) is important to the safety of the product, you should identify the drying step as a CCP for this hazard.

   Example:

   A salmon jerky processor that distributes the product unrefrigerated should set the CCP for controlling the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying at the drying step. The processor would not need to identify the processing steps prior to drying as CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

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

2. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because refrigeration (in addition to drying) is important to the safety of the product, you should identify the finished product storage step and the labeling step, where you will ensure that the "keep refrigerated" labeling is included on every package, as a CCP, for this hazard.

   Example:

   A partially dried catfish processor that distributes the product refrigerated and reduced oxygen packaged should set the CCPs for controlling the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying at the drying step, finished product labeling step, and finished product storage step. The processor would not need to identify the processing steps prior to drying as CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

The control by drying is covered in "Control Strategy Example 1 - Control by Drying." Control of labeling is referred to in this chapter as "Control Strategy Example 2 - Control by Refrigeration With Labeling." It should be used along with "Control Strategy Example 1 - Control by Drying." Note that control of refrigerated finished product storage is covered in Chapter 12. Note also that Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of two control strategies for pathogenic bacteria growth and toxin formation that occurs as a result of inadequate drying. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. It is important to note that you may select a control strategy that is different from those that are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Control by drying	✓	✓
Control by refrigeration with labeling	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING**

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

Set Critical Limits.

- The minimum or maximum values for the critical factors established by a scientific study (i.e., for shelf-stable products, those which must be met in order to ensure that the finished product has a water activity of 0.85 or below; for refrigerated (not frozen), reduced oxygen packaged products, those which must be met in order to ensure that the finished product has a water activity of less than 0.97). These will likely include drying time, input/output air temperature, humidity, and velocity, as well as flesh thickness. Other critical factors that affect the rate of drying of the product may also be established by the study;

OR

- The minimum percent weight loss established by a scientific study (i.e., for shelf-stable products, that which must be met in order to ensure that the finished product has a water activity of 0.85 or below; for refrigerated (not frozen), reduced oxygen packaged products, that which must be met in order to ensure that the finished product has a water activity of less than 0.97);

OR

- For shelf-stable products:
  - Maximum finished product water activity of 0.85 or above;

OR

- For refrigerated (not frozen), reduced oxygen packaged products:
  - Maximum finished product water activity of less than 0.97.

Note: A heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

Establish Monitoring Procedures.

» What Will Be Monitored?

- Critical factors of the established drying process that affect the ability of the process to ensure the desired finished product water activity (i.e., 0.85 or below for shelf-stable products, less than 0.97 for refrigerated (not frozen), reduced oxygen packaged products). These may include drying time, air temperature, humidity, and velocity, as well as flesh thickness;

OR

- Percent weight loss;

OR

- Water activity of the finished product.

» How Will Monitoring Be Done?

For batch drying equipment:

- For drying time and input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity analysis:
  - Collect a representative sample of the finished product and conduct water activity analysis.

For continuous drying equipment:

- For input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For drying time:
  - Measure:
    - The revolutions per minute (RPM) of the belt drive wheel, using a stopwatch or tachometer;

    OR

    - The time necessary for a test unit or belt marking to pass through the equipment, using a stopwatch;

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity:
  - Collect a representative sample of the finished product and conduct water activity analysis.

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

For batch drying equipment:

- For time and temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once during each batch;

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each batch;

  OR
- For water activity:
  - Each batch.

For continuous drying equipment:

- For temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once per day;

  AND
- For time:
  - At least once per day, and whenever any changes in belt speed are made;

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each lot of finished product;

  OR
- For water activity:
  - Each lot of finished product.

» **Who Will Do the Monitoring?**

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

  AND
- For all other critical factors specified by the study:
  - Any person who has an understanding of the nature of the controls;

  OR
- For percent weight loss:
  - Any person who has an understanding of the nature of the controls;

  OR
- For water activity:
  - Any person with sufficient training to perform the analysis.

Establish Corrective Action Procedures.

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

- Redry the product (provided that redrying does not present an unacceptable opportunity for pathogenic bacteria growth);

  OR
- Chill and hold the product for an evaluation of the adequacy of the drying process. The evaluation may involve water activity determination on a representative sample of the finished product. If the evaluation shows that the product has not received an adequate drying process, the product should be destroyed, diverted to a use in which

pathogenic bacteria growth in the finished product will be controlled by means other than drying, diverted to a non-food use, or redried;

OR

- Divert the product to a use in which the critical limit is not applicable because pathogenic bacteria growth in the finished product will be controlled by means other than drying (e.g., divert inadequately dried fish to a frozen fish operation);

OR

- Divert the product to a non-food use;

OR

- Destroy the product.

AND

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

- Adjust the air temperature or velocity;

OR

- Adjust the length of the drying cycle to compensate for a temperature or velocity drop, humidity increase, or inadequate percent weight loss;

OR

- Adjust the belt speed to increase the length of the drying cycle.

Establish a Recordkeeping System.

For batch drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

AND

- Record of notation of the start time and end time of the drying periods;

AND

- Records that are appropriate for the other critical factors (e.g., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

For continuous drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

AND

- Drying log that indicates the RPM of the belt drive wheel or the time necessary for a test unit or belt marking to pass through the drier;

AND

- Records that are appropriate for the other critical factors (e.g., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

Establish Verification Procedures.

- Process validation study (except where a water activity analysis of the finished product is the monitoring procedure):
    - The adequacy of the drying process should be established by a scientific study. For shelf-stable products, the drying process should be designed to ensure the production of a shelf-stable product with a water activity of 0.85. For refrigerated (not frozen), reduced oxygen packaged products, it should be designed to ensure a finished product water activity of less than 0.97. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment may be required

to establish such a drying process. Such knowledge can be obtained by education or experience or both. Establishment of drying processes may require access to adequate facilities and the application of recognized methods. The drying equipment should be designed, operated, and maintained to deliver the established drying process to every unit of a product. In some instances, drying studies may be required to establish the minimum process. In other instances, existing literature that establishes minimum processes or adequacy of equipment is available. Characteristics of the process, product, and/or equipment that affect the ability to achive the established minimum drying process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Finished product sampling and analysis to determine water activity at least once every 3 months (except where such testing is performed as part of monitoring);

  AND

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

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

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

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

  AND

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

  AND

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

device). For example, devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Calibrate other instruments as necessary to ensure their accuracy;

AND

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

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Maximum product thickness: ¼ inch	Product thickness	Preset slicer to just less than ¼ inch	Once per day before operations	Slicer operator	Re-adjust slicer	Processing log	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

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CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

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Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum drying time: 5 hours	Drying time	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Continue drying	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum oven temperature: 140°F To achieve a final water activity of 0.85 or less	Oven air input temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Extend drying process Segregate the product and hold under refrigeration for evaluation Evaluate by performing water activity analysis on finished product Redry if less than 0.85	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING**

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

Set Critical Limits.

- All finished product labels must contain a "keep refrigerated" statement (e.g., "Important, keep refrigerated until used").

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Finished product labels for presence of "keep refrigerated" statement.

» **How Will Monitoring Be Done?**

- Visual examination.

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

- Representative number of packages from each lot of a finished product.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Segregate and relabel any improperly labeled product.

AND

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

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper statement;

AND

- Determine and correct the cause of improper labels.

Establish a Recordkeeping System.

- Record of labeling checks.

Establish Verification Procedures.

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

TABLE 14-2

CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Control by Refrigeration With Labeling." This example illustrates how a processor of refrigerated, partially dried catfish can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of labeling	C. botulinum toxin formation during finished product storage	All finished product labels must contain a "keep refrigerated" statement	Finished product labels for the presence of the "keep refrigerated" statement	Visual examination	One label from each case of labels at receipt	Receiving employee	Segregate and re-label any improperly labeled product Segregate and return or destroy any label stock that does not contain the proper statement Determine and correct the cause of improper labels	Label receiving record	Review monitoring and correction action records within 1 week of preparation

*Note: Chapter 12 covers control of pathogenic bacteria growth at the CCP of finished product storage.

BIBLIOGRAPHY.

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

- Hilderbrand, K. S. 1992. Fish smoking procedures for forced convection smokehouses, Special report 887. Oregon State University, Extension Service, Corvallis, OR.
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- McClure, P. J., M. B. Cole, and J. P. P. M. Smelt. 1994. Effects of water activity and pH on growth of *Clostridium botulinum*. J. Appl. Bact. Symp. Suppl. 76:105S-114S.
- Tatini, S. R. 1973. Influence of food environments on growth of *Staphylococcus aureus* and production of various enterotoxins. J. Milk Food Technol. 36:559-563.