

## Hazard Analysis Worksheet

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

Pathogen growth in the finished product as a result of inadequate drying of fishery products can cause consumer illness. Examples of dried fish products are: salmon jerky; octopus chips; dried shrimp; and, stock fish.

#### • Control of drying

Dried products are usually considered shelf stable and are, therefore, often stored and distributed unrefrigerated. 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 pathogens. A water activity of 0.85 or below will prevent the growth and toxin production of pathogens, including *Staphylococcus aureus* and *Clostridium botulinum*. *S. aureus* grows at a lower water activity than other pathogens, and should, therefore, be considered the target pathogen for drying.

This chapter covers the control of the drying process to prevent the growth and toxin production of pathogens, including *S. aureus*, in the finished product. Such control is critical to product safety if the product is distributed or stored unrefrigerated.

This chapter does not cover the growth of pathogens, including *S. aureus*, that may occur as a result of time/temperature abuse during processing, including before or during the drying process. That hazard is covered in Chapter 12.

Controlling pathogen 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; and,

- Designing and operating the drying equipment so that every unit of product receives at least the established minimum process.

Pathogen growth is not a concern in dried products that are stored, distributed, displayed and sold frozen, and are so labeled. These products need not meet the control measures outlined in this chapter since drying in this case is not critical to product safety. Similarly, drying may not be critical to the safety of dried products that are stored refrigerated, since refrigeration may be sufficient to prevent pathogen growth.

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. Drying controls for these products are described in Chapter 13.

Because spores of *Clostridium botulinum* are known to be present in the viscera of fish, any product that will be preserved using salt, drying, pickling, or fermentation must be eviscerated prior to processing (see Compliance Policy Guide sec. 540.650). Without evisceration, toxin formation is possible during the process. Small fish, less than 5 inches in length, that are processed in a manner that prevents toxin formation, and that reach a water phase salt content of 10 percent, a water activity of below 0.85, or a pH of 4.6 or less are exempt from the evisceration requirement.

#### • Strategies for controlling pathogen 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, unsafe water, and sewage. There are a number of strategies for the control of pathogens in fish and fishery products. They include:

- Controlling the amount of moisture that is available for pathogen growth, water activity, in the product (covered in this chapter for shelf-stable dried products; and for refrigerated products in Chapter 13);

Continued

- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of acidity, pH, in the product (covered by the acidified foods regulations, 21 CFR 114 for shelf-stable acidified products; and for refrigerated acidified products in Chapter 13);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogens by cooking (covered in Chapter 16), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113).

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

At each processing step, determine whether “pathogen growth and toxin formation as a result of inadequate drying” is a significant hazard. The criteria are:

1. 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 meets these conditions before drying, then drying will usually be important to the safety of the product, because it provides the barrier to *S. aureus* growth. 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. However, see also the information contained in “Intended use and method of distribution and storage,” below.

2. Can *S. aureus* toxin formation, 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.)

“Pathogen 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 (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

Step #10 discusses a number of pathogen control strategies. This chapter covers control of pathogens by drying the product to lower the  $A_w$  to 0.85 or less. Delivering a properly designed drying process can be an effective preventive measure for the control of pathogens. If this preventive measure is applied list it in Column 5 of the Hazard Analysis Worksheet at the drying step.

If the answer to either question 1 or 2 is “Yes” the potential hazard is significant at the drying step in the process and you should answer “Yes” in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer “No.” You should record the reason for your “Yes” or “No” answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a “No.”

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

**• Intended use 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 Steps #4 and 3, respectively. Because of the highly stable nature of *S. aureus* toxin, it is unlikely that the intended use will affect the significance of the hazard.

However, the hazard may not be significant if: 1) the product is distributed and stored frozen throughout the chain of commerce, and is labeled to be held frozen and to be thawed under refrigeration immediately before use; or 2) the product is distributed refrigerated throughout the chain of commerce, and is labeled to be kept refrigerated. In both of these cases, the hazard of pathogen growth is controlled by the control of

temperature, rather than by the drying of the product. In these cases, you may enter “No” in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. In addition, for each “No” entry briefly explain in Column 4 that the hazard is controlled by freezing or refrigeration. In this case, you need not complete Steps #12 through 18 for this hazard. However, refer to Chapter 12 for the control of pathogen growth by refrigeration.

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

For each processing step where “pathogen growth and toxin formation as a result of inadequate drying” is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

You should identify the drying step as the critical control point for this hazard. Therefore, you should answer “Yes” in Column 6 of the Hazard Analysis Worksheet at the drying step and “No” in that column for the other processing steps for which the hazard was identified as a significant hazard. In addition, for each “No” entry make sure that Column 5 indicates that the hazard is controlled at the drying step. (Note: if you have not previously identified “pathogen growth and toxin formation as a result of inadequate drying” as a significant hazard at the drying step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to “Yes”.)

This 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.

#### *Example:*

*A salmon jerky processor could set the critical control point for controlling the hazard of “pathogen 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 critical*

*control points for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogens as a result of time/temperature abuse during processing, covered by Chapter 12.*

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

## **HACCP Plan Form**

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

For the drying step, 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 drying step.

#### **• Control Strategy Example 1 - Control of drying**

**CRITICAL LIMIT:** The minimum or maximum values for the critical factors established by a scientific study (i.e. those which must be met in order to ensure that the finished product has a water activity of 0.85 or less. These will likely include drying time, input/output air temperature, humidity, and velocity, and 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. those which must be met in order to ensure that the finished product has a water activity of 0.85 or less);

OR

Maximum finished product water activity of 0.85 or less.

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

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

For the drying step, describe monitoring procedures that will ensure that the critical limits are consistently met.

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

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

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

Following is guidance on establishing monitoring procedures for the drying step. 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 - Control of drying**

**WHAT:** Critical factors of the established drying process that affect the ability of the process to ensure a finished product water activity of 0.85

or below. These may include drying time, air temperature, humidity, and velocity, and flesh thickness;

OR

Percent weight loss;

OR

Water activity.

### **How Will Monitoring Be Done?**

- **Control Strategy Example 1 - Control of drying**

#### **For batch drying equipment:**

**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 air input/output temperature;

AND

Monitor all other critical factors specified by the study with equipment appropriate for the measurement;

OR

Using all or a portion of the batch, determine the percent weight loss by weighing the product before and after drying;

OR

Collect a representative sample of finished product and conduct water activity analysis.

#### **For continuous drying equipment:**

**HOW:** Monitor 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 air input/output temperature;

AND

Monitor the time by measuring either:

- The RPM of the belt drive wheel, using a stop watch or tachometer;

OR

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

AND

Monitor all other critical factors specified by the study with equipment appropriate for the measurement;

OR

Using all or a portion of the lot, determine the percent weight loss by weighing the product before and after drying;

OR

Collect a representative sample of finished product and conduct water activity analysis.

### How Often Will Monitoring Be Done (Frequency)?

- Control Strategy Example 1 - Control of drying

#### For batch drying equipment:

**FREQUENCY:** Temperature requirements of the drying process should be monitored continuously;

AND

Time requirements of the drying process should be monitored for each batch;

AND

Monitor all other critical factors specified by the study as often as necessary to maintain control;

OR

Percent weight loss should be determined for each batch of finished product;

OR

Water activity should be determined for each batch of finished product.

#### For continuous drying equipment:

**FREQUENCY:** Temperature requirements of the drying process should be monitored continuously;

AND

Time requirements of the drying process should be monitored at least once per day, and whenever any changes in belt speed are made;

AND

Monitoring of all other critical factors specified by the study as often as necessary to maintain control;

OR

Percent weight loss should be determined for each lot of finished product;

OR

Water activity should be determined for each lot of finished product.

### Who Will Perform the Monitoring?

- Control Strategy Example 1 - Control of drying

#### For batch drying equipment:

**WHO:** Time and temperature monitoring is performed by the equipment itself. However, a visual check should be made of the recorded data at least once at the end of each cycle in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the other critical factors in the drying process, the percent weight loss, or the water activity may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, or any other person who has an understanding of the operation of the equipment and the critical limit. In assigning responsibility for monitoring you should consider the complexity of the monitoring equipment. For example, accurately performing water activity analyses requires considerable training.

#### For continuous drying equipment:

**WHO:** Temperature monitoring is performed by the equipment itself. However, a visual check should be made of the recorded data at least daily in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the drying time and the other critical factors in the drying process, the percent weight loss, or the water activity may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, or any other person who has an understanding of the operation of the equipment and the critical limit. In assigning responsibility for monitoring you should



consider the complexity of the monitoring equipment. For example, accurately performing water activity analyses requires considerable training.

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 the drying step, 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 drying step.

• **Control Strategy Example 1 - Control of 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 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;

AND

When there has been a failure to maintain specified critical factors of the drying process, or when the prescribed minimum percent weight loss is not met, take one of the following actions to the product involved in the deviation:

- Destroy the product;
- OR
- Redry the product (provided that redrying does not present an unacceptable opportunity for pathogen growth);

OR

- Segregate and hold the product (under refrigerated conditions) 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 non-food use, or redried;

OR

- Divert the product to a use in which the critical limit is not applicable because pathogen 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.

AND

When finished product testing shows that the water activity is above 0.85, take one of the following actions to the product involved in the deviation:

- Destroy the product;

OR

- Re-dry the product (where re-drying does not create a hazard for pathogen growth);

OR

- Divert the product to a use in which the critical limit is not applicable because pathogen 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.

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

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

For the drying step, 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 drying step.

• Control Strategy Example 1 - Control of drying

**For batch drying equipment:**

**RECORDS:** Temperature recorder charts or digital time/temperature data logger printout;  
AND  
Records that are appropriate for the other critical factors (e.g. drying log that indicates input/output air humidity and/or velocity);

OR

Records of weight before and after drying;

OR

Records of water activity analysis for each lot of product.

**For continuous drying equipment:**

**RECORDS:** Temperature recorder charts or digital time/temperature data logger printout;  
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. drying log that indicates input/output air humidity and/or velocity);

OR

Records of weight before and after drying;

OR

Records of water activity analysis for each lot of product.

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

**STEP #18: Establish verification procedures.**

For the drying step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of “pathogen growth and toxin formation as a result of inadequate drying; and, 2) consistently being followed. Following is guidance on establishing verification procedures for the drying step.

• Control Strategy Example 1 - Control of drying

**VERIFICATION:** Process establishment (except where finished product water activity analysis is the monitoring procedure): The adequacy of the drying process should be established by a scientific study. It should be designed to ensure the production of a shelf stable product with a water activity of 0.85. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment is required to establish such a drying process. Such knowledge can be obtained by education or experience or both. Establishment of 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, drying studies will be required to establish the minimum process. 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 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 three months (except where such testing is performed as part of monitoring);

AND

Check the accuracy of the temperature recording device or digital time/temperature data loggers against a known accurate thermometer (NIST-traceable) at least once per day;

AND

Calibrate other instruments as necessary to ensure their accuracy;

AND

Review monitoring, corrective action, and verification records within one week of preparation.

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

*Continued*

TABLE #14-1

**Control Strategy Example 1 - Control of drying**

This table is an example of a HACCP plan relating to the control of pathogen growth and toxin formation as a result of inadequate drying for a processor of salmon jerky, using Control Strategy Example 1 - Control of drying. It is provided for illustrative purposes only. Pathogen growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs, chemical contaminants, parasites, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6) Frequency	(7)		(8) Corrective Action(s)	(9) Records	(10) Verification
			What		How	Who	Who						
Drying (forced convection oven)	Pathogen growth and toxin formation	<ul style="list-style-type: none"> <li>Maximum product thickness 1/4"</li> <li>Minimum drying time 5 hours</li> <li>Minimum oven temperature 140°F</li> </ul>	<ul style="list-style-type: none"> <li>Product thickness</li> <li>Drying time</li> <li>Oven air input temperature</li> </ul>	<ul style="list-style-type: none"> <li>Preset slicer to just less than 1/4"</li> <li>Digital time/temperature data logger</li> <li>Digital time/temperature data logger</li> </ul>	<ul style="list-style-type: none"> <li>Once per day before operations</li> <li>Continuous, with visual check each batch</li> <li>Continuous, with visual check each batch</li> </ul>	<ul style="list-style-type: none"> <li>Slicer operator</li> <li>Oven operator</li> <li>Oven operator</li> </ul>	<ul style="list-style-type: none"> <li>Readjust slicer</li> <li>Continue drying</li> <li>Extend drying process</li> <li>Segregate product and hold for evaluation. Evaluate by performing water activity analysis on finished product. Re-dry if more than 0.85</li> </ul>	<ul style="list-style-type: none"> <li>Processing log</li> <li>Data logger printout</li> <li>Data logger printout</li> </ul>	<ul style="list-style-type: none"> <li>Documentation of drying process establishment</li> <li>Review monitoring, verification and corrective action records within one week of preparation</li> <li>Check the accuracy of the data logger daily.</li> <li>Analyze finished product sample once every 3 months for water activity</li> </ul>				

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