Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Staphylococcus aureus toxin formation in hydrated batter mixes can cause consumer illness. This toxin in particular is a concern because the toxin cannot be destroyed by heating steps that may be performed by the processor or the consumer. Pathogens other than *S. aureus*, such as those described in Chapter 12, are, in many cases, less likely to grow in hydrated batter mixes, and are likely to be killed by the heating steps that follow.

• Control of *Staphylococcus aureus* in batter mixes

S. aureus can enter the process on raw materials. It can also be introduced into foods during processing from unclean hands and insanitary utensils and equipment.

The hazard develops when a batter mix is exposed to temperatures favorable for *S. aureus* growth for sufficient time to permit toxin development. *S. aureus* toxin does not normally reach levels that will cause food poisoning until the numbers of the pathogen reach 100,000 to 1,000,000/gram. *S. aureus* will grow at temperatures as low as 41-43˚F (5.0-6.1˚C) and at a water activity as low as .85 (additional information on conditions favorable to *S. aureus* growth are provided in Table #A-1 (Appendix 4). However, toxin formation is not likely at temperatures lower than 50˚F (10˚C). For this reason, toxin formation can be controlled by minimizing exposure of hydrated batter mixes to temperatures above 50˚F (10˚C). Exposure times greater than 12 hours for temperatures between 50˚F (10˚C) and 70˚F (21.1˚C) could result in toxin formation. Exposure times greater than 3 hours for temperatures above 70˚F (21.1˚C) could also result in toxin formation.

• Strategies for controlling pathogen growth

There are a number of strategies for the control of pathogens in fish and fishery products. They include:

- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered in this chapter for *S. aureus* in hydrated batter mix; Chapter 13 for *C. botulinum*; and Chapter 12 for other pathogens and conditions);

- 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);

- Controlling the amount of moisture that is available for pathogen growth, water activity, in the product by drying (covered in Chapter 14);

- Controlling the amount of moisture that is available for pathogen 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 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).

Continued

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "*S. aureus* toxin formation in hydrated batter mixes" is a significant hazard. The criteria are:

1. Is it reasonably likely that *S. aureus* will grow and form toxin in the hydrated batter mix at the hydrated batter mix storage/recirculation step?

Remember that you should consider the potential for time/temperature abuse in the absence of controls. You may already have controls at the hydrated batter mix storage/recirculation step that minimize the potential for time/temperature abuse that could result in *S. aureus* growth and toxin formation. This and the following steps will help you determine whether those or other controls should be included in your HACCP plan.

Step #10 provides information to help you decide if the time/temperature conditions of your hydrated batter mix storage/recirculation step are significant for this hazard.

2. Can *S. aureus* growth and 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.)

"*S. aureus* toxin formation in hydrated batter mixes" 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.

Step #10 discusses a number of pathogen control strategies. This chapter covers control of *S. aureus* toxin formation that occurs as a result of time/temperature abuse at the hydrated batter mix storage/recirculation step. A preventive measure for toxin formation can include controlling the amount of time that batter mixes are exposed to temperatures above 50˚F (10˚C).

List this preventive measure in Column 5 of the Hazard Analysis Worksheet at the batter mix storage/recirculation step.

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."

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 the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, because of the highly stable nature of *S. aureus* toxin, it is unlikely that the intended use will affect the significance of the hazard.

STEP #12: *IDENTIFY CRITICAL CONTROL POINTS (CCP).*

For each processing step where "*S. aureus* growth and toxin formation in hydrated batter mixes" 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.

You should identify the hydrated batter mix storage/recirculation step as the critical control point for this hazard. For hand battering operations, where hydrated batter mix is stored at each hand battering station, each station should be identified as a CCP.

This control approach will be 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.

You should answer "Yes" in Column 6 of the Hazard Analysis Worksheet at the hydrated batter mix storage/recirculation 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 hydrated batter mix storage/recirculation step. (Note: if you have not previously identified "*S. aureus* growth and toxin formation in hydrated batter mixes" as a significant hazard at the hydrated batter mix storage/recirculation step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".)

Example:
A breaded fish processor could set the critical control point for controlling the hazard of "S. aureus growth and toxin formation in hydrated batter mixes" at the hydrated batter mix storage/recirculation step. The processor would not need to identify other processing steps as critical control points for that hazard.

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 hydrated batter mix storage/recirculation 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 may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the hydrated batter mix storage/recirculation step.

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Critical Limit: Hydrated batter mix temperatures should not exceed 50˚F (10˚C) for more than twelve hours, cumulatively;
AND
Hydrated batter mix temperatures should not exceed 70˚F (21.1˚C) for more than three hours, cumulatively.

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

Continued

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For the hydrated batter mix storage/recirculation 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 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 hydrated batter mix storage/recirculation 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 - HYDRATED BATTER MIX CONTROL

What: The temperature of the hydrated batter mix.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

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;
OR
Use an indicating thermometer.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Frequency: Continuous monitoring, with visual check at least once per day;
OR
For indicating thermometers: at least every two hours.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Who: With recorder thermometers, high temperature alarms, maximum indicating thermometers, and digital data loggers, monitoring is performed by the equipment itself. However, when such instruments are used, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. These checks, as well as indicating thermometer checks, may be performed by a production employee, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the process and the monitoring procedure.

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 hydrated batter mix storage/recirculation 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 hydrated batter mix storage/recirculation step.

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Corrective Action: Take one or more of the following actions to regain control over the operation after a CL deviation:

- Add ice to the hydrated batter mix storage/recirculation tank;

OR

- Make repairs or adjustments to the hydrated batter mix refrigeration equipment;

AND

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

- Destroy the product and the remaining hydrated batter mix;

OR

- Divert the product and the remaining hydrated batter mix to a non-food use;

OR

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

OR

- Hold the product and hydrated batter mix until the hydrated batter mix can be sampled and analyzed for the presence of staphylococcal enterotoxin.

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

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For the hydrated batter mix storage/recirculation 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 hydrated batter mix storage/recirculation step.

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

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;
OR
Record showing the results of the indicating thermometer checks.

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

Continued

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For the hydrated batter mix storage/recirculation step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "*S. aureus* growth and toxin formation in hydrated batter mixes"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the hydrated batter mix storage/ recirculation step.

- CONTROL STRATEGY EXAMPLE 1 -

HYDRATED BATTER MIX CONTROL

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

When digital time/temperature data loggers, recorder thermometers, or high temperature alarms are used, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;

AND

When indicating thermometers or maximum indicating thermometers are used, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

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

TABLE #15-1

Control Strategy Example 1 - Hydrated batter mix control

This table is an example of a portion of a HACCP plan relating to the control of *S. aureus* toxin formation in hydrated batter mixes for a breaded fish processor, using Control Strategy Example 1 - Hydrated batter mix control. It is provided for illustrative purposes only. *S. aureus* toxin formation in the hydrated batter mix 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. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Batter mix recirculation	*S. aureus* growth and toxin formation	Hydrated batter mix temperature not to exceed 50°F for more than 12 hrs, nor 70°F for more than 3 hrs, cumulative	Hydrated batter mix temperature	Recorder thermometer	Continuous with visual check once per day	Production employee	• Adjust hydrated batter mix refrigeration equipment • Destroy hydrated batter mix and any product produced during deviant period	Recorder thermometer chart	• Check accuracy of recorder thermometer once per day; • Review monitoring, corrective action and verification records within one week of preparation

See Text for Full Recommendations
Example Only

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

Notes: