

## CHAPTER 15: *Staphylococcus aureus* Toxin Formation in Hydrated Batter Mixes

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### UNDERSTAND THE POTENTIAL HAZARD.

*Staphylococcus aureus* (*S. aureus*) toxin formation in hydrated batter mixes can cause consumer illness. *S. aureus* is the bacterium responsible for Staphylococcal Food Poisoning (SFP). Ten to thirty outbreaks of SFP occur annually in the United States, from all sources. Symptoms include: vomiting, diarrhea, abdominal pain, nausea, and weakness. Symptoms usually start within 4 hours of consumption. Everyone is susceptible to intoxication by *S. aureus* toxin, with more severe symptoms, including occasionally death, occurring in infants, the elderly, and debilitated persons. Generally, it is a self-limiting illness.

This chapter covers control of *S. aureus* toxin formation that occurs as a result of time and temperature abuse at the hydrated batter mix storage or recirculation step. This toxin in particular is a concern at this step because it is not likely to be destroyed by subsequent heating steps that the processor or the consumer may perform. Pathogenic bacteria other than *S. aureus*, such as those described in Chapter 12, are less likely to grow in hydrated batter mixes and/or are likely to be killed by subsequent heating.

- **Control of *S. 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 500,000 to 1,000,000 per gram. *S. aureus* will grow at temperatures as low as 44.6°F (7°C) and at a water activity as low as 0.83 (additional information on conditions favorable to *S. aureus* growth is provided in Table A-1 (Appendix 4)). However, toxin formation is not likely at temperatures lower than 50°F (10°C) or at water activities below 0.85. 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 at temperatures between 50°F (10°C) and 70°F (21.1°C) could result in toxin formation. Exposure times greater than 3 hours at 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 *Clostridium botulinum*; and Chapter 12 for other pathogenic bacteria and conditions);
- Killing pathogenic bacteria by cooking or pasteurizing (covered in Chapter 16), or 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 the raw product characteristics (covered in Chapter 17);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- 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 level of acidity (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 4);
- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18).

## **DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.**

The following guidance will assist you in determining whether *S. aureus* toxin formation in hydrated batter mixes is a significant hazard at a processing step:

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

The previous section, “Understand the Potential Hazard,” provides information to help you decide whether the time and temperature conditions of your hydrated batter mix storage or recirculation step are favorable for *S. aureus* growth and toxin formation.

2. Can the hazard of *S. aureus* growth and toxin formation that was introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

*S. aureus* toxin formation in hydrated batter mixes 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 measure that can be applied for *S. aureus* toxin formation in hydrated batter mixes is controlling the amount of time that hydrated batter mixes are exposed to temperatures above 50°F (10°C).

### **• Intended use**

Because of the highly heat-stable nature of *S. aureus* toxin, it is unlikely that the intended use will affect the significance of the hazard.

## **IDENTIFY CRITICAL CONTROL POINTS.**

If the hazard of *S. aureus* toxin formation in hydrated batter mixes is significant, you should identify the hydrated batter mix storage or recirculation step as the critical control point (CCP) for this hazard. For hand-battering operations, where hydrated batter mix is stored at each hand-battering station, the hand-battering stations also should be identified as a CCP.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example - Hydrated Batter Mix Control.”

### *Example:*

*A mechanized breaded fish processor should set the CCP for controlling the hazard of *S. aureus* growth and toxin formation in hydrated batter mixes at the hydrated batter mix storage or recirculation step. The processor would not need to identify other processing steps as CCPs for that hazard.*

## DEVELOP A CONTROL STRATEGY.

The following guidance provides an example of a control strategy for *S. aureus* toxin formation in hydrated batter mixes. It is important to note that you may select a control strategy that is different from that which is suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following is an example of the control strategy included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Hydrated batter mix control	✓	✓

- CONTROL STRATEGY EXAMPLE - HYDRATED BATTER MIX CONTROL**

### ***Set Critical Limits.***

- Hydrated batter mix should not be held for more than 12 hours, cumulatively, at temperatures between 50°F (10°C) and 70°F (21.1°C);  
AND
- Hydrated batter mix should not be held for more than 3 hours, cumulatively, at temperatures above 70°F (21.1°C).

### ***Establish Monitoring Procedures.***

#### » **What Will Be Monitored?**

- The temperature of the hydrated batter mix and the time of exposure at temperatures above 50°F (10°C) and above 70°F (21.1°C).

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

- Use a continuous temperature-recording device (e.g., a recording thermometer);  
OR
- Use a temperature-indicating device (e.g., a thermometer) and observe the time of exposure.

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

- For continuous temperature-recording devices:
    - Continuous monitoring, with a visual check of the recorded data at least once per day;
- OR
- For temperature-indicating devices:
    - At least every 2 hours.

#### » **Who Will Do the Monitoring?**

- For temperature-recording devices:
    - Monitoring is performed by the device itself. The visual check of the data generated by the device, 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;
- OR
- For temperature-indicating devices:
    - 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:

- Destroy the product and remaining hydrated batter mix;
- OR
- Divert the product and 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 and 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.

AND

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

- Add ice to the hydrated batter mix storage and recirculation tank;  
AND/OR
- Make repairs or adjustments to the hydrated batter mix refrigeration equipment.

### ***Establish a Recordkeeping System.***

- For continuous temperature-recording devices:
  - Recorder thermometer charts or digital time and temperature data logger printouts;  
AND
  - Record of visual checks of recorded data;
- OR
- For temperature-indicating devices:
  - Record of visual checks of devices (time and temperature).

### ***Establish Verification Procedures.***

- Before a temperature-indicating device (e.g., a thermometer) or 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., batter temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-indicating device or 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-indicating device or 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). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

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 15-1

**CONTROL STRATEGY EXAMPLE - HYDRATED BATTER MIX CONTROL**

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example - Hydrated Batter Mix Control." This example illustrates how a breaded fish processor can control *S. aureus* toxin formation in hydrated batter mixes. It is provided for illustrative purposes only. *S. aureus* toxin formation in hydrated batter mixes 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 metal fragments).

**Example Only**  
**See Text for Full Recommendations**

(1) CRITICAL CONTROL POINT	(2) SIGNIFICANT HAZARD(S)	(3) CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	(4)	(5)	(6)	(7)	(8)	(9)	(10)
MONITORING						CORRECTIVE ACTION(S)	RECORDS	VERIFICATION	
						WHO			
Batter mix recirculation tank	<i>S. aureus</i> growth and toxin formation	Hydrated batter mix temperature not to exceed 50°F for more than 12 hours, cumulatively, nor 70°F for more than 3 hours, cumulatively	The temperature of the hydrated batter mix and the time of exposure at temperatures above 50°F (10°C) and above 70°F (21.1°C)	Recorder thermometer	Continuous, with visual check once per day	Production employee	Destroy hydrated batter mix and any product produced during the period of the deviation	Recorder thermometer chart	Check the recorder thermometer 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
							Adjust hydrated batter mix refrigeration equipment		Review monitoring, corrective action, and verification records within 1 week of preparation

## 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.

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