

CHAPTER 21: Glass Inclusion

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UNDERSTAND THE POTENTIAL HAZARD.

Ingesting glass fragments can cause injury to the consumer. These injuries may include damage to teeth, laceration of the mouth and throat, or perforation of the intestine. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass 0.3 inch (7 mm) to 1 inch (25 mm) in length. The Federal Food, Drug, and Cosmetic Act (the FFD&C Act) prohibits interstate commerce of adulterated foods (21 U.S.C. 331). Under the FFD&C Act, a food containing foreign objects is considered adulterated (21 U.S.C. 342). See FDA's "Compliance Policy Guide," Sec. 555.425. Foreign objects that are less than 0.3 inch (7 mm) may cause trauma or serious injury to persons in special risk groups, such as infants, surgery patients, and the elderly.

Glass inclusion can occur whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Most products packed in glass containers are eaten with minimal handling on the part of the consumer providing little opportunity to detect glass inclusion.

The purpose of this chapter is to address only the hazard of glass fragments that results from the use of glass containers. Glass fragments originating from sources such as overhead light fixtures must be addressed where applicable in a prerequisite sanitation program. The Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document), requires such a program.

• Control of glass inclusion

Once introduced into a product container, the hazard of glass fragments may be controlled by (1) removing the fragments by cleaning the containers before filling or (2) detecting the fragments by visual inspection before or after filling. Glass containers may be cleaned using water or compressed air and inverted during or after cleaning to help with glass removal. This measure may be suited only to processes that do not use automated filling systems which include filled container conveyors or capping equipment, because this equipment can result in glass breakage after glass container cleaning.

The effectiveness of visual inspection depends on the nature of the product and the process. For most fishery products, this measure also may be suited only to processes that do not use automated filled container conveyors or capping equipment, because visual inspection after the glass containers are filled is not practical. However, for clear liquids (e.g., some fish sauces), candling may be used to visually inspect all filled containers. Candling is a visual inspection process in which the container is illuminated from behind.

Alternatively, the hazard of glass inclusion may be controlled by periodically checking the processing areas and equipment for glass breakage. This measure will not necessarily prevent glass fragments from being incorporated into the product, but it will enable you to separate products that may have been exposed to glass fragments.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether glass inclusion is a significant hazard at a processing step:

1. Is it reasonably likely that glass fragments will be introduced at this processing step (e.g., do they come in with the raw material or will the process introduce them)?

For example, under ordinary circumstances, it would be reasonably likely to expect that glass fragments could enter the process during the processing of any product that is packed in a glass container. These are likely areas of concern for glass containers:

- Glass container receiving;
 - Glass container storage, when cases are moved mechanically;
 - Mechanized glass container cleaning;
 - Glass container conveyor lines;
 - Glass container filling;
 - Mechanized capping of glass containers;
 - Pasteurizing product in glass containers.
2. Can glass fragments that were introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

Glass inclusion should be considered a significant hazard at any processing step where a preventive measure is or can be used to prevent or eliminate the hazard (or is adequate to reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. Preventive measures for glass inclusion can include:

- Visually examining the empty glass containers;
- Cleaning (water or compressed air) and inverting the empty glass containers;

- Periodically monitoring processing lines for evidence of glass breakage;
- Visually examining glass containers containing transparent liquid fishery products.

• **Intended use**

In most cases, you should assume that the product will be consumed in a way that would not eliminate any glass fragments that may be introduced during the process.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will also assist you in determining whether a processing step is a critical control point (CCP) for glass inclusion:

1. Will the containers be visually inspected for detection of glass fragments or be cleaned (water or compressed air) and inverted on or after the last step where glass inclusion is identified as a significant hazard?
 - a. If they will be, you should identify the final visual inspection or cleaning as the CCP. For example, you should visually inspect the containers for broken glass or clean and invert the containers after the processing steps where breakage is reasonably likely to occur.

For most fishery products, this method may be suited only to processes that do not use automated filling systems which include filled container conveyors or capping equipment. However, if your product is a clear liquid, you should visually inspect all filled containers by candling. In this case, the candling step would be designated as the CCP.

Example:

A processor that manually packs caviar into glass jars has identified the glass container receiving and storage steps as the only steps that are reasonably likely to introduce

glass fragments into the process. The processor should visually inspect each jar prior to the filling process. The processor should also collect a representative sample of inspected glass jars at the start of processing, every 4 hours during processing, at the end of processing and after any jams. The processor should identify the container inspection step as the CCP for this hazard.

Example:

Another processor that manually packs caviar has identified the glass container receiving and storage steps as the only steps that are reasonably likely to introduce glass fragments into the process. Just before filling, the empty glass jars are inverted and cleaned using filtered, compressed air. The processor should also collect a representative sample of cleaned glass jars at the start of processing, every 4 hours during processing, at the end of processing and after any jams. The processor should identify the container cleaning and inverting step as the CCP for this hazard.

Example:

A processor that bottles a transparent fish sauce has identified glass container receiving and storage, mechanical conveyor lines, mechanical filling, and mechanical capping as processing steps that are reasonably likely to introduce glass fragments into the process. The processor should visually inspect each filled and capped bottle for visible glass fragments by candling. The processor should also collect a representative sample of inspected glass jars at the start of processing, every 4 hours during processing, at the end of processing and after any

jams. The processor should identify the finished product candling step as the CCP for this hazard.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 1 - Cleaning or Visual Inspection of Containers.”

You should recognize that by setting the CCP at or near the end of the process, rather than at the point of potential glass fragment entry into the process, you are likely to have more labor and materials invested in the product before the problem is detected or prevented.

- b. If the containers will not be visually inspected or cleaned and inverted on or after the last step, you should periodically check the processing areas and equipment for glass breakage at each processing step where glass inclusion is identified as a significant hazard. In this case, those processing steps should be CCPs. It would not ordinarily be necessary to identify these steps as CCPs in addition to identifying a final inspection or cleaning step as a CCP.

Example:

A processor bottles clam juice and has identified glass container receiving and storage, mechanical conveyor lines, mechanical filling, and mechanical capping as processing steps reasonably likely to introduce glass fragments into the process. The processor should visually inspect all processing areas for broken glass at start-up and once every 4 hours during processing. If broken glass is observed, the line should be stopped, the glass removed and the product that has moved through that area since the last inspection

placed on hold to be filtered or destroyed. The processor should identify glass container receiving and storage, mechanical conveyor lines, mechanical filling, and mechanical capping as the CCPs for this hazard.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 2 - Equipment Checks.”

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of two control strategies for glass inclusion. You may select a control strategy that is different from those which 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
Cleaning or visual inspection of containers	✓	✓
Equipment checks	✓	✓

• CONTROL STRATEGY EXAMPLE 1 - CLEANING OR VISUAL INSPECTION OF CONTAINERS

Set Critical Limits.

- All containers pass through an operating glass container inspection or cleaning process;
- AND
- No detectable glass fragments are in glass containers that pass through the glass container inspection or cleaning process.

Establish Monitor Procedures.

» What Will Be Monitored?

- The presence of an operating glass container cleaning or inspection process;

AND

- Cleaned or inspected containers for the presence of glass fragments.

» How Will Monitoring Be Done?

- Visual examination for the presence of equipment and employees for cleaning or inspecting glass containers;

AND

- Visual examination of a representative sample of glass containers after cleaning or inspecting.

» How Often Will Monitoring Be Done?

- Check that the glass container cleaning or inspection process is in place and operating at the start of each production day and after each shift change;

AND

- Examine a representative sample of glass containers after cleaning or inspection daily, at the start of processing, every 4 hours during processing, at the end of processing, and after any breakdowns.

» 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:

- Hold and evaluate all of the product processed since controls were last confirmed as functioning properly;

OR

- Destroy all of the product produced since controls were last confirmed as functioning properly;

OR

- Divert all of the product produced since controls were last confirmed as functioning properly to a non-food use;

OR

- Rework all of the product produced since controls were last confirmed as functioning properly to eliminate glass fragments by visually examining for the presence of glass or by running the product through a filter or screen.

AND

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

- Correct operating procedures to ensure that the product is not processed without an operating glass container visual inspection or cleaning process;

AND/OR

- Stop operations and locate and correct the source of the glass fragments.

Establish a Recordkeeping System.

- Record documenting that the glass container cleaning or inspection process is in place and operating;

AND

- Record documenting the visual examination of glass containers after cleaning or inspection.

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 21-1

CONTROL STRATEGY EXAMPLE 1 - CLEANING OR VISUAL INSPECTION OF CONTAINERS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Cleaning or Visual Inspection of Containers." This example illustrates how a processor of pickled herring in glass jars can control glass inclusion. It is provided for illustrative purposes only.

Glass inclusion 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., parasites, scombrotoxin (histamine), environmental chemical contaminants and pesticides, unapproved food and color additives, metal fragments, *Clostridium botulinum* toxin formation, and pathogen growth as a result of temperature abuse).

**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			WHO	CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY				
Jar cleaning and inversion	Glass inclusion	All containers pass through an operating glass cleaning process No glass fragments are in glass containers passing through the glass container cleaning process	The presence of the glass cleaning process The presence of glass fragments in cleaned containers	Visual check Visual examination of a representative sample of glass containers after cleaning	At the start of the production and shift changes One dozen jars after cleaning daily, at the start of processing, every 4 hours during processing, at the end of processing, and after any breakdowns	Quality control staff	Hold all of the product for an evaluation Correct operating procedures to ensure that the product is not processed without jar cleaning Stop operations and locate and correct the source of the glass fragments	Glass inspection record	Review monitoring and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS**

Set Critical Limits.

- No broken glass on or near equipment.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The presence of broken glass on or near equipment.

» **How Will Monitoring Be Done?**

- Visually check the glass handling areas for broken glass.

Examples:

- *Check pallets and packing cases for damage, broken jars, and glass fragments;*
- *Check mechanical glass cleaning area for broken glass;*
- *Check floors around conveyors for broken glass;*
- *Check filling and capping equipment and surrounding floors for broken glass;*
- *Check glass containers for breakage after exposure to heat (e.g., after heated product is added or after pasteurization).*

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

- Check before starting operations each day;
AND
- Check at least every 4 hours during operation;
AND
- Check at the end of operations each day;
AND
- Check whenever there is an equipment malfunction that could increase the likelihood that glass containers could be damaged.

» **Who Will Do the Monitoring?**

- Any person who has a thorough understanding of the proper condition of the equipment and surrounding area.

Establish Corrective Action Procedures.

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

- Hold and evaluate all of the product produced since the previous satisfactory equipment check;
OR
- Destroy all of the product produced since the previous satisfactory equipment check;
OR
- Divert all of the product produced since the previous satisfactory equipment check to a non-food use;
OR
- Rework the product packaged since the previous satisfactory equipment check by visually examining for the presence of glass or by running the product through a filter or screen.

AND

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

- Stop production;
AND
- If necessary, adjust or modify the materials, equipment, and/or processes to reduce the risk of recurrence;
AND
- Remove all broken glass from the equipment and surrounding area.

Establish a Recordkeeping System.

- Records of equipment and processing area inspections.

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 21-2

CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Equipment Checks." This example illustrates how a processor of clam juice in glass jars can control glass inclusion. It is provided for illustrative purposes only.

Glass inclusion may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., pathogens from the harvest area, environmental chemical contaminants and pesticides, natural toxins, unapproved food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)				(7)	(8)	(9)	(10)
			WHAT	HOW	FREQUENCY	WHO				
Glass bottle receiving, mechanical bottle conveyors, mechanical filling, and mechanical capping	Glass inclusion	No broken glass on or around processing equipment	Broken glass on or around equipment	Visual check	Before start-up, every 4 hours during operations, after equipment jams, and end of day	Filler Operator	Stop production Determine the source of the broken glass Adjust equipment that caused the breakage, if necessary Remove broken glass from the area Hold and evaluate the product since the last satisfactory check	Glass inspection record	Review monitoring and corrective action records within 1 week of preparation	
										CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE

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.

- Olsen, A. R. 1998. Regulatory action criteria for filth and other extraneous materials. I. Review of hard or sharp foreign objects as physical hazards in food. *Regul. Toxicol. Pharmacol.* 28:181-189.
- U.S. Food and Drug Administration. 1999. Foods – Adulteration involving hard or sharp foreign objects. *In* Compliance Policy Guide, Sect. 555.425. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD.

NOTES: