

**DRAFT**

This chapter is provided as draft guidance at this time. FDA requests that interested parties with information on the hazard of glass inclusion and its control provide comments on the content of the chapter.

## **Hazard Analysis Worksheet**

### **STEP #10: UNDERSTAND THE POTENTIAL HAZARD.**

Glass fragments can cause injury to the consumer. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of 0.3" (7 mm) to 1.0" (25 mm) in length. See FDA Compliance Policy Guide #555.425.

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 intended as a ready-to-eat commodity.

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 other sources must be addressed where applicable in a prerequisite sanitation program. The Seafood HACCP Regulation requires such a program.

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

At each processing step, determine whether "glass inclusion" is a significant hazard. The criteria are:

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

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

- Receiving;
- Storage, when cases are moved mechanically;
- Mechanized Cleaning;
- Conveyor Lines;
- Mechanized Filling;
- Hot-filling;
- Mechanized Capping;
- Pasteurizing.

2. Can glass fragments from glass containers, which were introduced at an earlier step, 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.)

"Glass inclusion" should also be considered a significant hazard at any processing step where a preventive measure is or can be used to prevent or eliminate the inclusion of glass fragments from glass containers, that have been introduced at a previous step, or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Preventive measures for "glass inclusion" can include:

- Visual examination of empty glass containers;
- Cleaning (water or compressed air) and inverting empty glass containers;
- Periodically monitoring processing lines for evidence of glass breakage;
- Proper adjustment of capping equipment (not a complete control);
- Visual examination of glass containers containing transparent liquid fishery products;
- Passing the product through x-ray equipment or other defect rejection system.

*Continued*

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

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 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](#)

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step 4. 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. In this case, you would need to identify the hazard as significant if the above criteria are met.

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

For each processing step where “glass inclusion” 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.

The following guidance will also assist you in determining whether a processing step is a CCP for “glass inclusion”:

Will the containers be run through x-ray equipment or other defect rejection system, undergo visual inspection 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?

1. If it will be, you may identify final glass detection or separation as the CCP. Processing steps prior to glass detection or separation will then not require control and will not need to be identified as CCPs for the hazard of glass inclusion.

In this case enter “Yes” in Column 6 of the Hazard Analysis Worksheet for the glass detection or separation step, and enter “No” for the other processing steps where “glass inclusion” was identified as a significant hazard. In addition, for each “No” entry, note in Column 5 that the hazard is controlled by the glass detection or separation step. (Note: if you have not previously identified “glass inclusion” as a significant hazard at the glass detection or separation step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to “Yes”.) This control approach will be referred to as “Control Strategy Example 1” in Steps 14 through 18.

*Example:*

*A pickled herring processor that mechanically packs the product into glass jars could set the critical control point for “glass inclusion” at the packaged product x-ray examination step, and would not need to have critical control points for this hazard at each of the steps at which there was a reasonable likelihood that glass fragments could be introduced.*

*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 does not have finished product x-ray equipment. The processor manually inspects each container during the filling process. The processor identifies the container inspection step as the CCP for this hazard.*

*Example:*

*Another 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 does not have finished product x-ray equipment. Just before filling, the empty glass jars are inverted and cleaned, using filtered, compressed air. The processor identifies the container cleaning and inverting step as the CCP for this hazard.*

You should recognize that by setting the critical control point 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.

2. If the containers will not be run through detection equipment, visually inspected, or cleaned and inverted on or after the last step where “glass inclusion” is identified as a significant hazard, you should have procedures to 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 you should identify those processing steps as CCPs. It would not ordinarily be necessary to identify these steps as CCPs in addition to identifying a final glass detection or separation step as a CCP.

In this case, you should enter “Yes” in column 6 of the Hazard Analysis Worksheet for each of those processing steps. This control approach will be referred to as “Control Strategy Example 2” in Steps 14 through 18.

*Example:*

*A processor bottles clam juice and has identified receiving, storage, mechanical conveying, mechanical filling, and mechanical capping, as processing steps reasonably likely to introduce glass fragments into the process. The processor does not have on-line x-ray equipment. The processor visually inspects all processing areas for broken glass at start-up and once every four hours. If broken glass is observed, the line is stopped, the glass is removed and the*

*product that has moved through that area since the last inspection is placed on hold to be run through off-line x-ray equipment. The processor identifies receiving, storage, mechanical conveying, mechanical filling, and mechanical capping as the CCP’s for this hazard.*

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

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 each processing step where “glass inclusion” is identified as a significant hazard on the HACCP Plan Form 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 control strategy examples discussed in Step 12.

- **CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION**

**Critical Limit:** No glass fragments in finished product. (Note: FDA’s Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of 0.3” [7 mm] to 1.0” [25 mm] in length. See also FDA Compliance Policy Guide #555.425.)

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

**Critical Limit:** No broken glass at the CCPs for “glass inclusion”.

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

**STEP #15: ESTABLISH MONITORING PROCEDURES.**

For each processing step where “glass inclusion” is identified as a significant hazard on the HACCP Plan Form, 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 control strategy examples discussed in Step 12. 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 - GLASS DETECTION OR SEPARATION**

**What:** The presence of glass fragments in glass containers passing the CCP.

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

**What:** The presence of broken glass on or near equipment at the CCP’s.

**How Will Monitoring Be Done?**

- **CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION**

**How:** Use of x-ray equipment or other defect rejection system;  
OR  
Visual examination of empty glass containers;  
OR  
Visual examination of glass containers containing transparent liquid fishery products;  
OR  
Cleaning (water or compressed air) and inverting of empty glass containers.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

**How:** Visually check the glass handling areas for broken glass.

*Examples:*

- Check pallets and cases of empty jars for damage, broken jars, and glass fragments;
- Check mechanical glass cleaning equipment and surrounding floors for broken glass;
- Check floors around conveyors for broken glass;
- Check filling and capping equipment and surrounding floors for broken glass;
- Check hot-filling and pasteurizing equipment and surrounding floors for broken glass.

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

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

**Frequency:** Continuous. Each container is subjected to detection or separation. For x-ray equipment, other defect rejection systems and glass separation equipment, check that the device is operating at least at the start of each production day. For visual inspection, check that appropriate personnel are assigned to the processing step at the start of each production day.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

**Frequency:** Check before starting operations each day;  
AND

Check at least every four hours during operation;  
AND

Check at the end of operations each day;  
AND

Check whenever there is an equipment or other malfunction that could increase the likelihood that glass containers could be damaged.

### Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

**Who:** For x-ray detection, other defect rejection systems, glass separation equipment and visual examination, monitoring is performed by the equipment itself or by properly trained and qualified inspection personnel. A check should be made at least once per day to ensure that the device is operating or that the appropriate personnel are on hand. This check 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 or the staffing needs.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

**Who:** Monitoring 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, production personnel, or any other person who has a thorough understanding of the proper condition of the equipment and surrounding area. In assigning responsibility for this monitoring function you should consider the complexity of the equipment and the level of understanding necessary to evaluate its condition.

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 each processing step where “glass inclusion” is identified as a significant hazard on the HACCP Plan Form, 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 control strategy examples discussed in Step 12.

- **CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION**

**Corrective Action:** Take the following corrective actions to regain control over the operation after a CL deviation:

- Stop operations and attempt to locate and correct the source of the glass fragments;

AND

- Make adjustments to the materials, equipment, and/or process, as needed, to prevent future introduction of glass fragments;

AND

Take one of the following corrective actions to product in which glass fragments were detected:

- Destroy the product;

OR

- Rework the product to eliminate the glass fragments;

OR

- Divert the product to non-food use;

OR

- Hold and evaluate the product;

AND

Take one of the following corrective actions when product is processed without properly functioning glass detection or separation equipment or without proper visual inspection:

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

OR

- Hold all product produced since controls were last confirmed as functioning properly until it can be examined by x-ray equipment or other defect rejection system, or visual inspection, where appropriate;

OR

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

AND

- Repair or replace the glass detection or separation equipment.

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

**Corrective Action:** Take one of the following corrective actions to regain control over the operation after a CL 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;

AND

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

- Destroy all product produced since the previous satisfactory equipment check;

OR

- Hold all product produced since the previous satisfactory equipment check until it can be examined by x-ray equipment or other defect rejection system, or visual inspection if appropriate;

OR

- Divert all product produced since the previous satisfactory equipment check 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 each processing step where “glass inclusion” is identified as a significant hazard on the HACCP Plan Form, 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 control strategy examples discussed in Step 12.

- **CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION**

**Records:** Records documenting that the glass detection or separation device is operating, or that glass inspection personnel are assigned to the processing step, as appropriate.

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

**Records:** Records of equipment and processing area inspection results.

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

**STEP #18: ESTABLISH VERIFICATION PROCEDURES.**

For each processing step where “glass inclusion” is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of glass inclusion; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step 12.

- **CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION**

**Verification:** Test the effectiveness of the x-ray equipment, other defect reject system or glass separation equipment at least once per day, before start of operations;

AND

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

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

**Verification:** Review monitoring and corrective action records within one week of preparation.

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

TABLE #21-1

**Control Strategy Example 1 - Glass Detection or Separation**

This table is an example of a HACCP plan relating to the control of glass inclusion for a processor of pickled herring in glass jars, using Control Strategy Example 1 - Glass Detection or Separation. It is provided for illustrative purposes only. Glass inclusion may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, 3-3 (Chapter 3) for other potential hazards (e.g., parasites, histamine, chemical contaminants, unapproved food & color additives, metal fragments, *Clostridium botulinum* toxin formation, and pathogen growth as a result of temperature abuse).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(6) Monitoring	(7)		(8) Corrective Action(s)	(9) Records	(10) Verification
			(4) What	(5) How	(6) Frequency		(7) Who				
X-ray equipment	Glass inclusion	No detectable glass fragments in finished product	Presence of detectable glass fragments in finished products	X-ray device	Every finished product package, with operation check before startup	Production employee	Production employee	<ul style="list-style-type: none"> <li>Destroy any product rejected by x-ray equipment</li> </ul> AND <ul style="list-style-type: none"> <li>Stop operations and identify source of glass found in product and fix damaged equipment</li> </ul> AND <ul style="list-style-type: none"> <li>If product is processed without x-ray equipment, hold for detection by off-line x-ray equipment</li> </ul>	X-ray operation log	<ul style="list-style-type: none"> <li>Test x-ray device before production each day, and recalibrate if needed</li> <li>Review monitoring, corrective action and verification records within one week of preparation.</li> </ul>	



TABLE #21-2

**Control Strategy Example 2 - Equipment Checks**

This table is an example of a portion of a HACCP plan relating to the control of glass inclusion for a processor of clam juice in glass jars, using Control Strategy Example 2 – Equipment checks. It is provided for illustrative purposes only. Glass inclusion 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., pathogens from the harvest area, chemical contaminants, natural toxins, unapproved food & color additives, 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	What	Who	Frequency	Who				
Receiving	Glass inclusion	No broken glass on pallets of empty jars	Presence of broken glass or physical damage to cases	Visual	Each pallet of jars	Receiving personnel	Receiving report	<ul style="list-style-type: none"> <li>Reject pallets with more than 3 damaged cases or with broken jars.</li> <li>Isolate pallets with 1 to 3 damaged cases and open and inspect all cases.</li> <li>Reject cases that contain broken glass.</li> </ul>	<ul style="list-style-type: none"> <li>Review monitoring and corrective action records within one week of preparation.</li> </ul>					
Mechanical filling and capping	Glass Inclusion	No broken glass at the filler/capper station	Broken glass on & around filler/capper station	Visual	Before start-up, every 4 hours during operation, after breaks, and after equipment jams.	Capper operator	Equipment maintenance log	<ul style="list-style-type: none"> <li>Stop production AND</li> <li>Adjust capping equipment AND</li> <li>Isolate and hold product since last satisfactory check until it can be run through off-line x-ray and destroy rejects AND</li> <li>Remove broken glass from area.</li> </ul>	<ul style="list-style-type: none"> <li>Review monitoring and corrective action records within one week of preparation</li> </ul>					

Note: Storage and conveying of empty jars are not identified as CCPs because cases of empty jars are handled manually, without forklifts or mechanized conveyors

## Notes: