CHAPTER 20: **Metal Inclusion**

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UNDERSTAND THE POTENTIAL HAZARD.

Ingesting metal fragments can cause injury to the consumer. These injuries may include dental damage, laceration of the mouth or throat, or laceration or perforation of the intestine. FDA's Health Hazard Evaluation Board has supported regulatory action against products with metal fragments 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. In addition, 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.

Metal-to-metal contact (e.g., mechanical cutting or blending operations and can openers) and equipment with metal parts that can break loose (e.g., moving wire mesh belts, injection needles, screens and portion control equipment, and metal ties) are likely sources of metal that may enter food during processing.

- **Control of metal inclusion**

Once introduced into a product, metal fragments may be removed from the product by passing it through a screen, magnet, or flotation tank. The effectiveness of these measures depends on the nature of the product. These measures are more likely to be effective in liquids, powders, and similar products in which the metal fragment will not become imbedded.

Alternatively, metal fragments may be detected in the finished food by an electronic metal detector. The use of electronic metal detectors is complex, especially with regard to stainless steel, which is difficult to detect. The orientation of the metal object in the food affects the ability of the equipment to detect it. For example, if a detector is not properly calibrated and is set to detect a sphere 0.08 inch (2 mm) in diameter, it may fail to detect a stainless steel wire that is smaller in diameter but up to 0.9 inch (24 mm) long, depending on the orientation of the wire as it travels through the detector. Processing factors, such as ambient humidity or product acidity, may affect the conductivity of the product and create an interference signal that may mask metal inclusion unless the detector is properly calibrated. You should consider these factors when calibrating and using this equipment.

Finally, the hazard of metal inclusion may also be controlled by periodically examining the processing equipment for damage that can contribute metal fragments to the product. This measure will not necessarily prevent metal fragments from being incorporated into the product, but it will enable you to separate products that may have been exposed to metal fragments. Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and may require controls such as metal detection or separation.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

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

1. Is it reasonably likely that metal 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 metal fragments could enter the process from the following sources as a result of worn, damaged, or broken equipment parts:

   - Mechanical crabmeat pickers;
   - Wire-mesh belts used to convey products;
   - Saw blades used to cut portions or steaks;
   - Wire from mechanical mixer blades;
   - Blades on mechanical chopping, filleting, or blending equipment;
   - Rings, washers, nuts, or bolts from breading, batter, sauce cooling, liquid dispensing, and portioning equipment;
   - Injection needles;
   - Metal ties used to attach tags or close bags;
   - Can slivers from opening cans.

   Under ordinary circumstances, it would not be reasonably likely to expect that metal fragments could enter the food from the following sources:

   - Utensils used for manual blending, cutting, shucking, or gutting;
   - Metal processing tables or storage tanks.

2. Can the hazard of metal inclusion that was introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

   Metal 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 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 metal inclusion can include:

   - Periodically checking equipment for damaged or missing parts;
   - Passing the product through metal detection or separation equipment.

- **Control of metal inclusion**

In most cases, you should assume that the product will be consumed in a way that would not eliminate any metal fragments that may be introduced during the process. However, in some cases, if you have assurance that the product will be run through a metal detector, for detection of metal fragments, or through screens or a magnet, for separation of metal fragments, by a subsequent processor, you would not need to identify metal inclusion as a significant hazard.

Example:

A primary processor produces frozen fish blocks by mechanically heading, eviscerating, and filleting fish in the round. The primary processor sells exclusively to breaded fish stick processors and has been given assurance by these processors that the finished breaded product will be subjected to a metal detector. The primary processor would not need to identify metal inclusion as a significant hazard.

IDENTIFY CRITICAL CONTROL POINTS.

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

1. Will the product be run through a metal detector or a separation device, such as a screen, magnet, or flotation tank, on or after the last step where metal inclusion is identified as a significant hazard?

    a. If it will be, you should identify final metal detection or separation as the CCP. Then processing steps prior to metal detection or separation would not require controls and would not need to be identified as CCPs for the hazard of metal fragments.

    Example:

    A breaded fish processor uses saws, breading and batter machines, and wire conveyor belts. The processor should choose to use a metal detector on the finished product containers and should set the CCP for metal inclusion at the metal detection step for packaged products. The processor would not need to have CCPs for this hazard at each of the previous processing steps at which there was a reasonable likelihood that metal fragments could be introduced.

    This control approach is a control strategy referred to in this chapter as "Control Strategy *Example 1 - Metal Detection or Separation.*"

    You should recognize that by setting the CCP at or near the end of the process, rather than at the point of potential metal 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 product will not be run through such a device, you should have procedures to periodically check the processing equipment for damage or lost parts at each processing step where metal inclusion is identified as a significant hazard. In this case, you should identify those processing steps as CCPs.

    Example:

    A processor that cuts tuna steaks from frozen loins has identified the band saw cutting step as the only step that is reasonably likely to introduce metal fragments into the product. The processor should identify the band saw cutting step as the CCP for this hazard and should check the condition of the band saw blade every 4 hours to ensure that it has not been damaged.

    This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Equipment Checks." Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and may require controls such as metal detection or separation.

DEVELOP A CONTROL STRATEGY.

The following guidance provides two examples of control strategies for metal inclusion. It is important to note that 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
Metal detection or separation	✓	✓
Equipment checks	✓	✓

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

Set Critical Limits.

- All of the product passes through an operating metal detection or separation device;

  AND

- No detectable metal fragments are in the product that passes through the metal detection or separation device.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The presence of an operating metal detection or separation device;

  AND

- The product for the presence of metal fragments.

» **How Will Monitoring Be Done?**

- Visual examination for the presence of an operating electronic metal detector, magnet, intact screen, or flotation tank;

  AND

- Product monitoring is performed by the metal detection or separation device itself.

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

- Check that the metal detection or separation device is in place and operating at the start of each production day;

  AND

- Continuous monitoring by the metal detection or separation device itself.

» **Who Will Do the Monitoring?**

- Monitoring is performed by the metal detection or separation device itself. Visual checks to ensure that the device is in place and operating may be performed by 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:

- When processing occurred without an operating metal detector or intact or operating separation device:
  - Hold all of the product produced since controls were last confirmed as functioning properly until it can be run through a metal detection or separation device;

    OR

  - Hold all of the product produced since controls were last confirmed as functioning properly until an inspection of the processing equipment that could contribute metal fragments can be completed to determine whether there are any broken or missing parts (may be suitable only for relatively simple equipment);

    OR

  - Divert all of the product produced since controls were last confirmed as functioning properly to a use in which it will be run through a properly calibrated metal detector (e.g., divert fish fillets to a breading operation that is equipped with a metal detector);

    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.

AND

- When product is rejected by a metal detector:
  - Hold and evaluate the rejected product;

    OR
  - Rework the rejected product to eliminate metal fragments;

    OR
  - Destroy the rejected product;

    OR
  - Divert the rejected product to a non-food use.

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 metal separation or detection device;

  OR
- Attempt to locate and correct the source of the fragments found in the product by the metal detector or separated from the product stream by the magnets, screens, or other devices;

  OR
- Repair or replace the metal separation device.

Establish a Recordkeeping System.

- Record documenting that the metal detection or separation device is in place and operating.

Establish Verification Procedures.

For metal detectors:

- Develop sensitivity standards that are based on whether the potential hazard is ferrous, non-ferrous, or stainless steel, or obtain such standards from the equipment manufacturer. The standards should be designed to ensure that metal fragments will be detected in the product. Conduct a validation study to identify the range of values for each of the processing factors over which the equipment will detect the standards that affect its operation in your product (e.g., ambient humidity and product acidity), or obtain such a study from the equipment manufacturer. The study should identify the appropriate equipment settings over the range of each of the processing factors. The study also should consider the range of orientations in which the metal fragments may be present;

  AND
- Challenge the metal detector using validated sensitivity standards daily, at the start of production, every 4 hours during operation, when processing factors (e.g., ambient humidity and product acidity) change, and at the end of processing;

AND

For all metal detection and separation devices:

- 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 20-1

CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Metal Detection or Separation." This example illustrates how a frozen fish sticks processor can control metal fragment inclusion. It is provided for illustrative purposes only.

Metal 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., environmental chemical contaminants and pesticides and Staphylococcus aureus toxin formation in the hydrated batter mix).

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				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Metal detection	Metal inclusion	All of the product passes through an operating metal detector	Metal detector present and operating	Visual examination	Daily, at start of operations	Production employee	If the product is processed without metal detection, hold it for metal detection Correct operating procedures to ensure that the product is not processed without metal detection Rework to remove metal fragments from any product rejected by the metal detector Identify the source of the metal found in the product and fix the damaged equipment	Metal detector operation log	Conduct a validation study to determine appropriate settings for the metal detector Develop metal detector sensitivity standards Challenge the metal detector with sensitivity standards daily, before start-up, every 4 hours during production, whenever processing factors change, and at the end of processing Review monitoring, corrective action and verification records within 1 week of preparation
		No detectable metal fragments are in the product passing the through the metal detector	The product for the presence of metal fragments	Electronic metal detector	Continuous	Equipment itself			

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

Set Critical Limits.

- No broken or missing metal parts from equipment.

Establish Monitoring Procedures.

» **What Will be Monitored?**

- The presence of broken or missing metal parts from equipment.

» **How Will Monitoring Be Done?**

- Visually check the equipment for broken or missing parts.

  Examples:
  - Check saw blades for missing teeth or sections;
  - Check that all parts are present and secure on blending equipment;
  - Check for missing links or broken wires on metal belts.

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

- Check before starting operations each day;

  AND

- Check 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 metal could be introduced into the food.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Hold all of the product produced since the previous satisfactory equipment check until it can be run through a metal detector;

  OR

- Divert all of the product produced since the previous satisfactory equipment check to a use in which it will be run through a properly calibrated metal detector (e.g., divert fish fillets to a breading operation that is equipped with a metal detector);

  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.

AND

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

- Stop production;

  AND

- If necessary, adjust or modify the equipment to reduce the risk of recurrence.

Establish a Recordkeeping System.

- Records of equipment 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 20-2

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 frozen tuna steak processor can control metal fragment inclusion. It is provided for illustrative purposes only.

Metal 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., scombrotoxin (histamine) and parasites).

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				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Fish cutting	Metal inclusion	No damage or missing parts to the saw blade	Check the saw blade	Visual check	Before start-up, every 4 hours during operation, at the end of day, and after an equipment jam	Saw operator	Stop production Adjust equipment Hold all of the product since the last visual check until it can be run through a metal detector Destroy rejected product	Equipment maintenance log	Review monitoring and corrective action 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.

- 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 Guides, Sec. 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: