Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Metal fragments can cause injury to the consumer.

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

FDA's Health Hazard Evaluation Board has supported regulatory action against product with metal fragments of 0.3" (7 mm) to 1.0" (25mm) in length. See FDA Compliance Policy Guide #555.425.

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

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

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

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 product in a batter/breading operation;
- Teeth from saw blades used to cut portions or steaks;
- Wire from mechanical mixer blades;
- Blades from mechanical chopping or blending equipment;
- Rings, washers, nuts, or bolts from sauce cooling, liquid dispensing, and portioning equipment;
- Blades from automatic filleting equipment;
- Injection needles;
- Metal ties used on raw material, in-process, or finished product containers or equipment.

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

- Manual cutting, shucking, gutting, or boning knives;
- Metal processing tables or storage tanks;
- Wire mesh baskets or utensils.

2. Can metal fragments, 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.)

"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 inclusion of metal fragments, that have been introduced to the product at a previous step, or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Preventive measures for "metal inclusion" can include:

- Periodically checking cutting or blending equipment or wire-mesh belts for damage or missing parts;
- Passing the product through metal detection or separation equipment.

Visually inspecting equipment for damage or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire-mesh belts. Other, more complex, equipment may contain to many parts, some of which may not be readily visible, to make such visual inspection reliable in a reasonable time period.

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 metal 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.

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 may not need to identify metal fragment 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.

In this case, you should enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. In addition, for each "No" entry briefly explain in column 4 that the hazard is controlled by a subsequent processor. In this case, you need not complete Steps #12 through 18 for this hazard.

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

For each processing step where "metal 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 "metal inclusion":

Will the product be run through a metal detector, or through a screen, magnet, flotation tank, or other equipment for separation of metal fragments, on or after the last step where metal inclusion is identified as a significant hazard?

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

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the metal detection or separation step, and enter "No" for the other processing steps where "metal inclusion" was identified as a significant hazard. In addition, for each "No" entry, note in Column 5 that the hazard is controlled by the final metal detection or separation step. (Note: if you have not previously identified "metal inclusion" as a significant hazard at the metal 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 breaded fish processor could set the critical control point for "metal inclusion" at the packaged product metal detection step, and would not need to have critical control points for this hazard at each of the steps at which there was a reasonably likelihood that metal fragments could be introduced.

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 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.

2. 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. It would not ordinarily be necessary to identify these steps as CCPs in addition to identifying a final metal detection or separation step as a CCP.

Visually inspecting equipment for damage or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire-mesh belts. Other, more complex, equipment may contain to many parts, some of which may not be readily visible, to make such visual inspection reliable in a reasonable time period.

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 that cuts tuna steaks from whole fish has identified the band saw cutting step as the only step that is reasonably likely to introduce metal fragments to the process. The processor does not have a final metal detection or separation step. The processor checks the condition of the band saw blade every four hours to ensure that it has not been damaged. The processor identifies the band saw cutting step as the CCP 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 "metal 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 - METAL DETECTION OR SEPARATION

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

Continued

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Critical Limit: No broken or missing metal parts from equipment at the CCPs for "metal inclusion"

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

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "metal 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 - EQUIPMENT CHECKS

What: The presence of metal fragments in product passing the CCP.

- CONTROL STRATEGY EXAMPLE 2 - METAL INCLUSION PREVENTION PROCEDURES

What: The presence of broken or missing metal parts from equipment at the CCPs.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

How: Use a metal detection device;
OR
Use a magnet for separating metal fragments from a product stream, where feasible (e.g. dry ingredients);
OR
Use screens for separating metal fragments from a product stream, where feasible (e.g. dry or liquid ingredients).

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

How: Visually check the equipment for broken or missing parts.

Examples:
- *Check saws for missing teeth;*
- *Check that all parts are secure on blending equipment;*
- *Check for missing links in metal belts.*

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Frequency: Subject all product to the control.
Check that device is operating or is in place at start of each production day.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Frequency: Check before starting operations each day;
AND
Check every four 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 Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Who: Monitoring is performed by the equipment itself. A check should be made at least once per day to ensure that the device is operating or is in place. This 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.

- 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, or any other person who has a thorough understanding of the proper condition of the equipment.

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 "metal 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 - METAL DETECTION OR SEPARATION

Corrective Action: Take the following corrective action to regain control over the operation after a CL deviation:
- Attempt to locate and correct the source of the fragments found in product by the metal detector or separated from the product stream by the magnets, screens, or other devices;

Continued

AND

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

AND

Take the following action to product involved in a CL deviation:

- Destroy;

OR

- Divert to non-food use;

OR

- Rework to eliminate metal fragments;

OR

- Hold and evaluate any product in which the metal detector has detected metal fragments;

AND

Take one of the following actions to the product when product is processed without a properly functioning metal detector or separation device:

- Destroy the product;

  OR
- Hold all product produced since controls were last confirmed as functioning properly until it can be run through a metal detector;

  OR
- Hold all 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;

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

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

AND

- Repair or replace the metal detector or separation device

- 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 equipment to reduce the risk of recurrence;

AND

Take one of the following actions to product involved in a CL deviation:

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

OR

- Run all product produced since the previous satisfactory equipment check through a metal detector;

OR

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

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 "metal 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 - METAL DETECTION OR SEPARATION

Records: Record documenting that the metal detection or separation device is operating or is in place, as appropriate.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Records: Record of equipment inspections.

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 "metal 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 metal 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 - METAL DETECTION OR SEPARATION

Verification: Test the effectiveness of the metal detection device, or check the condition of the magnet, screen, or other metal separation device 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 #20-1

Control Strategy Example 1 - Metal detection or separation

This table is an example of a portion of a HACCP plan relating to the control of metal fragment inclusion for a processor of frozen fish sticks, using Control Strategy Example 1 - Metal detection or separation. It is provided for illustrative purposes only. Metal 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. chemical contaminants and *Staphylococcus aureus* toxin formation in the hydrated batter mix).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Metal detection	Metal inclusion	No detectable metal fragments in finished product	Presence of detectable metal fragments in finished product	Metal detector	Every finished product package, with operation check before start-up	Production employee	• Destroy any product rejected by metal detector • Identify source of metal found in product and fix damaged equipment • If product is processed without metal detection hold for metal detection	Metal detector operation log	• Test metal detector with three test units before production each day, and recalibrate if needed • Review monitoring, corrective action and verification records within one week of preparation

TABLE #20-2

Control Strategy Example 2 - Equipment Checks

This table is an example of a portion of a HACCP plan relating to the control of metal fragment inclusion for a processor of frozen tuna steaks, using Control Strategy Example 2 - Metal inclusion prevention procedures. It is provided for illustrative purposes only. Metal 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. histamine and parasites).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Band saw	Metal inclusion	No damage to saw blade	Check saw blade for damage	Visual	Before start-up, every four hours during operation, at end of day, and after equipment jam	Saw operator	• Stop production • Adjust equipment • Isolate product since last visual check • Hold product until it can be run through metal detector and destroy rejects	Equipment maintenance log	Review monitoring and corrective action records within one week of preparation

Notes: