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contaminated seeds during inspection processes. This may be manual or by more advanced electronic instrumental selection.

4.3.8 Use of Exclusion Strategies as a Process Control for Physical Hazards

4.3.8.1 Exclusion Strategies as a Process Control for Metal Hazards

Metal-to-metal contact during processing can introduce metal fragments into products. For example, metal fragments can break off during mechanical cutting and blending operations, and some metal equipment has parts that can break or fall off, such as wire-mesh belts. You can control metal hazards by using physical separation techniques (such as magnets, sieves, screens, or flotation tanks), by using electronic or X-ray metal detection devices, and by regularly inspecting at-risk equipment for signs of damage.

The effectiveness of physical separation techniques 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.

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.

X-ray devices can also be used for metal detection. One advantage in using such a device is that X-rays can detect non-metal foreign objects that may also be hazardous, such as glass fragments.

Preventive maintenance of equipment and periodically examining your processing equipment for damage that can contribute metal fragments can be a useful control measure, particularly when you have a piece of equipment that is prone to break, such as saw blades, or equipment that has metal-to-metal contact. The success of this strategy depends in large part on the nature of the equipment inspected and the frequency of the inspection. However, this approach will not necessarily prevent metal fragments from being incorporated into the product in all cases, but may 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 physical separation techniques.

See "Chapter 13-- Preventive Controls for Physical Hazards" of this guidance for additional information on the control of metal hazards.

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5.4 Overview of the Application of Preventive Controls for Physical Hazards

Table 5-5 provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of physical hazards in finished foods. See “Chapter 13 – Preventive Controls for Chemical Hazards” of this guidance for further examples for the implementation of preventive controls for physical hazards.

Table 5-5 Applicability of Preventive Controls to Physical Hazards

Preventive Control Category	Common Procedures, Practices, and Processes	Applicability to Metal Hazards	Applicability to Glass Hazards (Products Packed in Glass)	Applicability to Other Hard/Sharp Physical Hazards
Process Control – Exclusion	Use screens, flotation tanks, riffle board, sifters, magnets, inversion/air to exclude metal and glass	Physically removes metal fragments	Physically removes glass	Physically removes hard plastic, wood, stones
Process Control – Detection	Use metal or X-ray detectors to detect and divert foods containing metal and glass	Metal and X-ray detectors detect metal pieces, which generally allows for exclusion of foods containing metal	X-ray detectors detect glass pieces, which generally allows for exclusion of foods containing glass	X-rays can often detect hazardous objects such as hard plastic, stones, bones, pits

5.5 Preventive Control Management Components

5.5.1 Overview of Preventive Control Management Components

Preventive control management components include monitoring, corrective actions and corrections, and verification activities (and their associated records). You must apply appropriate preventive control management components by considering the nature of the preventive control and its role in the facility's food safety system to ensure the effectiveness of the preventive control. For example, monitoring may be limited for certain control measures such as preventive maintenance for equipment to prevent metal hazards (although you should have a record that the activity took place). When sanitation controls are required for environmental pathogens, little or no monitoring may be needed when cleaning and sanitation are conducted in accordance with established written protocols. Occasional verification that procedures are being followed may suffice. See 21 CFR 117.140.

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5.5.2 Monitoring

You must establish and implement written procedures, including the frequency they are to be performed, for monitoring preventive controls (as appropriate to the nature of the preventive control and its role in your food safety system). See 21 CFR 117.145. Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, "Establish Monitoring Procedures," that provides information about appropriate monitoring procedures for each control strategy example discussed.

To fully describe your monitoring program, the procedures should answer four questions: (1) What will be monitored? (2) How will monitoring be done? (3) How often will monitoring be done (frequency)? and (4) Who will do the monitoring?

What you monitor should be directly related to control of the hazard. For example, for process controls you would monitor parameters to ensure the minimum/maximum values are met. For other preventive controls, you could monitor that the activity has been conducted consistent with a defined procedure.

The frequency of monitoring depends upon the circumstances. Continuous monitoring is always desirable, and in some cases necessary. In other cases, it may not be necessary or practical. You should monitor often enough that the normal variability in the values you are measuring can be determined and a deviation from normal will be detected. This is especially true if these values are typically close to the control values. Even with continuous monitoring, you should periodically check the paper or electronic record of the continuous monitoring to determine whether deviations from the control value have occurred. The frequency of that check should be at least daily.

If a measurement shows that a deviation from the control value has occurred, you should assume that the control value had not been met since the last check in which the value was acceptable. As a result, the greater the time span between measurements, the more products you are putting at risk.

You should specify in the written procedures the position of the employee who will do the monitoring and describe how they are to perform the monitoring procedure. See Chapters 6 through 13 of this guidance for monitoring examples that include "who" and "how."

You must document your monitoring of preventive controls. See 21 CFR 117.145(c)(1). Although, as noted above, continuous monitoring (with associated records) is desirable, in some circumstances the monitoring records may be "exception records" that document loss of control. See 21 CFR 117.145(c)(2).

5.5.3 Corrective Actions and Corrections

You must establish and implement corrective action procedures that would apply if preventive controls are not properly implemented, as appropriate to the nature of the hazard and the nature of the preventive control. These include corrective action procedures that must be taken if you detect the presence of a pathogen or appropriate indicator organism in a ready-to-eat product as a result of product testing or if you detect the presence of an environmental pathogen or appropriate indicator organism through your environmental monitoring activities. See 21 CFR 117.150(a) and (a)(1).