

# Foreign Material Control

Operations must have a comprehensive foreign material control plan in place for known and reasonably foreseeable physical hazards. The foreign material control plan at a minimum must include:

- Specifications that include physical hazard parameters for all raw materials (including primary packaging).
- An incoming raw material (including primary packaging) inspection procedure that includes documented verification against specifications at a defined frequency. Corrective actions shall be documented when variances are identified and a trend analysis shall be conducted at a defined frequency. Preventive actions shall be documented when trends are identified.
- Storage, handling, and transport procedures that include necessary controls to prevent foreign material contamination, and the corrective actions should incidents occur.
- A glass and brittle plastic policy which maintains a map of glass and brittle plastic in product zones and areas, verified at a defined frequency.
- A policy that restricts the use of materials in product zones and areas that are not easily cleanable or prone to creating foreign material contamination. These materials include - but are not limited to - foam rubber, any type of carpet, wood, non-food grade plastic, cardboard, tape, etc.. Clothes, towels, and other cleaning materials that pose a risk of contamination or adulteration shall not be used to remove dirt and debris from products. Workers must not handle products in a manner that results in contamination or adulteration.
- A mechanism for employees to report concerns that includes specific language for foreign material contamination.
- Annual training on foreign material hazards for all employees at the facility, including instruction on the mechanism employees can use to report concerns.
- Procedure for visitor and contractor awareness and acknowledgement of the operation's requirements.
- Documented inspections at a defined frequency of equipment, glass and brittle plastic, and other reasonably likely sources of foreign material. Corrective actions shall be documented where deficiencies are identified and trend analysis shall be conducted at a defined frequency. Preventive actions shall be documented when trends are identified.
- Customer complaint procedures that address foreign material investigation and the documentation of corrective and preventive actions. Trend analysis shall be conducted at a defined frequency and preventive actions shall be documented when trends are identified.

All manufacturing operations must have a properly installed and calibrated X-ray detection device for finished product, except in the following circumstances:

- Product texture, density, or chemical composition is such that it limits the performance of the X-ray technology to an unacceptable level. These operations will be required to have a metal detector installed as well as a letter from a subject matter expert confirming that Xray is not applicable.
- Shell Eggs, whole raw agricultural commodities, whole roasted coffee beans, whole muscle meats, and packaging products will be exempt from the X-ray requirement. The operation will need to maintain current good manufacturing practices and prerequisite programs to mitigate foreign material contamination.
- Operations that utilize a physical barrier (e.g. screen, filter, sieve) that's appropriately sized and placed will be exempt from the X-ray device requirement. The operation will need to conduct integrity checks at a defined frequency, and maintain current good manufacturing practices and prerequisite programs to mitigate foreign material contamination.

All X-ray and metal detection devices must have a proper rejection mechanism to segregate rejected products. Rejected products must be physically controlled and have access restricted until evaluation by designated personnel can be completed.

Operations must perform documented X-ray and metal detector challenges at a defined frequency, but at a minimum:

- At the start and finish of daily production/shift.
- At  $\leq 2$  (two) hour intervals during the production run.
- When changes in production batches occur.
- When changes in machine settings occur.
- After downtime for repairs.

Challenge materials must conform to the manufacturer's recommendations (e.g. metal, glass, plastic, wood, etc.) and reflect the known and likely contaminants of the product and production process. Where metal detection is deployed, Ferrous, Non-Ferrous, and Stainless Steel test pieces must be used. Facilities that have not installed a detection device by the time of their Costco anniversary audit will receive an automatic audit failure.