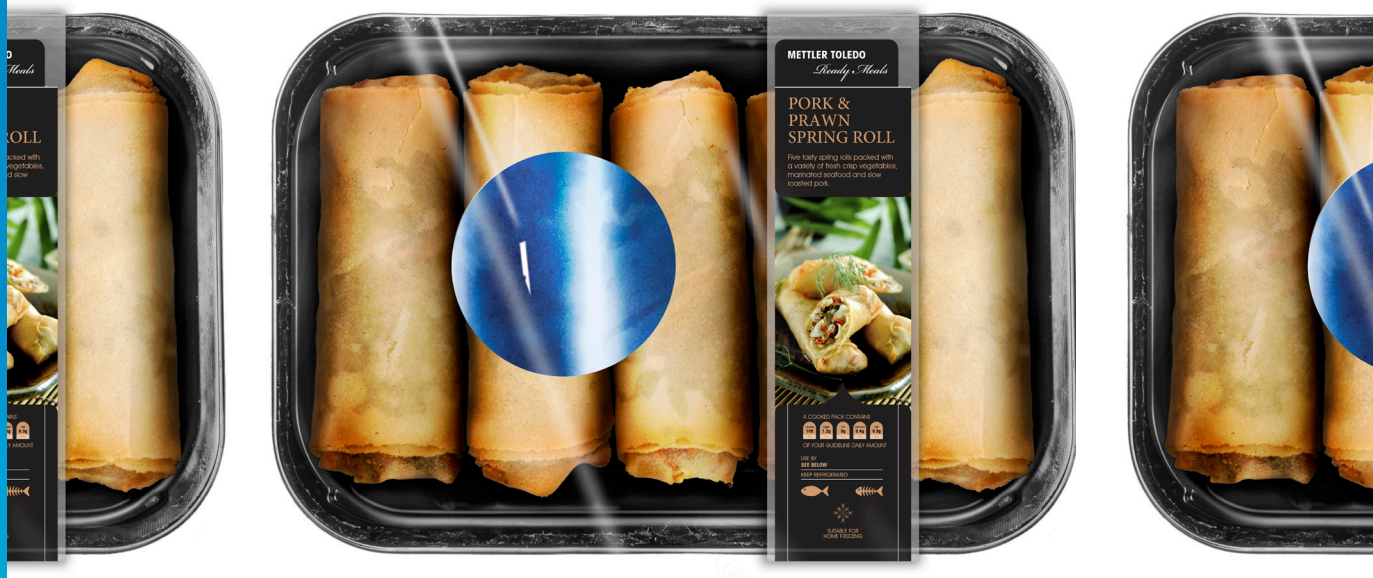
White Paper

SAFELINE
Metal Detection & X-ray Inspection

How to Prevent
Foreign Body Contamination



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More than twice as many product recall notices issued by the Food Standards Agency (FSA)[1] were a result of foreign body contamination, compared to microbiological contamination, in 2010 (Food Standards Agency's Annual Report of Incidents 2010, page 25).

X-ray inspection systems help to ensure the safety of food and pharmaceutical products by providing unsurpassed detection of foreign bodies such as metal, glass, mineral stone, calcified bone and high-density plastic and rubber.

Despite this, foreign bodies can still be a cause for customer complaints. However, rather than the x-ray system failing, such complaints tend to be associated with a lack of effective controls, poor working methods, incorrect system specification and design.

1. Introduction

Complaints do not always relate to tiny pieces of metal, glass or stone, but frequently to larger items such as washers, bolts and pieces of blades or screens that should be detectable by even the most basic type of x-ray system.

This white paper shows how a well-designed x-ray inspection program can address these issues. It focuses on how to minimize foreign bodies in the first place by monitoring the quality of suppliers' ingredients, taking care when conducting maintenance routines and performing new installations, and adopting good engineering and manufacturing practices.

Please note that selection and location of the correct equipment are also paramount in preventing foreign body contamination and the success of an x-ray inspection program, but are outside the scope of this white paper.

A separate white paper is available entitled *How to Select Critical Control Points for X-ray Systems* which addresses these issues.

Preventing foreign bodies in the first instance is better than detecting them, which is why it is recommended food and pharmaceutical manufacturers follow the practical advice in this white paper. Furthermore, taking preventive actions will also help to reduce the amount of product rejected by x-ray systems, minimizing waste and increasing productivity.

The paper begins by looking at how the main sources of foreign body contamination come from raw materials used in the production of food, as well as from the food's origin and the manufacturing process itself.

2. Contaminated Raw Materials

Raw ingredients come with a high risk of contamination and manufacturers are reliant on the quality control standards of their suppliers.

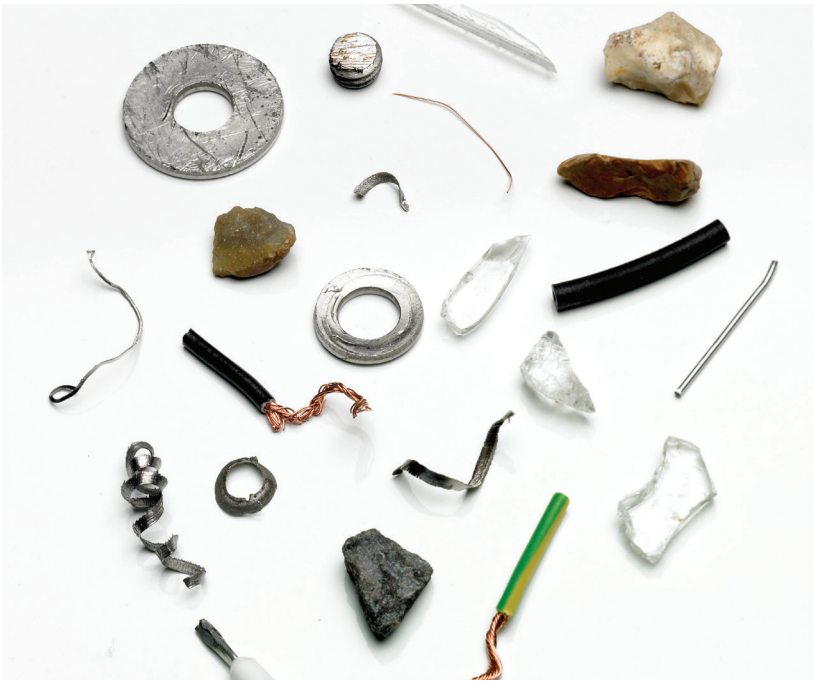

Figure 1: Typical Foreign Bodies

Eliminating foreign bodies as early as possible in the production process is vital for a number of reasons. One of these is that processing changes the nature of the product, often making it more difficult to detect foreign bodies.

For example, cooking can produce chemical changes that alter the density of foreign bodies, while mechanical processing can break foreign bodies down into smaller, less detectable pieces that are more widely spread.

Sample Application: If a pork pie manufacturer receives 100 kilograms of pork with the bones still present, calcified bones will be easily detected when x-rayed, meaning only a minimal amount of meat will be wasted. However, if the raw meat is first processed and then inspected, the bones will have become fragmented, spread more widely and will consequently prove harder to detect. As a result, a larger volume of product will be contaminated and potentially wasted.

An undetected stone or piece of metal can also damage downstream processing equipment (Figure 1), leading to downtime, costly repairs and additional metallic foreign bodies from damaged machinery.

Furthermore, early detection keeps costs down by eliminating foreign bodies before further value is added to the product.

The best approach is to ensure suppliers take full responsibility for the quality of their products by operating an effective x-ray inspection program. In fact some manufacturers insist their suppliers have x-ray inspection systems installed in order to reduce the risk of contaminated raw ingredients.

Supplier agreements or individual ingredients specifications should clearly state applicable operational sensitivity standards, in addition to any other specific precautions that the supplier should take depending on the product type.

3. Maintenance Procedure

Although modern manufacturing techniques constantly strive to eliminate foreign bodies, processes or procedures inevitably break down. There is an inherent risk of contamination during the production process every time a product is transferred from one process to the next or during a single production process. For example, glass jars and bottles can break on the production line as a result of conveyor vibrations or back pressure, as well as during the filling process due to misaligned filling heads striking the top of containers or closures being over-tightened.

The probability of breakages leading to contamination is increased on high-speed lines due to the increased momentum.

Crushers, mixers, blenders, slicers, sieves, fillers and transport systems are also typical potential sources of contamination if they are not properly maintained.

In addition, the risk of contamination exists when conducting maintenance routines or performing new installations.

For this reason, carrying out preventive maintenance under controlled conditions is essential to the effective operation of any x-ray inspection program.

Procedures for maintenance should ensure the following:

- Product safety and quality are not jeopardized during maintenance operations and installations.
- A documented, company-wide planned maintenance program is in place.
- Instructions are available to maintenance personnel indicating what is to be done during planned maintenance, including strip-down and re-build procedures.
- Personnel are trained with regard to these instructions. This training should be provided by the equipment provider or by the organization's own staff who have been trained by the provider.
- All outside contractors and engineers are made aware of (through an induction program), and adhere to, the company manufacturing practices and hygiene standards.
- Arrangements for ensuring that tasks are raised and completed on time and highlighted if they are not carried out for any reason.
- A full test of all applicable systems is carried out following repairs, maintenance or adjustments.
- Provision is made for the management of spare parts and replacement equipment.

It is essential that any potential hazards, such as defective machinery, are reported as soon as they are identified. Therefore it needs to be clear to whom such instances should be reported. Once such feedback is received, it is important that the necessary action is promptly taken and maintenance procedures are reviewed in light of the new experience. Appropriate revisions must also be made, in order to keep procedures and work practices live and effective.

3.1 Planned Preventive Maintenance Program

The planned preventive maintenance program should aim to limit wear and tear on equipment that might otherwise result in contamination or contribute to a reduction in equipment efficiencies.

Total Productive Maintenance (TPM) or Reliability Centered Maintenance (RCM) are examples of industry-recognized programs.

The objective of TPM is not simply to keep machines running smoothly, but to extend and optimize their performance overall by creating a sense of joint responsibility between supervisors, operators and maintenance workers.

RCM is a maintenance approach that prioritizes some machines over others to increase reliability and optimize financial resources.

For a planned preventive maintenance program to be effective, the degree and frequency of the maintenance activity should be based upon the following:

- Plant breakdown history.
- Equipment provider's recommendations.
- Lubrication requirements.
- Importance of the equipment in the manufacturing process.
- Risk assessment of critical control points where foreign body contamination might occur.
- Equipment known to be vulnerable to wear and tear, for example, bearings, slicer and mincer blades, mixing vessels, sieves and fillers.

3.2 Documentation and Records

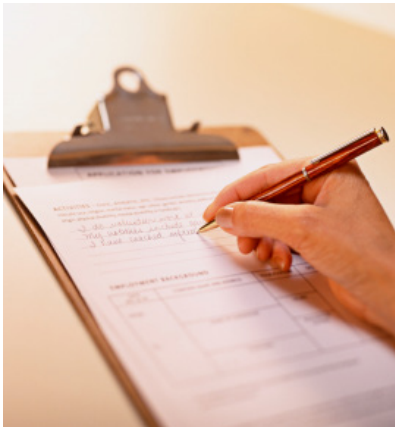

Figure 2: Maintenance Work Being Recorded

Records of maintenance performed and any subsequent corrective actions should be recorded (Figure 2). This information is helpful when reviewing the effectiveness of the planned maintenance program and incident resolution.

The maintenance status should ideally be indicated on the equipment itself for maximum visibility. Additional information should typically include the date the equipment was last checked, who made the check and when the next check is due.

3.3 Good Engineering Practice

Good Engineering Practice (GEP) is a term applied to engineering and technical activities aimed at ensuring a company manufactures quality products.

Pieces of metal, such as swarf and metal filings, are inherently produced when repairing, modifying or installing equipment. There is always a risk that metal and other foreign bodies may get into and contaminate the product. This risk can be significantly reduced if maintenance personnel are trained in safety and hygiene, and the work is carried out in accordance with good engineering practices.

Examples of what constitutes good engineering practice are listed below:

- Engineering work should take place outside the production areas and preferably in the engineering workshop whenever possible. Welding, drilling, riveting and soldering should never take place on equipment being used for production or any equipment immediately adjacent unless suitable hygienic screening is in place. For major work or new installations, complete floor-to-roof screens may be necessary.
- Workshops should be kept clean and tidy. Generally they should be swept or vacuumed at least daily, with a clean-as-you-go mentality being the preferred approach.
- Engineering spares and equipment should be stored off the floor to enable access for cleaning. Equipment used within the workshop should be maintained in a good working condition and subjected to the same regular cleaning.
- Any equipment that has been maintained or repaired in the workshop should be thoroughly cleaned to remove all debris using the appropriate method before being returned to the production area.
- If the workshop is within the production environment, a suitable foot scraper mat (or other similar trap) should surround the workshop, accompanied by a clear note requesting staff to scrape their footwear before leaving the workshop.
- Personnel carrying out repairs on production lines should be provided with an enclosed toolbox for tools, nuts, bolts and screws.
- Production packaging should never be used to store parts or machinery components.
- Wooden-handled tools should not be allowed into the production area and magnetic trays should be used to secure magnetic fixings. Non-magnetic fixings, such as rubber seals or washers that have been removed or replaced during engineering work, should be stored in clearly-marked containers.
- Tool boxes should be kept clean and free of any unnecessary content that could be hazardous to production.
- Once repairs, installation and commissioning have been completed in the production area, the equipment and the surrounding area should be independently inspected to confirm that cleaning has been performed in accordance with agreed procedures. Documentation should be in place confirming the designated personnel have checked to confirm that production lines are clean and that production can restart.
- Tape or wire (temporary engineering solutions) should not be used to repair equipment. Damaged fittings and missing or loose screws should be repaired promptly and permanently. Any metal debris, along with other potential foreign bodies, should be disposed of safely and promptly. Missing fixings on equipment should be accounted for and/or replaced and nylock nuts or similar secure fixings should be used whenever possible.
- Nuts, bolts, seals, connectors, washers, sieve and mesh used on processing equipment should be made from high-density materials whenever possible.

4. Good Manufacturing Practice

Good Manufacturing Practice (GMP) is a production and testing practice designed to ensure that products meet safety, quality and legal requirements. GMP guidelines are not prescriptive instructions on how to manufacture products, rather they are a series of general principles that should be observed.

Personal effects and operational consumables present a real contamination risk if there is poor awareness and lack of good working practices. Time spent identifying potential risks, defining good working practice and having the correct equipment will minimize the risk of contamination. Clear and concise policies should be implemented and communicated on a regular basis in order to ensure personnel remain informed and supportive of the cause.

Listed below are examples of what could constitute good manufacturing practice. However, there are undoubtedly many more control measures that are relevant to specific industries, companies and manufacturing processes.

This list demonstrates risks that could easily be overlooked:

- Paper clips and staples should not be used on documents in production areas.
- Pins should not be used on notice boards.
- Hair clips, watches and jewelry should not be allowed in production areas, although sometimes an exception is made for plain wedding bands.
- Protective clothing should have no outside pockets.
- Only x-ray detectable plasters or wound dressings should be used by personnel to aid detection if lost in production processes. Unlike metal-detectable plasters, for which the plastic material is made conductive by carbon 'doping', x-ray detectable plasters contain strips of high-density tungsten, making the plasters both metal and x-ray detectable.
- Only x-ray detectable pens and ancillary equipment should be used by personnel, to aid detection of lost items.
- Containers should be covered at all times.
- Conveyor lines carrying open cans or glass jars should be covered until the containers are filled and closed or capped.

5. Conclusion

On its own, an x-ray inspection system cannot guarantee a product is in a suitable condition for sale or free from foreign bodies. X-ray technology is most effective when purchased as part of an all-encompassing, company-wide contaminant reduction program; the objective being to prevent foreign bodies, not simply catch them before they leave the factory.

With the main sources of foreign body contamination coming from the raw materials used in the production of food, as well as from the manufacturing process itself, it is essential manufacturers keep the line and its surroundings free of foreign bodies at every stage of the production process.

As this white paper shows, this means inspecting all raw materials as they come into the factory and carrying out preventive maintenance under controlled conditions, in addition to adhering to good engineering and manufacturing practices.

[1] The Food Standards Agency (FSA) is an independent government department responsible for food safety and hygiene across the UK.

Notes

Further Information About X-ray Inspection

FREE Technical Guide

Make an informed decision

METTLER TOLEDO has published an authoritative product inspection guide for x-ray inspection systems.

The 73 page guide enables you to select the right x-ray inspection system for your production line. It supports you to install an all-encompassing product inspection program and to achieve compliance with standards, regulations and legislation.

Register today for your **FREE** copy: **www.mt.com/pius-guides**

FREE White Papers

How Safe is X-ray Inspection of Food?

Some of the most popular misconceptions about x-ray inspection of food are tackled in this White Paper. It is an indispensable white paper for food manufacturers who consider x-ray inspection to comply with food-safety regulations and legislations.

Register today for your Free copy: **www.mt.com/xrayus-safety**

X-ray Inspection: More Than Just Contamination Detection

X-ray inspection can detect numerous quality shortfalls that lie hidden within product packaging or deep within the product itself. This white paper explains that x-ray inspection is no longer just a technique for catching contaminants; its become a wide-ranging tool for defending brand values and keeping customers happy.

Register today for your Free copy: **www.mt.com/xrayus-integrity**

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