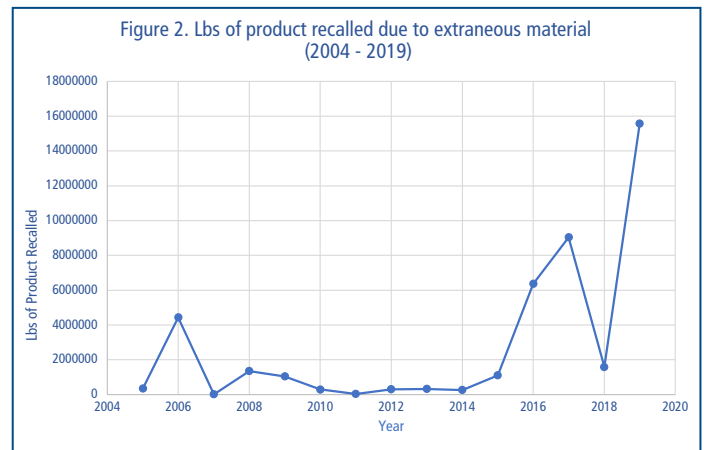
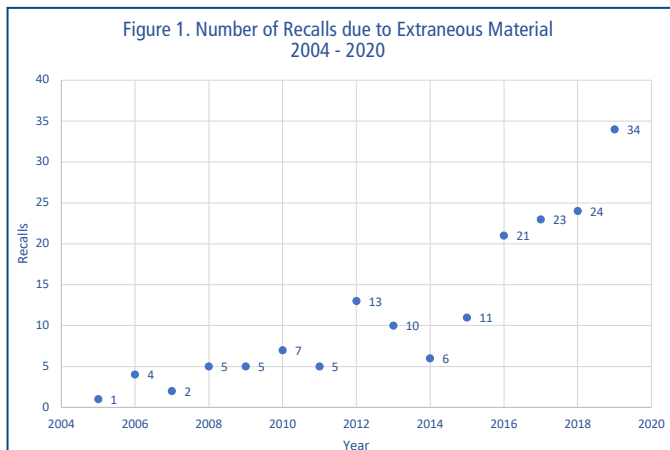


FOREIGN MATERIAL PREVENTION

Technical Contributor: Alex O'Brien, CDR

Foreign material comes in many shapes and forms, whether it be gasket material, a piece of plastic broken from a gauge, sampling utensil, or metal shards from a piece of equipment that has broken down. All these items, as we know, fall under the physical hazard category. The U.S. Food and Drug Administration (FDA) guidance on “hard and sharp objects” defines that foreign material becomes a food safety concern in the range of 7-25 mm. This guidance also discusses the hazards of items less than 7 mm being a potential danger for infants.

Over the past 5 years, the industry has been moving toward rejecting material that is less than 7 mm, even if it is compliant with the FDA minimum. The amount of recalls due to extraneous material has been trending up over the past 15 years (Figure 1 and Figure 2).



This has prompted suppliers and manufacturers to take a long and hard look on how to prevent foreign material from appearing in product to avoid a voluntary recall or a serious customer complaint that leads to loss of business.

There are several factors and ways to improve your foreign material program and awareness to avoid costly finds of foreign material.

The 3 categorical pillars that hold up the foreign material prevention program are:

- P: People | P: Programs**
- D: Detecting and Separating Equipment**

P: People

People are the foundation to having any successful operation and are key to ensuring your customers do not receive product with foreign material. A company can implement the best programs and have state of the art equipment, but these will fail if the individuals you employ do not enforce them.

An anti-foreign material culture starts from the top. If employees bring concerns of foreign material to the attention of a supervisor, manager, CEO or owner, and this concern appears to be downplayed by management, this will discourage future reporting of issues of foreign

material. Treat every report of foreign material as serious; let the employee know that you will investigate the cause, and thank the employee for being vigilant. If you deem their concern as low risk, explain your thought process to the employee and thank them for their effort. Secondly, if part of your company’s core mottos isn’t already stated in a short memorable quip on remembering food safety, quality and foreign material, it may a good thing to implement. One quip that is used and that has been successful is, “If you see something, say something.”

Prioritize foreign material in your employee training and lay out the consequences for not complying with procedures. Include pictures of what your expectations are regarding: what your tools and equipment should look like and examples of when to report a problem. Do not be afraid to hold individuals accountable for not following foreign material processes. It is imperative that employees running preventive controls are properly trained and that anyone not capable of the responsibility is relieved of those duties.

If there is not already a good reporting culture in your company, you can develop an incentive program. For instance, you can reward individuals who reports the most foreign material near misses over a certain time span. For this type of program to work, you must know ➔

the demographic of your workforce and what will motivate employees. Also, encourage employees to suggest ideas on how to make a process more foreign material free or ask them to identify items along a production line that could potentially fall into or contaminate the product stream.

For items that are reported, create a way to track the amount, production line, employees who reported it and type of material found. Some organizations call this a “near miss” or “near hit” and create a log of all the relevant information. Although this terminology has mostly been used in a safety context, it can be used to apply to foreign material. If an employee points out a piece of equipment that was about to be damaged and become a foreign material concern or notices something in a raw ingredient, this can all be documented and used for data analysis.

Lastly, supervisor and managers should be consistently walking the floor, asking questions and investigating if there are any new potential sources of foreign material contamination. Have a management team member be the point person to lead foreign material mitigation strategies. Once a month, post what your employees have found and prevented from getting to your customers. Try to assign a dollar value for cost savings. Report the near misses/hits, customer complaints and pictures of items found. This will help improve foreign material communication throughout the plant.

P: Program – Pre-Operational Inspections Program

The modern food industry has certainly moved toward more documentation over the last few years, partially due to the Food Safety and Modernization Act. However, while adding yet another checklist seems to be futile, with foreign material prevention, you must create a comprehensive pre-operational checklist.

Before creating a foreign material pre-operational checklist, the management team must complete a foreign material assessment. There are three main categories that must be considered when completing this assessment:

- 1.** Evaluate customer foreign material complaint trends. Determine your plant’s biggest concern. Are you seeing a large amount of metal reported? Are they all the same type of metal? Are they coming from the same line? Are they coming from the same product? Do finished products that have foreign material share a common raw ingredient?
- 2.** Evaluate the process. Gather a cross-functional team and walk through your process. Search for potential sources of foreign material and analyze the probability of occurrence.

- 3.** Evaluate behaviors. Are there habits, tendencies, or processes that employees or management have that would lead to higher foreign material risk? Also question your operators to find out what items they believe are the highest risks.

Once you have completed these items, evaluate the data. If there are possible adjustments to daily processes or how equipment is engineered, tackle the changes that give you the most reward. This includes tools or utensils located in production that easily could fall into product.

After these steps, you are ready to develop your foreign material pre-operational inspections checklist.

For the tools that are necessary to the process but have a high risk of entering the product stream, check them on a daily/per shift basis. For instance, you can create an intentional time before each shift for employees to check that all high-risk items are accounted for. This will help avoid having your customer find the problem before you do.

P: Program – Preventive Maintenance Program

Preventive maintenance, when done correctly, will save downtime in any operation. It is also imperative in foreign material control. Evaluate the items that are in your near miss log, foreign material assessment, and items reported on the pre-operational inspections.

Are you receiving complaints with gasket pieces, cheese cloth, etc.? Replacing or repairing these items before they break and cause customer complaints is the objective of the preventive maintenance program for foreign material prevention.

When purchasing replacement gaskets, check to see if there are any color variants. If you replace certain gaskets on a quarterly basis, a color-coding scheme may help in your investigation process as well as provide a visual prompt for your maintenance/production crews and alert them that they need to change the gasket. Other considerations for gaskets, if cost effective, would be to purchase metal detectable gaskets. In addition to gaskets, plastic utensils such as shovels, forks and hoes (used in cheese vats), cheese forms, and buckets should all be inspected regularly and either taken out of service or repaired. Having an intentional check interval paired with empowering your employees to remove any items in circulation they deem as a foreign material risk is a winning combination.

P: Program – Approved Supplier Program

Utilize your critical approved supplier program, not only to maintain food safety and quality, but as an ➡

important means to control potential foreign material. When evaluating your suppliers, make sure they have documented foreign material controls in place, such as sieves, x-ray detection, metal detection, or magnets. Buyers can mandate foreign material control measures for their suppliers and these requirements should be written in the specifications of the particular product you purchase.

P: Program – Pallet Management Program

In most plants, pallets are the only potential source of wood foreign material. You should have in place pallet specifications, storage standards and an inspection program. When pallets arrive at your facility, they should be checked for cleanliness and structural integrity. Check for boards that might have loose nails, which can be a biological contaminant as well as a foreign material contamination if it punctures your packaging.

P: Program – Good Manufacturing Practices

Good Manufacturing Practices are foundational in any Food Safety Program but are also essential to foreign material reduction. Jewelry control and making sure your employees abide by the jewelry policy is one of the biggest concerns when thinking about GMP policies. Uniforms must be clean before work and torn clothing is prohibited. Uniforms should not have pockets above the waist, should be made of materials that will not fray or shed, nor have buttons. Hair restraints worn in the plant must be distributed by the plant and not brought in from the outside. Hair nets must cover all hair on the head, including the ears, and any facial hair must be covered by a beard net. You might want to consider having arm coverings or uniform vacuums at the entrance of the plant to remove any loose hair or other foreign material. When wearing gloves, change them frequently and immediately report when there missing pieces. Ear plugs should be harnessed together and verified by lot that they are metal detectable.

P: Program – Glass, Brittle Plastic, and Ceramics Program

A good glass, brittle plastic and ceramics program is crucial to controlling potential foreign material risks. Eliminating any unnecessary glass and plastic reduces the risk of these materials shattering or breaking and finding its way into product. Having a current comprehensive glass and brittle plastic register with a manageable and reasonable check frequency will ensure a lower risk of seeing foreign material complaints. You can



Foreign material in Cheddar cheese.

make verification of the register easier to check by creating maps of where these items are, as well as pictures of what the items look like.

P: Program – Sanitation Program

A good sanitation program is effective at removing foreign material contaminants after equipment maintenance. Implementing a triple wash after invasive maintenance with a lot of grinding as well as messy routine maintenance will greatly reduce the risk of foreign material contamination. Recording these actions to ensure they happen is equally integral.

D: Detecting and Separation Equipment – Separating Equipment

Screen and filters are a good way to mitigate foreign material in the fluid milk stages of the process. However, once there are too many solids, filters and screens will be more of a hindrance than advantageous.

Magnets can be a useful tool help remove metallic material from a product stream. There are two main types: Ferrous and Rare earth magnets, with rare earth being the superior option of the two. There are several different applications of magnets such as tube, liquid line, pneumatic, chute, drum, or plate magnets. These magnets can be validated by a pull test or a gauss meter.

Pros | Magnets will actively remove foreign material from the product stream.

Pros | Magnets will also remove small ferrous and non-ferrous materials that may be below the level of detection of a metal detector or X-ray machine (example fine metal dust or abraded stainless steel).

Pros | Magnets can last a very long time if handled carefully (dropping magnets will cause their shelf life to be reduced).

Cons | Magnets do not have alarms to notify you when items are collected.

Cons | Magnets are not useful for detecting material embedded deep within a solid product.

Cons | There are also some safety issues to consider with using magnets. Proper engineering for the magnet holder and proper ways to inspect, handle, and clean the instrument is very important. Magnets if carried improperly will be attracted to any metal close to it and may lead to appendages being caught between metal and magnet.

D: Detecting and Separation Equipment – Detecting Equipment

Detecting equipment can be a very helpful tool in the fight to prevent foreign material from leaving the plant in your product. Properly trained personnel and maintaining proper settings for all equipment is imperative for success. In addition, detection equipment like metal detectors and x-ray detection equipment should be calibrated or validated by a 3rd party at minimum once per year. ➔

Metal detectors are a good tool for detecting many types of metal including ferrous, non-ferrous and stainless steel. Once the metal detector is programmed and calibrated to find what it needs to, it works well. Metal detectors have either a reject mechanism or a conveyor that stops upon alarm. There are some pros and cons to metal detection.

Pros | Metal Detectors are capable of detecting ferrous, non-ferrous, and stainless-steel objects in dairy products. All metal alloys are either magnetic, conductive, or both. Metal detectors work on these parameters, allowing them to detect metal with great accuracy, even lighter metals such as aluminum (lower in density) which are more difficult to detect using x-ray.

Pros | Metal detectors work well with bulk conveyed and gravity flow products. Metal detectors trigger based on interference with their electromagnetic field. The density and consistency of the shape of the product does not impact the ability of a metal detector to work as much as it would impact an x-ray machine.

Cons | Metal detectors can be influenced by iron, salt and moisture content of the product it is detecting. This can cause false positives.

Cons | Metal detectors are limited to detecting metal and are not designed to detect rubber, plastic, or glass.

Cons | Metal detectors can also miss objects based on how those objects are oriented. For example, if there is a .25 mm diameter wire, but it is 3 inches in length, a metal detector will only be able to detect this item if it goes through a certain way. Since the metal detector triggers based on interference with its electromagnetic field, the product will only be caught if it triggers the interference. So, if the orientation of the material is just right, it can slip past the metal detector.

X-ray detection equipment works by sending x-rays through the product and creating an image. What the x-ray detection equipment is trying to evaluate are changes in product density. It looks at the density of the package, learns the density and then rejects items that exhibit drastic changes. The larger the size of product, the larger the x-ray generator that is necessary. This in turn will mean more additional shrouding is needed to protect from X-ray leakage.

When verifying the X-ray detector is working, standard cards are available for checking objects such as quartz, rubber, ceramic, and other items. There are some pros and cons with using X-ray detection equipment.

Pro | X-ray equipment can be made to detect all types of foreign material including, glass, plastic, rock, and other high-density materials, especially items of non-magnetic or non-conductive nature.

Cons | Contaminants such as paper, hair or other less dense materials will not trigger the unit. No technology on the market is capable of this task.

Cons | The temperature and size of the product can cause false positives.

Cons | Products with high densities and random textures may be difficult for the x-ray machine to effectively detect.

Cons | It is an expensive technology. For instance, a metal detector capable of detecting foreign materials in 1lb blocks of cheese would cost approximately \$10,000 dollars, whereas an x-ray detector could cost approximately \$100,000.

Cons | There are also safety concerns. This piece of equipment can emit radiation. It requires more regulations to operate and service the machines, which means more safety devices to service on a regular basis.

Finding the Origin is Key

It may be very difficult to pinpoint an exact origin of foreign material when you have multiple potential sources of metal contamination. If you have a customer complaint that gives you metal shavings, with nothing wholly intact, one viable option is metallurgy testing. Submitting samples of metal from various equipment around your plant and comparing them to the material found from a customer for metallurgy testing will help confirm where the source of your problems may be coming. It can also confirm where they aren't coming from!

Other Things to Consider

There may be other tools you can try out or purchase. For instance, there are metal detectable pens, gaskets, and other items. Work with suppliers to get samples to test out the product and see if it is detectable on your equipment.

Overall, foreign material prevention is pivotal in maintaining food safety and reducing customer complaints. There are several different factors that lead to a successful foreign material program including people, programs, and detecting equipment. Company culture and employee participation are the foundation to successful foreign material prevention measures.

It is also essential to analyze the greatest risks of foreign material contamination and then implement sustainable pre-operational inspections programs as well as performing preventive maintenance on equipment before it becomes a problem. Removal and detecting equipment like filters, magnets, metal detectors, and x-ray detection equipment can also help reduce the risk of foreign material. A successful foreign material control program can prevent recalls and maintain customer relationships. 🌟

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