White Paper

SAFELINE
Metal Detection & X-ray Inspection

Enhancing Levels of Due Diligence

Exceeding Standards In The Food Industry

Contents

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1 Introduction

It is an ever increasing responsibility of food manufacturers to take every precaution to ensure that their products are safe, free from contamination and are unlikely to harm the end consumer in any way.

The Food Safety Modernization Act was signed in 2011 and tougher government and retailer food safety standards are here to stay. Demands on you to demonstrate your regulatory compliance and due diligence will continue to increase – just one failed performance verification audit or one product recall can significantly damage your business.

HACCP leads the way in providing a framework for food manufacturers to work within while the Global Food Safety Initiative (GFSI) manages and controls the bodies that can provide the certification and accreditation.
The organizations and bodies that provide GFSI recognized schemes include the following:

- The British Retail Consortium - BRC
- The International Food Standard - IFS
- Food Safety System Certification 23000 - FSSC 22000
- Safe Quality Food - SQF

Other schemes exist but the ones mentioned above probably equate to over 90% of the adopted standards currently being worked to.

In these litigious times, lawyers and consumers alike will seize on any opportunity to take legal action against manufacturers in the event of finding something awry with the product they have purchased. Food manufacturers supplying retail organizations will fully understand the need to ensure their product quality is of the highest level.

It is therefore in the best interests of manufacturers to take steps to ensure systems and procedures are in place to minimize the risk of litigation and, in the event of such an instance, have the necessary documentary evidence to prove they have been duly diligent in the manufacturing process.

Are you confident that your systems and procedures will stand up to scrutiny?

Duty of Care

In law, we each have a Duty of Care which requires that we adhere to a standard of reasonable care while performing any acts that could foreseeably harm others. The Standard of Care is the degree of watchfulness, attentiveness, prudence and caution of an individual who is under a Duty of Care. In the food industry, the Standard of Care is determined by the standard that would be exercised by the reasonably prudent manufacturer of a product. Failure to meet the standard could be regarded as negligence, and any resulting damages may be claimed in a lawsuit by the injured party.

Due Diligence: what is it?

The Due Diligence defense is available to manufacturers accused of a breach of food safety regulations. Essentially, the defense is that the "accused" took all reasonable practicable steps to avoid the breach. It is a sufficient defense for the person charged to prove that:

- All reasonable precautions were taken
- They exercised all due diligence to avoid the occurrence, whether personally or through any person under their control.

"Taking all reasonable precautions" includes setting up systems of control which are appropriate to the risk. What is reasonable is determined by the size and resources of the business. "Exercising all due diligence" involves having procedures in place which review and audit the system to ensure it is operating effectively.

Whether or not a defense will be successful depends on the circumstances surrounding each case.

Hazards Analysis Critical Control Points

In food production, most manufacturers utilize a Hazards Analysis Critical Control Points (HACCP) based system as a framework to identify where hazards might occur. The HACCP structure is then used to put into place procedures to mitigate the risk of the hazard from occurring in the first place. The HACCP process strictly monitors and controls each manufacturing step, to reduce the probability for hazards to occur.

HACCP is based on 7 core principles:

- Conduct a food safety hazard analysis
- Identify the Critical Control Points (CCPs) (point at which a hazard is optimally controlled)
- Establish critical limits for each CCP
- Establish CCP monitoring requirements
- Establish corrective actions when monitoring indicates that a particular CCP is not under control
- Establish record keeping procedures
- Establish procedures to verify system is working as intended

Instances of Metal Contamination

The manufacturing environment and general food processing can create the risk of metal contamination occurring. A metal detector often acts as a critical control point to mitigate this risk. This paper considers what additional elements should be included in the process in order to safeguard customer welfare and provide the basis for a robust due diligence defense.

Furthermore, a suitable metal detection system will allow manufacturers to fully maximize the opportunity to deliver the absolute best level of consumer and brand protection. All conveyor systems used to inspect products should be specifically designed to do just that and not just simply provide a "tick in a box" that says metal detection equipment is on the line and functioning.

2 A Metal Detection System: Concerns and Solutions

The opportunities for metal to find its way into a food product are numerous. The majority of equipment used in food processing plants is made of metal. For example, cutting blades, grinders, mixers, transport conveyors and packaging machinery are all predominantly metal based as are hand tools, machinery structures and support frameworks. It is conceivable that some of these items could shed a small piece of metal into the manufacturing process during normal working without the equipment failing. A metal detector downstream of all processes ensures that the resulting food product has been checked for the inclusion of metal.

Metal detectors are a common site in most modern food manufacturing plants and the technology employed is considered highly reliable. However, the incidence of metal reaching the end consumer remains high. More alarming is the fact that upon investigation, the metal being returned as a complaint is invariably detectable by the on-line

equipment. This points the finger of suspicion at the operational procedures in place in the manufacturing or inspection process.

Simply installing a metal detection system will not eradicate the incidence of metal reaching the end user. A total approach to Quality Management must be employed and, as many metal detectors are defined as Critical Control Points (CCPs), it seems common sense that this CCP is managed accordingly.

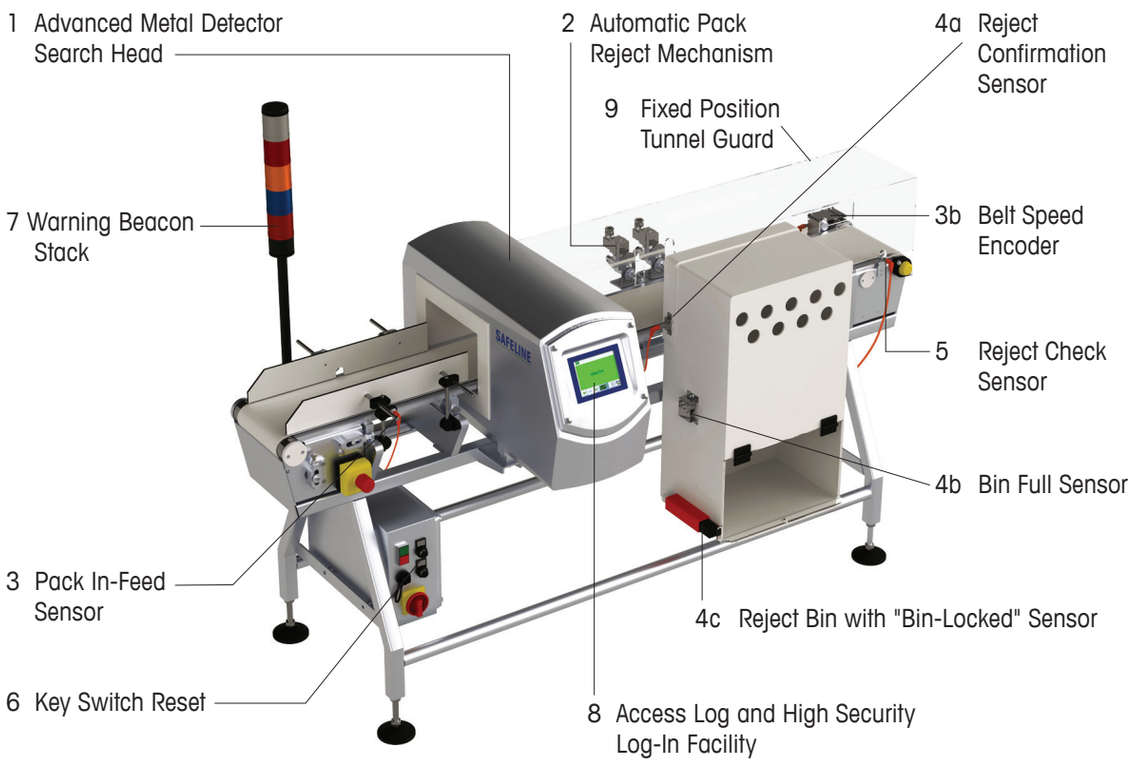
A metal detection system fitted with a suitable reject mechanism and lockable reject bin will go a long way in providing a solution but, as highlighted earlier, system and procedural failure can have a serious impact on the overall effectiveness of the system employed.

In order to ensure all contaminated food packages are rejected efficiently from the process or packing line (and remain rejected) and to ensure the highest levels of compliance with the necessary standards are met, we should look at the table below which identifies concerns and solutions available to overcome the problem.

Concern	**Solution**
How can I ensure that metal contamination is detected to the highest levels of performance?	Install a metal detector that is capable of detecting all metal types and understand its ability to detect non-spherical contaminants such as wire and thin slivers of metal.
Metal detection system failure leads to costly downtime. How do I maximize uptime?	Undertake a preventative maintenance program on the conveyor system while ensuring the metal detector has a built-in condition monitoring system which can give an early warning of potential downtime.
How do I ensure the metal detector is set correctly and I do not suffer from false rejections?	Ensure the metal detector has an accurate auto set-up feature and one that displays the margin of safety between the background product signal and the metal detectors' trigger point.
If metal is detected, how can the contaminated pack be rejected from the process without causing production stoppages?	Utilize an automatic pack reject mechanism that has been designed specifically for the application in question.
How can I ensure that consecutive contaminated packs are rejected and how do I guarantee that the correct pack is rejected irrespective of the position of the metal within the pack?	Ensure the reject mechanism is working in conjunction with a pack sensor which controls the operation of the reject mechanism and the metal detector.
How do I ensure I have a sufficient supply of compressed air to deal with multiple reject events?	Fit an air reservoir to the system or fit an air failure switch to the pneumatic feed of the conveyor.
How do I ensure that the reject mechanism is functioning correctly when the conveyor system runs from a variable speed drive?	The timing of the photogated reject mechanism (as described above) must be controlled via a belt speed encoder to ensure accurate rejection irrespective of belt speed.

Concern	Solution
How can I ensure contaminated product is not removed from the line after detection but before rejection?	Install a system tunnel guard from the detector to a point past the reject device.
Where should the contaminated packs be collected when they are rejected?	Inside a lockable reject collection bin – with the emphasis here on lockable – i.e. key locked.
How can I ensure that the contaminated pack has been rejected from the process or packing line?	Install a reject confirmation system linked to both the pack in-feed sensor and metal detector.
What if the reject bin gets full of contaminated product and there is no more room to accommodate further rejected product?	Install a bin-full sensor at the 80% of full level, to alarm if the situation becomes critical.
How do I prevent unauthorized removal of rejected products from the reject collection bin?	Manage the key accordingly or install a bin door locked/unlocked alarm where only authorized password holders have access rights.
How can I confirm the pack in-feed sensor and reject confirmation systems are working correctly?	Install a reject check sensor linked to the other sensors. This provides real time monitoring of the sensors employed.
How can I be alerted if and when a problem occurs?	Install a warning beacon stack with an audible or visual alarm linked to a conveyor stop function.
How can I be sure operators do not override the system when a problem occurs?	Utilize a key-operated reset switch which allows only an appointed member of staff to re-start the system and manage the key accordingly.
How can I demonstrate increased levels of user compliance to standards and set up an audit trail?	• Utilize a metal detector with individual language specific high security operator access levels and a built-in log with a time and date stamp to record all access to the metal detector controls. • Document procedures throughout all processes and keep detailed records of all operator training. • Subscribe to an external annual audit and certification process

3 Components of a Failsafe Metal Detection System



1 Advanced Metal Detector Search Head

You will need a metal detector that is able to meet the required detection standard. This means it must be capable of being set-up to operate within the sensitivity guidelines detailed in either your own code of practice or, as is the case for many metal detector users, in line with the requirements of third party customers such as a retailer.

It is worth noting here that the general rule which governs metal detection performance is that the smaller the aperture, the better the performance. Therefore, in general the aperture size chosen should be based on the maximum size of the product being inspected.

When comparing sensitivities of one metal detector to another don't just compare their ability to detect spheres of metal also compare their ability to detect non-spherical types of contamination such as wire and fine slivers of metal.

Fault monitoring is standard to many metal detection search heads. If a fault should occur, the metal detector alerts the user to the problem and shuts down the system. The downside of fault monitoring is that the system is potentially out of operation until the fault is fixed.

More advanced detectors utilize Condition Monitoring technology which is consistent with HACCP monitoring requirements. It checks that the critical elements of the metal detector are working and measures any changes that potentially could lead to a reduction in performance, or ultimately to a detector fault. Before these changes become critical, an early warning system brings the changes to the attention of the user. This allows maintenance to take place thereby avoiding the potentially high costs of lost production through line downtime. Planned corrective actions can take place when the system is scheduled to be off-line.

2 Automatic Pack Reject Mechanism

Where possible, the system should include an automatic product reject mechanism. The mechanism is activated when the metal detector has identified metal contamination. Its purpose is to remove the contaminated pack(s) from the production line prior to dispatch. The type of rejection mechanism should be designed for the products being inspected and will therefore be dependent upon the parameters of the application. It should take into account line and pack speed, pack weight, pack shape and dimensions, and the nature of the packaging material. This not only ensures maximum rejection capability but also takes away reliance on line operators which can in many instances be the biggest area of system failure. It is recommended that only in extreme circumstances should the use of a "stop-alarm and manual rejection" type system be specified.

Many types of reject mechanisms are available. Most are pneumatically-operated such as air-blast mechanisms, pushers, sweep arms, etc. Such pneumatically-operated reject systems may be fitted with an air failure switch which will raise an alarm if the air pressure falls below a critical point that could prevent efficient rejection taking place.
To increase the overall failsafe nature of pneumatically operated reject systems air reservoirs can also be fitted.

3 Pack Sensor and Conveyor Belt Speed Encoder

These work in conjunction with the reject device and metal detector to determine the exact position of a contaminated pack on the conveyor belt so that the pack is removed successfully from the line. The pack sensor identifies the presence of each pack at known fixed distances from the metal detector and the reject mechanism.

The use of the built-in timer in the metal detector alone without the use of an additional pack sensor is not recommended. Failure to use a photocell is potentially the single biggest reason for contaminated products still reaching the end consumer. This is because the timing of the reject mechanism can vary depending on the position of the metal within the product and the actual size of the contaminant. This can make the timing of the operation of the reject system prone to variation and potential failure to accurately reject the correct contaminated product. The combination of the external pack sensor and the built-in reject timer ensure far greater levels of successful rejection.

If using a conveyor system that utilizes a variable speed drive, a belt speed encoder should be used in conjunction with the pack in feed sensor to control the operation of the reject mechanism. This ensures that the time between metal being detected and the reject mechanism operating is calculated accurately enabling the reject mechanism to identify the contaminated pack irrespective of line speed. This is also a requirement if the line in question is prone to frequent stopping and starting.

4 Lockable Reject Collection Bin, Reject Confirmation Sensor, and Bin Full Sensor

The purpose of the reject collection bin is to provide temporary storage of rejected (i.e. contaminated) packs. The bin must be lockable to make sure that contaminated packs cannot be removed and re-introduced to the production line after the inspection system. The key for the lock should never be left in situ and should be held by a senior/authorized staff member. This removes the potential for others to gain access to contaminated product, consistent with Due Diligence and HACCP principles.

A reject confirmation sensor should be situated in or across the mouth of the reject bin. Once metal has been detected, the system can be configured to expect a further signal from the reject confirmation sensor that a pack has entered the reject bin. If no such signal is received, a system alarm is raised and the conveyor is stopped. The reject confirmation system must be intelligent enough to be able to handle multiple detection events whether they are detection events caused by multiple packs containing metal or multiple detection events caused by one or more large pieces of metal.

A bin full sensor removes the risk that a contaminated pack fails to be removed from the conveyor because the reject bin is full of rejected product. Once the level bin approaches its capacity (recommended to be set at 80% full), an alarm can be activated or the conveyor can be configured to stop so that the bin can be opened and the reject packs removed for disposal. This avoids the risk of a failed rejection due to the reject bin being full.

Advanced metal detectors can be configured to activate a timer when the reject bin door is opened and can automatically shut down the system if the bin is inadvertently left open for more than a pre-set time. Likewise, systems can be supplied that replace the need for a physical key with an unlocking password. This acts to further enhance the security and integrity of the reject bin as only authorized personnel can gain access.

5 Reject Check Sensor

For the reject mechanism to perform accurately, both the metal detector and pack in-feed sensor need to function 100% of the time. If the metal detector were to fail, the built-in fault monitoring system would stop the conveyor. If the pack in-feed sensor should fail, the reject mechanism would be inoperable, and the reject confirmation sensor would identify this the next time metal was detected as no reject confirmation signal would have been received. This of course assumes the reject confirmation system has not also failed.

However, waiting for the system to fail is contrary to good working practice and would result in all product inspected since the last successful performance verification test having to be quarantined and subsequently re-inspected. The addition of the reject check sensor provides real-time monitoring of the pack in-feed sensor and vice-versa. If failure were to be identified by either sensor, the system would issue an alarm allowing the necessary corrective action to be undertaken. As well as providing a health check of the in-feed pack sensor, the reject check sensor also acts as a back-up to the reject confirmation system dramatically increasing the overall failsafe nature of the entire system.

There are some unlikely scenarios in which the reject confirmation system has been satisfied yet the contaminated product can still be allowed to travel down the production line; for instance, if the contaminated pack should somehow bounce out of the reject bin having been confirmed as being successfully rejected. In this case the reject check sensor will act as a back-up to the reject confirmation system because it expects the contaminated pack to have been rejected. In the scenario described, the reject check sensor would issue an alarm when identifying a pack where a gap should be. Subsequently, a fault condition would be created and the conveyor stops.

6 Key Switch Reset

All of the failsafe elements that result in the conveyor being stopped should be linked to a key reset switch rather than a push button. Only authorized and nominated key holders should be allowed to restart the system after the fault or condition has been rectified. The key should never be left with the system and should be held by the authorized key holder.

7 Warning Beacon Stack

A warning beacon stack attached to the metal detection system can signal warning faults. It is usually a high visibility color-coded fault beacon, enabling rapid identification and rectification of the problem. This will help to ensure downtime is kept to a minimum. Audible alarms can also be configured to be activated when the warning beacon operates. It is recommended that if any of these fault conditions occur during normal manufacturing, the process should cease immediately until the fault condition in question is rectified and the system has been validated and documented as fully functioning by the appropriate system test procedure.

8 Access Log and High Security Log-in Facility

Sophisticated metal detection systems can assist the user in complying with standards and provide an audit trail. This is achieved by issuing unique single user passcodes and by making these passcodes language specific ensuring each user carries a level of personal responsibility for his/her actions. A system of this type is normally sufficient to prevent misuse and supports the needs of regular inspections providing the basis of a Due Diligence defense.

In such systems, an automatic log is produced recording all log-ins made at the metal detector and detailing the date, time and name of the person logging on. By recording this information and instituting system access only through individual password control, compliance with standards and HACCP record keeping requirements can be demonstrated forming a robust basis for a Due Diligence defense.

9 Fixed Position Tunnel Guard

A tunnel guard or enclosure should be fitted to the out-feed side of the system. This should extend from the out-feed side of the metal detector to a point beyond the end of the reject bin as a minimum. The purpose of this guard is to prevent unauthorized removal of products from the system that may be contaminated which could accidentally be re-introduced to the system after the point of rejection.

Management Responsibility

As many metal detectors in use are considered to be CCPs, it is a management responsibility to ensure that all personnel treat these control points accordingly. Operators must be aware that their actions are critical to the operation of the control point and as such, any misdemeanor will be subject to disciplinary action.

4 Summary

This paper has introduced the concept of Due Diligence and explained its importance in terms of providing a basis for a legal defense if a customer claims to have found metal contamination in a food product.

The paper identifies how a metal detection system, if suitably configured, can help you meet your due diligence needs, and also conform to the seven HACCP principles:

- Conduct a food safety hazard analysis
- Identify the Critical Control Points (CCPs) (point at which a hazard is optimally controlled)
- Establish critical limits for each CCP
- Establish CCP monitoring requirements
- Establish corrective actions when monitoring indicates that a particular CCP is not under control
- Establish record keeping procedures
- Establish procedures to verify system is working as intended.

Furthermore, a suitable metal detection system will provide the opportunity to deliver the highest level of consumer and brand protection. All conveyor systems used to inspect food products should be specifically designed to do just that and not just simply provide a "tick in a box" that says metal detection equipment is on the line and functioning.

Checklist

When considering the purchase of a metal detector to meet your due diligence needs, this paper can be used as a checklist to evaluate alternative systems. If a proposed system does not include some or all of the features identified, then it is likely to indicate a weakness in its ability to mount a full Due Diligence defense.

5 Literature References

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http://www.brc.org.uk

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