The Principles of Due Diligence
For Quality Control and Legal Defence

Contents

1 Introduction
2 Standards
3 Instances of Physical Contamination
4 Product Inspection Systems: Concerns and Solutions
5 Components of a Failsafe Product Inspection System
6 Summary
7 Literature References

Updated to include:
BRC V7
HARPC
FSMA
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.

Hazards Analysis Critical Control Points (HACCP) leads the way in providing a framework for food manufacturers to work within, whilst the Global Food Safety Initiative (GFSI) provides a platform for collaboration between some of the world’s leading food safety experts from retailer, manufacturer and food service companies, service providers associated with the food supply chain, international organizations, academia and government.

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. Thus, the ‘Due Diligence’ philosophy can and should be extended to all product inspection technologies incorporated within a manufacturer’s food safety program, not just those that are deemed to be Critical Control Points (CCPs).

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?

1.1 **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.

1.2 **Due Diligence: What is it?**

The Due Diligence defence is available to manufacturers accused of a breach of food safety regulations. Essentially, the defence is that the “accused” took all reasonable practicable steps to avoid the breach. It is a sufficient defence 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 defence will be successful depends on the circumstances surrounding each case.
2 Standards

2.1 Global Standards

For many years, the food industry had many different auditing standards. These were chosen in accordance with:

- The preferences of manufacturers’ most significant customers.
- The particular choices of individual plants.
- Strategic selection by companies.

As a result of this lack of common standards, the industry was vulnerable to inconsistent protection, which put consumer safety and businesses at risk.

To solve this problem, the GFSI was established by a group of international retailers in May 2000. The GFSI now reviews food safety standards and approves those which meet specific criteria.

Different standards apply to different stages in the food supply chain, and many food manufacturers now only need to certify themselves to one of the GFSI accepted programs in order to meet most retailers’ requirements; however, some larger retailers also have their own standards.

Hazards Analysis Critical Control Points (HACCP) and Pre-Requisite Programs (PRP) define good practice in hygiene and manufacturing - and are the foundation of all GFSI standards. Further information about HACCP is found in section 2.2 of this white paper.

From 1 January 2006, EU food hygiene legislation has applied throughout the UK, and food business operators (except farmers and growers) are now required to put in place, implement and maintain a permanent procedure (or procedures), based on HACCP principles.

In the USA, the Food Safety Modernization Act (FSMA) is requiring a similar food safety program based on Hazard Analysis Risk Based Preventative Controls (HARPC) which will come into effect for most manufacturers in September 2016. Significant to the FSMA is a focus on documentation of the food safety program and regular verification that all processes are functioning properly - essentially a mandating of due diligence practices. The FSMA have also issued a rule on Foreign Supplier Verification Programs (FSVP) for importers of Food for Humans and Animals. The final rule mandates that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards, which again pertains to a due diligence defence. Further information about FSMA and HARPC is found in Section 2.3 of this white paper.

The organizations and bodies that provide GFSI-recognized schemes include the following:

1. British Retail Consortium - BRC
2. International Featured Standards - IFS
3. Food Safety System Certification - FSSC 22000
4. Safe Quality Food - SQF

Other schemes exist but those mentioned above probably equate to over 90% of all adopted standards currently being worked to. Common to all of the above is the requirement for all food manufacturers to provide a processing environment which ensures the risks of product contamination are minimized - an essential component of a due diligence approach.
Two important distinctions should be made between GFSI and FSMA. Firstly, GFSI is a global standard, whereas FSMA is more U.S.-centric, focused on protecting the American consumer. Secondly, GFSI is more guidance-based documents and adopts a broad scope, while FSMA is the law.

Some food retailers adopt a different approach; investing heavily in the GFSI, they have established their own Codes of Practice which are designed to support the GFSI-approved HACCP-based standards. In addition to the standards, both SQF and the BRC publish guidance documents. The BRC also includes a 'Foreign Body Detection' guidance document relevant to product inspection equipment, available on the BRC website.

These guidance documents present a state-of-the-art interpretation of how to implement the standards and many auditors and certification bodies expect food manufacturers to implement standards in accordance with them. The standards are, increasingly, being accepted across all continents – and, whilst they are not a legal obligation, almost all retailers now insist that manufacturers are certified to one of them.

### 2.2 Hazards Analysis Critical Control Points

In food production, most manufacturers utilize a HACCP-based system as a framework to identify where hazards might occur. The HACCP structure is then used to put procedures into place which monitor and control each manufacturing step, mitigating the risk of the hazard occurring in the first place.

HACCP is based on seven core principles:

1. Conduct a food safety hazard analysis
2. Identify the CCPs - the point at which a hazard is optimally controlled
3. Establish critical limits for each CCP
4. Establish CCP monitoring requirements
5. Establish corrective actions when monitoring indicates that a particular CCP is not under control
6. Establish record keeping procedures
7. Establish procedures to verify system is working as intended

These seven core principles are fundamental to industry food safety standards and regulations. For example, they continue to underpin the latest guidance from the BRC, as documented in the BRC Global Standards Issue 7 publication. Clause 4.10.1.1 in Issue 7 states "a documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination." This can help food manufacturers select the most appropriate product inspection systems and place them where they will be most effective as designated CCPs.

A knowledgeable manufacturer of product inspection equipment should be able to provide guidance in implementing a HACCP-based programme. When selecting the right product inspection equipment, the decision-making process should take into account the equipment's ability to support monitoring requirements (such as reminders when performance monitoring test are due or overdue) and available software to facilitate record-keeping procedures.

### 2.3 Hazards Analysis and Risk-Based Preventative Controls For Human Food

The FDA Food Safety Modernization Act 'Preventive Controls for Human Food' rule is now final. Compliance dates for some businesses begin in September 2016.

The stated purpose of the rule is to "better protect public health by, among other things, adopting a modern, preventive, and risk-based approach for food safety regulation" (Federal Register Vol. 80, No. 180, pg. 55911). In order to accomplish the goal, the rule sets out to "modernize FDA's…current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food" (FR80, pg. 55911).
According to the FDA website's fact sheet on the new rule, a cornerstone of the rule is the requirement for "covered facilities to establish and implement a food safety system that includes an analysis of hazards and risk-based preventative controls. The rule sets requirements for a written food safety plan." (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm). The food safety plan includes:

- Hazard analysis - which must consider biological, chemical and physical hazards
- Preventive controls - measures must be in place to address the hazards with the aim of minimizing or preventing the hazards entirely; supply chain controls must also be in place, in addition to having a recall plan
- Monitoring procedures - designed to provide assurance that preventative controls are consistently performed; monitoring conducted should be appropriate to the preventative control in place.
- Corrective actions and corrections - in light of problems or new information, corrective actions must be taken to improve the food safety plan, and must be documented with records.
- Verification processes - these activities are required to ensure preventative controls are consistently implemented and effective. This includes validating with scientific evidence that a preventative control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments, and reviewing records to verify that monitoring and corrective actions if necessary are being conducted.

3 **Instances of Physical Contamination**

The manufacturing environment and general food processing can create the risk of physical contamination occurring. A standalone metal detection or x-ray inspection system, or a combi-unit that integrates one of these two technologies with a complementary technology such as a checkweigher or vision inspection system, often acts as a CCP 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 defence.

Furthermore, a suitable product inspection system will allow manufacturers to fully maximize the opportunity to deliver the absolute best level of consumer and brand protection. All 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 the equipment is on the line and functioning. Guidance in the latest BRC Standard Issue 7 allows manufacturers to place product inspection equipment throughout the production line (as opposed to at the end of the line as per previous guidance), as long as they "validate and justify" the location (Clause 4.10.1.2).

4 **Product Inspection Systems: Concerns and Solutions**

The opportunities for contamination 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 procedures without the equipment failing. Other contaminants such as glass, mineral stone, calcified bone or high density plastics and rubbers could also be introduced into the product either as a result of being included in the raw materials or during the manufacturing process. An inspection system downstream of all processes ensures that the resulting food product has been checked for the inclusion of contaminants.
Metal detection and x-ray inspection systems are common in most modern food manufacturing plants and the technologies are highly reliable. However, the incidence of contamination reaching the end consumer remains high. More alarming is the fact that upon investigation, the contaminant causing the complaint in many cases should have been detected 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 suitable product inspection system will not eradicate the incidence of contaminated products reaching the end user. A total approach to Quality Management must be employed and, as many metal detection and x-ray systems are defined as CCP's, each CCP must be established and managed accordingly.

A product inspection 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.

It is vital to ensure that all contaminated food packages are rejected efficiently from the process or packing line, and that they remain rejected. It’s equally important to provide the highest levels of compliance with the relevant standards. To help achieve these aims, the following table identifies various concerns, together with matching solutions designed to tackle each problem.

**Table 1**

<table>
<thead>
<tr>
<th>Concern</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>How can I ensure that foreign bodies are detected to the highest levels of performance?</td>
<td>Install a product inspection system, or combination of systems, that is capable of detecting all contaminant types and understand its ability to detect non-spherical contaminants.</td>
</tr>
<tr>
<td>System failure leads to costly downtime. How do I maximize uptime?</td>
<td>Undertake a preventative maintenance program on the conveyor system whilst ensuring the product inspection equipment has a built-in condition monitoring system which can give an early warning of potential downtime.</td>
</tr>
<tr>
<td>How do I ensure the product inspection equipment is set correctly and does not suffer from false rejections?</td>
<td>Ensure the equipment has an accurate auto set-up feature and one that displays the margin of safety between the background product signal and the metal detector/x-ray inspection system’s trigger point.</td>
</tr>
<tr>
<td>If contamination is detected, how can the contaminated pack be rejected from the process without causing production stoppages?</td>
<td>Utilize an automatic pack reject mechanism that has been designed specifically for the application in question.</td>
</tr>
<tr>
<td>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 contaminant within the pack?</td>
<td>Ensure the reject mechanism is working in conjunction with a pack sensor which controls the operation of the reject mechanism and the product inspection equipment.</td>
</tr>
<tr>
<td>How do I ensure I have a sufficient supply of compressed air to deal with multiple reject events?</td>
<td>Fit an air reservoir to the system or fit an air failure switch to the pneumatic feed of the conveyor.</td>
</tr>
<tr>
<td>How do I ensure that the reject mechanism is functioning correctly when the conveyor system runs from a variable speed drive?</td>
<td>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.</td>
</tr>
<tr>
<td>Concern</td>
<td>Solution</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>How can I ensure contaminated product is not removed from the line after detection but before rejection?</td>
<td>Install a system tunnel guard from the detector to a point past the reject device.</td>
</tr>
<tr>
<td>Where should the contaminated packs be collected when they are rejected?</td>
<td>Inside a lockable reject collection bin – with the emphasis here on lockable – i.e. key locked.</td>
</tr>
<tr>
<td>How can I ensure that the contaminated pack has been rejected from the process or packing line?</td>
<td>Install a reject confirmation system linked to both the pack in-feed sensor and the product inspection equipment.</td>
</tr>
<tr>
<td>What if the reject bin gets full of contaminated product and there is no more room to accommodate further rejected product?</td>
<td>Install a bin-full sensor at the 80% of full level, to alarm if the situation becomes critical.</td>
</tr>
<tr>
<td>How do I prevent unauthorized removal of rejected products from the reject collection bin?</td>
<td>Manage the key accordingly or install a bin door locked/unlocked alarm where only authorized password holders have access rights.</td>
</tr>
<tr>
<td>How can I confirm the pack in-feed sensor and reject confirmation systems are working correctly?</td>
<td>Install a reject check sensor linked to the other sensors. This provides real time monitoring of the sensors employed.</td>
</tr>
<tr>
<td>How can I be alerted if and when a problem occurs?</td>
<td>Install a warning beacon stack with an audible or visual alarm linked to a conveyor stop function.</td>
</tr>
<tr>
<td>How can I be sure operators do not override the system when a problem occurs?</td>
<td>Utilize a key-operated reset switch which allows only an appointed member of staff to re-start the system and manage the key accordingly.</td>
</tr>
<tr>
<td>How can I demonstrate increased levels of user compliance to standards and set up an audit trail?</td>
<td>Utilize a metal detector/x-ray inspection system 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 product inspection equipment controls. Document procedures throughout all processes and keep detailed records of all operator training. Subscribe to an external annual audit and certification process.</td>
</tr>
</tbody>
</table>
5 Components of a Failsafe Product Inspection System

A well designed and effective product inspection system designed to minimize the risk of contaminated product reaching the end consumer will include the following features:

- Advanced metal detector or x-ray inspection search device
- Automatic product reject device
- Pack in-feed sensor
- Reject confirmation, bin full and reject bin with a "bin locked" sensor
- Reject check sensor
- Key operated re-set switch
- Warning beacon stack
- Highly secure login facility to the operating system
- Fixed position tunnel guard
- Air Pressure Failure Indicator (if applicable)

It is important to note here that a metal detector or x-ray system may be combined with another complementary product inspection technology such as a checkweigher or vision inspection system. These so called combi-units may in fact be CCPs due to the incorporation of a metal detector or x-ray search device, and thus attention must be paid to ensuring the entire combi-unit possesses essential failsafe system components to ensure the complete system supports a 'Due Diligence' defence.

Figure 5a: Metal Detection System Due Diligence Components
5.1 Search/Inspection device
You will need a metal detector or x-ray inspection system 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 in line with the requirements of third party customers such as retailers.

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.

When comparing the sensitivities of one x-ray system with the sensitivities of another, you should ensure that the same test sample types are used to avoid unfair comparisons, e.g. there are several different types of glass test piece in use amongst different suppliers.

Fault monitoring is standard to many metal detection and x-ray search devices. If a fault should occur, the metal detector/x-ray system 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/x-ray system are working and measures any changes that potentially could lead to a reduction in performance, or ultimately to a system 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 unplanned line downtime. Planned corrective actions can take place when the system is scheduled to be offline.
5.2 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, or the x-ray inspection system identifies a particular type of foreign body. Its purpose is to remove the contaminated pack(s) from the production line before they are dispatched.

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
- Product characteristics / pack shape and dimensions
- The nature of the packaging material (if applicable)

Taking into account these factors ensures maximum rejection capability. 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 fail-safe nature of pneumatically operated reject systems air reservoirs can also be fitted.

5.3 Pack Sensor and Conveyor Belt Speed Encoder
These work in conjunction with the reject device and inspection device 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 inspection device and the reject mechanism.

The use of the in-built timer in the metal detector or x-ray inspection system 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 actual size and position of the contaminant within the product. 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 in-built 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 contamination 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.

5.4 Lockable Reject Collection Bin, Reject Confirmation Sensor, and Bin Full Sensor
The reject collection bin provides temporary storage for rejected (i.e. contaminated) packs. The bin must be lockable, to make sure that contaminated packs remain secure and are not re-introduced into the production line after inspection. Traditionally, these were locked with a physical key; the latest systems may utilize software-enabled locks for additional security.

The key, whether it is a physical entity or an electronic password, should never be left with the system 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 a contaminant has been detected, the system can be configured to expect a 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 a foreign body or multiple detection events caused by one or more large pieces of foreign body contaminants.

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 bin level 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 or rework. This avoids the risk of a failed rejection due to the reject bin being full.

Advanced metal detectors and x-ray systems 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, software-enabled 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.

An ‘Interlocked Bin’ is used on combi-units incorporating two or more product inspection technologies. The first bin collects contaminated products, for example, whilst the second bin collects products that do not meet other set quality criteria. This would be underweight/overweight products in the case of a checkweigher, or products missing specified pack components or incorrect labels in the case of a vision inspection system.

In this scenario, the door of each catch bin is locked electronically. Access to the bin is only allowed if the user is authorized and has logged in at the terminal. When the door is closed, it will be locked immediately. If the door is not closed after a predefined period of time, an alarm will be sent to the terminal.

The bins should be equipped with an electronic lock and integrated software should ensure that the bins can only be opened and emptied by authorized personnel. The lock should only be able to be opened when an authorized user is logged in. The configured parameters should also be independent of each other (with the exception of adjustable user-level) and should only be valid for the respective reject bin. All actions should be logged in an audit trail function incorporated within the equipment.
5.5 Reject Check Sensor

For the reject mechanism to perform accurately, both the inspection device and pack in-feed sensor need to function 100% of the time. If the metal detector or x-ray system were to fail, the in-built condition 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 contamination 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 monitoring 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 confirms the contaminated pack has 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 would stop.

In the case of combi-unit systems, a reject check sensor may be used for more than just contaminated products. In addition to "bad" products that have not been rejected, it may also be used when product is missing from a pack, or other quality criteria such as weight tolerance or label position have not been met and product has been rejected for one of these reasons as opposed to contamination being present.

5.6 Key-Operated Switch Reset

All of the failsafe elements that result in the conveyor being stopped should be linked to a key-operated reset switch rather than a push button. Only authorized personnel 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.

5.7 Warning Beacon Stack

A warning beacon stack attached to the product inspection 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 verified and documented as fully functioning by the appropriate system test procedure.

5.8 Access Log and High Security Log-in Facility

Sophisticated metal detection and x-ray 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. This ensures 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 defence.
In such systems, an automatic log is produced recording all log-ins made at the metal detector or x-ray system, 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 defence.

5.9 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 search head 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.

5.10 Air Pressure Failure Indicator
The air pressure monitoring device scrutinizes the compressed air supply. When the pressure in the pneumatic system drops below a certain preset level, the conveyor should stop automatically until the fault has been rectified and appropriate verification procedures have been completed.

5.11 Management Responsibility
As many metal detectors and x-ray inspection systems in use are considered to be CCP’s, it is a management responsibility to ensure that all personnel treat these control points accordingly and are properly trained. Operators must be aware that their actions are critical to the operation of the control point.

6 Summary
This paper has introduced the concept of ‘Due Diligence’ and explained its importance in terms of providing a basis for a legal defence if a customer claims to have found contamination in a food product. The due diligence philosophy can however, extend beyond equipment identified as a CCP, to processing and packaging equipment such as checkweighers and vision inspection systems for example, to support a manufacturer’s holistic approach to food safety and compliance with industry standards and regulations.

The paper identifies how a product inspection system - incorporating metal detection and/or x-ray technology - if suitably configured, can help you meet your due diligence needs, and also conform to the seven HACCP principles.

When considering the purchase of a metal detector and/or x-ray inspection system 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 support a full Due Diligence defence.

Furthermore, a suitable product inspection system, or combination thereof, will provide the opportunity to deliver the highest level of consumer and brand protection. All 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 product inspection equipment is on the line and functioning.

Governments, retailers and consumers are increasingly aware of the issue of food safety, and updates to regulations, such as BRC Global Standards Version 7 and the latest guidance from the FSMA, are constantly going into effect. Food manufacturers must understand any new guidelines and take active steps to ensure that their product inspection systems are compliant in every way. This is vital to safeguarding consumer wellbeing, protecting their brand, and growing their business in lucrative markets.
7 Literature References

British Retail Consortium (BRC)
http://www.brc.org.uk

Food Standards Agency (FSA)
http://www.food.gov.uk/

International Featured Standards (IFS)
https://www.ifs-certification.com

ISO 22000:2005 - Food Safety Management System Standard
http://www.lrqa.co.uk/products/otherproducts/iso22000/

Safe Quality Food (SQF) Institute
http://www.SQFI.com

http://www.mt.com/cwguide

http://www.mt.com/mdguide

www.mt.com/vision-guide

About Mettler-Toledo Product Inspection:

The Product Inspection Division of METTLER TOLEDO is a leader in the field of automated inspection technology. Our solutions increase process efficiency for manufacturers while supporting compliance with industry standards and regulations. Our systems also deliver improved product quality which helps to protect the welfare of consumers and reputation of manufacturers.

Metal Detection  
X-ray Inspection  
Checkweighing  
Vision Inspection

Disclaimer:

Information contained in this publication is provided "as is" and without warranty. METTLER TOLEDO disclaims all warranties, express or implied, and makes no warranty regarding the accuracy or applicability of the information contained in this publication, and is therefore explicitly not responsible for any damage, injury or death resulting from the use of or reliance on the information.

No part of this publication may be reproduced or distributed for any purpose without written permission from METTLER TOLEDO.

©2015 METTLER TOLEDO. All rights reserved. Subject to technical changes.