White Paper

Food Safety Standards and Legislation

Taking Steps to Ensure Compliance

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1 Introduction

Food safety is an increasing concern and affects consumers and businesses globally. While much of the world's food supply is safe, high profile safety scares and product recalls highlight the potential danger of foodborne threats. In addition to existing quality standards such as ISO9001, Good Manufacturing Practice (GMP), and Hazard Analysis and Critical Control Points (HACCP), it is becoming increasingly important for manufacturers to hold food safety certification to ensure the highest level of food safety in a more globalized economy.

Every year as many as 600 million people, or almost 1 in 10 people in the world, fall ill after consuming contaminated food according to the World Health Organization's (WHO) estimates of the global burden of foodborne diseases in 2015[1].

This white paper looks at the most common food safety standards and their latest requirements. Focusing on traceability, quality and quantity control, foreign body detection, hygienically-designed equipment and equipment calibration, it explains how the implementation of a product inspection program can help food manufacturers meet these requirements in order to achieve compliance.

2 Food Recalls are Rising

Food recalls have become a regular feature of today's headlines and the number of recalls per year in the U.S. for instance has almost doubled since 2002. Multiple reasons exist for the spike in the number of recalls, but contributing factors include the increasingly global and complex food supply chain, as well as heightened regulatory standards and media coverage of an issue that impacts public health. Ready-to-eat meals which are mass produced using many different ingredients are most affected by recalls, closely followed by fruits, vegetables and nuts, meat and poultry, and sugar and confectionery[2]. Unsafe food due to microorganisms is the most common cause of food recalls, with labeling and physical contamination also major causes.

Food manufacturers operate in a vast, globalized supply chain and one mislabeled product or contaminated ingredient has the potential to cause sickness, death, severe financial loss and reputational damage.

The average cost of a recall to a food company is estimated at USD 10 million in direct costs, with some recalls resulting in losses of more than USD 100 million[2]. This figure excludes the brand damage and lost sales that can take companies years to recover from. Round-the-clock media coverage and the power of social networking make it impossible to be oblivious to food recalls and, according to research by AMR, around 57% of consumers will stop buying an affected product for at least a year[3].

In this global movement of goods, the possibilities for errors are nearly boundless. METTLER TOLEDO has created a white paper[4] explaining how to prevent food recalls.

[1] http://www.who.int/mediacentre/news/releases/2015/foodborne-disease-estimates/en/
[2] http://www.swissre.com/media/news_releases/nr_20150715_foodrecall.html
[3] http://www.wipro.com/documents/unlocking-the-potential-of-product-lifecycle-management.pdf
[4] http://www.mt.com/pi-productrecalls

3 The Food Safety Legislation and Standards Landscape

In order to address the issues of food safety and consumer wellbeing, multiple industry standards are in place. Legislation is also in place in some regions to enforce exacting safety standards.

3.1 Global Food Safety Initiative (GFSI)

Founded in 2000 by leading retailers and food companies following a number of high-profile international food safety crises, the aim of the Global Food Safety Initiative (GFSI) was to harmonize food safety certification and reduce the need for multiple supplier audits. Its mission is to "Provide continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide".
Facilitated by the Consumer Goods Forum (CGF), the GFSI is governed by a multi-stakeholder group who have worked together to create the GFSI Guidance Document. The document lays down the requirements for food safety management schemes and provides a framework against which such schemes can be benchmarked.
The four most commonly used GFSI-recognized food safety schemes today are:

- British Retail Consortium Global Standard for Food Safety (BRC)
- International Featured Standard - Food (IFS)
- Food Safety System Certification 22,000 (FSSC 22,000)
- Safe Quality Food Code (SQF)

All four schemes must adhere to the same benchmarking criteria set by the GFSI Guidance Document and certification is achieved through a successful third party audit.

The topic of food safety standards is complex. Understanding the differences and similarities between the various standards is important for food manufacturers. METTLER TOLEDO has created a white paper[1] which compares the GFSI standards and makes understanding the requirements easier to comprehend.

3.2 Food Safety Modernization Act

Foodborne illness outbreaks have also triggered recent food safety legislative activity, including the U.S. Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) which was signed into US law in January 2011. The FSMA represents the first major reform of food safety laws in more than 70 years and shifts the FDA's approach to food safety from responding to foodborne illness outbreaks to preventing them from occurring in the first place in order to better protect public health and reduce the risk of recalls. The legislation applies not only to US-based food manufacturers and processors, companies outside the US intending to export into the US market must also meet the demands of the law through a Foreign Supplier Verification Program (FSVP).

The FSMA's more stringent requirements have led many manufacturers and suppliers to seek certification from a GFSI-approved food safety standard in order to reinforce their commitment to proactive prevention of contamination and assessment of their preventive systems. Although certification to a GFSI-approved scheme does not in itself eliminate the likelihood of an FDA inspection, it demonstrates a facility's commitment to meeting the requirement that it focuses on safety and creates a structure for continually improving production quality processes.

Are you ready to meet the needs of the FSMA? METTLER TOLEDO has created a white paper[2] which explains the FSMA and its requirements in more detail.

[1] http://www.mt.com/pi-global-certification-food
[2] http://www.mt.com/pi-fmsa

4 How Product Inspection Aids Compliance with Food Safety Standards

The four GFSI-approved standards are based on the Hazard Analysis and Critical Control Points (HACCP) framework while the FSMA legislation is based on the provision of the more recently introduced Hazard Analysis and Risk-Based Preventative Control approach (HARPC). Although requirements vary slightly in scope and structure, key requirements such as quality and safety parameter monitoring, weighing processes, product inspection and process documentation are common among them. The following themes are commonly featured through the standards:

- Tracking and tracing
- Quality and quantity control
- Foreign body detection
- Hygienically-designed equipment
- Calibration/control of measuring and monitoring devices

This white paper explores how implementing a product inspection program that incorporates stand alone and/or fully-integrated product inspection solutions on the market today can help food manufacturers meet the standards.

4.1 Traceability

Traceability is defined as the ability to trace and follow raw materials, components, and products through all stages of receipt, production, processing, and distribution both forwards and backwards.

As the food supply chain has become increasingly global, traceability has become critical to the establishment and operation of an effective food safety program. Whenever a food safety or quality incident occurs, time is the enemy as public health and lives are at stake, as well as the livelihoods of industries and companies. The ability to track and trace the paths of products through the food chain is vital to improve food safety and security, as well as avoid or mitigate devastating public health and economic impact.

Traceability:
"The site shall be able to trace all raw material product lots (including packaging) from its suppliers through all stages of processing and dispatch to its customers and vice versa."
- BRC (Issue 7) section 3.9

In addition to carrying out their primary functions, modern product inspection solutions offer previously unachievable levels of traceability, as well as quick and easy access to crucial information.

Data Collection
Advanced inspection systems support product traceability by storing and allowing easy access to reports and statistics on all inspected products. By recording large amounts of performance data, inspection systems can also help to identify trends and instigate preventive actions to reduce non-conformance issues. Furthermore, if a company is investigated following a customer complaint or legal claim, documentation gathered in the production process can form the basis of a robust due diligence defense by providing invaluable proof of risk management and compliance with industry regulations.

Weight Control
Computerized and intelligently networked formulation/weighing systems are important material identification points and can help food manufacturers document all processes without gaps. They offer numerous advantages over paper-based systems, including better data consistency, speedier data analysis and improved recall management. By assisting with component identification and overall traceability during processing, weighing stations can help to avoid material mix-ups and wrong quantities too.

In every production step from goods entry to shipment, database entries correspond to in-process materials, and barcode-reader enabled labels assist with component identification and overall traceability during processing. Printers connected to weighing workstations can print labels at the point of identification that enable fast materials recognition.

Label Integrity
Vision systems can also enhance the traceability of food products throughout the manufacturing process and supply chain with barcode and RFID track and trace technology. By improving product visibility and increasing accurate identification of unsafe products, such solutions can help to reduce the extent of a recall.

Integrated Systems and Data Management Software
Fully integrated product inspection solutions that include scales, scanners and printers from goods-in to shipment provide the highest level of traceability. By enabling all data to be linked and processed in real-time, such solutions provide clear identification of raw materials and intermediate components, along with warehousing/storage records.

Software is available which is designed to help streamline data analysis, facilitating the demonstration of due diligence and product traceability by allowing food manufacturers to network product inspection technologies to one or more remote processing and control locations within an operation.

4.2 Quality and Quantity Control

Product inspection equipment can help to ensure the production of consistently safe, high-quality, and legal products. Modern systems with integrated technologies are capable of performing a wide range of in-line quality control checks. These include:

- Detection of physical contaminants
- Package and label integrity checks
- Identification of print and labeling defects
- Measuring mass
- Counting components
- Checking fill levels and head space in containers
- Identifying missing or broken products
- Inspecting the integrity of product seals

Quality & Quality Control:
"The frequency and methodology of quantity checking shall be determined so that the legal requirements and customer specifications, or if appropriate, guidelines for nominal quantity are met."
- IFS (Version 6) section 5.5

Any product that fails to meet a manufacturer's quality standards can be tracked and rejected automatically from the production line.

Inline Checkweighing
Automatic checkweighers are frequently used as part of overall quality control programs and provide assurance that manufacturers are complying with regulations and supplying products in the right amounts. They are used to:

- Check for under and/or overweight packages
- Ensure compliance with net contents laws for pre-packaged goods
- Check for missing components in a package
- Verify component contents by weight
- Reduce product giveaway by using checkweigher values to determine filler adjustments
- Classify products into weight zones for grading or portioning
- Ensure product compliance with customer, association or agency specifications

Statistical Quality Control
Statistical Quality Control (SQC) and Statistical Process Control (SPC) software programs capture equipment and process level data and turn it into actionable information. SQC software programs can report on all aspects of packaging and filling quality control and help to reduce downtime, as well as form part of a continuous process improvement framework.

In addition, SQC and SPC ensure systems are operating at their full potential to produce a batch that meets legal requirements. Various solutions are available such as static scales with built-in SQC intelligence for random sampling of net content data or inline checkweighers for one hundred percent data checks.

A quality assurance system based on SQC provides the following core quality data:

- Production (period) mean value
- Number of violations of the legally defined tolerance limits T1- and T2-
- Mean standard deviation of the production (period)
- Other quality or safety relevant attributes

Integrated Systems
Weighing equipment can be integrated with other inspection devices such as cameras, scanners, marking systems, sensors, metal detectors and x-ray systems to form combination inspection systems making it easy to check a wide variety of quality control items in a single unit with a small footprint being required on the manufacturing floor.

4.3 Foreign Body Detection

Physical contamination is a major cause of product recalls and the inclusion of foreign bodies in products can occur at multiple points throughout the supply chain. Installing effective product inspection technology at critical control points (CCPs) can help to minimize the risk of foreign body contamination within finished products.

METTLER TOLEDO has created a white paper[1] which explains how to minimize the risk of physical contamination in more detail.

Contamination by Foreign Body:
"The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies. The metal detector or x-ray equipment shall incorporate one of the following:
(...)
- an automatic rejection device, for continuous in-line systems, which shall either divert contaminated product out of the product flow or to a secure unit accessible only to authorized personnel"

- BRC (Issue 7) section 4.1

Metal detection systems are available which provide exceptional ferrous, non-ferrous and stainless steel contaminant detection, even in products with high moisture contents (the most challenging applications). In addition, x-ray inspection systems provide scope for the unrivalled detection of metal, glass, mineral stone, calcified bone and high-density plastics and rubber, regardless of their size, shape or location, in a wide variety of packaged and unpackaged food products.

Reject System Design
The most effective foreign body detection systems include an integrated automatic product rejection system to remove any contaminated package which may have been identified. This is normally achieved without the need to stop the production process.

Ineffective reject systems are often the weakest part of detection systems and result in contaminated product not being effectively and reliably removed from the production line. A correctly-specified metal detector or x-ray system should be foolproof and capable of rejecting contaminated product under all circumstances, irrespective of the frequency of occurrence or the location of the foreign body within the product.

Optimized product inspection solutions should include integrated failsafe design features to mitigate the risks associated with system malfunction. Common features include built-in condition monitoring which provides early warning of operational state changes.

[1] http://www.mt.com/xray-preventforeignbodies

Other failsafe design features include:

- An automatic reject device to effectively remove suspect packs from the production line
- A lockable receptacle to receive suspect packs
- A warning device to indicate when the reject bin or receptacle is full of product
- A full enclosure between the point of inspection and the reject receptacle
- An audible and visual alarm display of system status
- A system to identify line blockages if and when they occur
- An air-pressure monitoring switch to ensure consistent pneumatic air supply pressure
- A system to verify that a package identified for rejection is actually removed from the line
- An automatic 'stop system' that operates in the event of the malfunction of any of the above systems

Equipment Testing
Regular testing of the performance of systems is an essential part of a product inspection program. Systems should be periodically verified to ensure that:

- They continue to operate in accordance with the specified sensitivity standard
- They continue to detect contaminants
- All additional warning/signaling devices are effective
- Installed failsafe systems are functioning correctly

Systems with built-in performance verification routines encourage regular testing and record generation. Most standards now require routines that automatically request a test after an agreed pre-set time interval.

METTLER TOLEDO has created a white paper[1] which explains the concept of Due Diligence and the effective design of product inspection systems in more detail.

4.4 Hygienically-designed Equipment

Inadequate cleaning and sanitizing programs and poor equipment design, construction, and maintenance of plant equipment have been listed as causative factors in many high-profile foodborne illness outbreaks in recent years.

To reduce the risk of microbiological and cross-contamination, all product inspection equipment should be designed with due consideration to the application, operating environment and cleaning regimes likely to be encountered.

Hygienic Design:
"All food processing equipment shall be suitable for the intended purpose and shall be used to minimize the risk of contamination of product.
- Equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.
- BRC (Issue 7) section 4.6

Product inspection solutions are available which fulfill international sanitary design guidelines. These guidelines describe criteria for the hygienic design of equipment intended for food processing and include:

[1] http://www.mt.com/pi-duediligence

- Elimination of cavities and bacterial traps
- Sealing of all hollow sections
- Avoidance of ledges and horizontal surfaces
- Use of open design and continuous welded frames for easy access and cleaning
- Hygienic management of electrical cables, trunking and pneumatic services
- Angled or sloping surfaces
- Drainage slots in catch trays
- Easy strip-down of belts and components to ensure complete and thorough cleaning

Construction Material

A range of materials are used in the construction of food processing equipment and it is important they are compatible with the product, environment, and cleaning and sanitizing chemicals. A good product inspection system provider will ensure equipment is corrosion resistant, non-toxic, mechanically stable and can be easily cleaned and maintained to ensure it performs as expected and avoids the risk of microbiological problems. Stainless steel is the preferred general-use metal for food contact surfaces due to its corrosion resistance and durability in most food applications.

METTLER TOLEDO has created a white paper[1] that explains all you need to know about hygienic design in more detail.

[1] http://www.mt.com/pi-hygienicdesign

4.5 Equipment Calibration

Effective product inspection equipment should be designed to provide assurance of its accuracy and reliability.

Well-designed systems will have built-in self-monitoring software. This continually checks all the components, as well as the operation of the equipment, and will ensure for example that any drift in sensitivity of detection is minimized. By flagging up a potential problem in advance, such systems provide an early warning system and potentially allow field-based service engineers to remotely dial into the machine via a manufacturer's Ethernet network, in order to fix the fault online or prepare parts and relevant personnel for a site visit.

Calibration:
"All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognized standard/methods. The results of the checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices and, if necessary, on process and products shall be carried out."
- IFS (Version 6) section 5.4

Performance Validation, Verification and Monitoring
Market-leading inspection systems are supplied with a set of performance validation documents to support the initial installation and set-up. Such documents or installation packs are designed to ensure the equipment can be correctly installed and maintained throughout its service life and can assist in the auditing process by:

- Meeting the limits of manufacturers' CCPs
- Giving manufacturers the tools to monitor CCP performance
- Providing a systematic approach to record keeping and documentation
- Ensuring a system is working optimally now and into the future

Regular performance verification should be conducted at regular intervals. When this is done by external resources, a certificate should be issued to confirm the activity. This can be used to prove due diligence and support regulatory compliance.

The regular periodic testing or monitoring of product equipment is also a requirement to meet the standards. This should be carried out using certified test pieces and weights and results should be fully documented.

There is much confusion regarding the terms Validation, Verification and Monitoring. On many occasions, the terms are misquoted or misused.

METTLER TOLEDO has created a white paper[1] which explains the difference between these terms in more detail.

[1] http://www.mt.com/pi-validation

5 Conclusion

As demand for food safety escalates, holding a recognized food safety certification has become increasingly important in helping manufacturers provide reassurance that products coming off their production lines are as safe as possible for consumers.

The inclusion of product inspection equipment into a company-wide product inspection program can play a critical role in helping manufacturers adhere to the rigors of industry standards.

METTLER TOLEDO Product Inspection solutions have been developed with FSMA regulations and GFSI-approved standards in mind, and are fully capable of performing the documentation, monitoring and verification required to aid compliance.

6 References

- http://www.mygfsi.com/
- http://www.brcglobalstandards.com/
- https://www.ifs-certification.com/index.php/en/
- http://www.fssc22000.com/documents/home.xml?lang=en
- http://www.sqfi.com/

7 Recommended Reading

Further information can be found at:

- The Organization for Machine Automation and Control (OMAC) – www.omac.org
- Organisation Internationale de Métrologie Légale (OIML) – www.oiml.org
- Fertigpackungsverordnung (FPVO) – www.bundesrecht.juris.de/bundesrecht/fertigpackv_1981/gesamt.pdf
- German Federal Institute of Physics and Technology (PTB) – www.ptb.de
- EHEDG – www.ehedg.org
- GFSI – www.mygfsi.com
- FSMA – www.fda.gov
- BRC – www.brcglobalstandards.com/
- IFS – www.ifs-certification.com/index.php/en/
- FSSC 22000 – www.fssc22000.com/documents/home.xml?lang=en
- SQF – www.sqfi.com/
- Preventing Product Recalls – http://www.mt.com/pi-productrecalls
- FSMA Final Requirements – http://www.mt.com/pi-fmsa
- How to Prevent Foreign Body Contamination – http://www.mt.com/xray-preventforeignbodies
- Principles of Due Diligence – http://www.mt.com/pi-duediligence
- How Hygienically-designed Equipment can Reduce Operational Costs – http://www.mt.com/pi-hygienicdesign
- Validation, Verification and Monitoring For Product Inspection Equipment – http://www.mt.com/pi-validation

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.

Checkweighing

Metal Detection

Track & Trace

Vision Inspection

X-ray Inspection

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