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INTELEX ENSURING FOOD SAFETY WITH QMS

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In 2013, thousands of consumers in the United Kingdom (UK) and Ireland bought, prepared - and *ate* - beef lasagna, hamburgers, and frozen dinners. What they didn't know is what they were *actually* putting in their mouths. Although a burger is only required by law in that region to contain 47% beef, some meat products contained up to 80% horsemeat, and 85% of products contained traces of pork. (Lawrence, 2013) In addition to potential health incidents due to allergic reactions, religious dietary guidelines and restrictions may also be violated when labels are incorrect. (Ali et al., 2017) The bottom line is this: people should be provided with accurate information so that they can decide for themselves what, and what not, to eat.

A crisis like this can have far reaching impacts. In addition to product recalls, safety alerts, and expensive market withdrawals, there can be loss of reputation among consumers as well as the general public. And since the food supply chain is extensive, global, and highly interconnected, a failure introduced by one supply chain partner can lead to adverse impacts on a company that isn't even directly responsible for the problems. (IFS, 2018)

Cases like the horsemeat scandal, involving deliberate food fraud, are not the only scenarios that an organization in the food supply chain must protect against. In addition to accidental violations of food safety regulations and targets such as failure to clean equipment between product changeovers, replacement of high-quality ingredients with lower cost (and lower quality) alternatives can adversely impact food quality and safety as well. Green vegetables such as romaine lettuce, which is particularly vulnerable to E. coli 0157 contamination during both production and processing, are frequent culprits in this area. Quality systems provide the structure needed to ensure compliance and reduce the risk associated with these possibilities.

If you're responsible for quality management in this industry, software may make it easier (and less stressful) for you to ensure that you are meeting your requirements and obligations by providing enhanced visibility into processes and improved communication. This Insight Report shows you how elements of a cloud-based quality management system (QMS) can help you address common international standards and regulations and make better business decisions to ensure the highest levels of food safety.

Ensuring Food Safety with Quality Management Software

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Food Safety Characteristics are Special Food Quality Characteristics

Food safety is *part* of food quality, and in many cases the *most important* part - but food quality characteristics span many additional factors like appearance, flavor, viscosity, and stability. Alli (2016) describes the difference this way:

"**Food quality** is the extent to which the all the established requirements relating to the characteristics of a food are met.

Food safety is the *extent* to which those requirements relating *specifically to characteristics or properties that have the potential to be harmful to health or to cause illness or injury* are met."

The researcher goes on to say that even though some food quality characteristics (like bacteria counts) can be used as proxies for food safety, typically they are different concerns. A food can be safe, but not conform to the other quality requirements, but the converse is not true. An unsafe food *does not*, by definition, meet food safety requirements.

Garvin's (1987) description of product quality includes eight dimensions: performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceptions. Safety considerations, using this conceptual framework, would fall under performance and reliability (and maybe conformance, when specific product characteristics related to food safety are governed by regulations). Caswell's classification on food quality attributes (1998), a widely used guidepost for simultaneously managing safety and quality characteristics, shows the same relationship: food safety characteristics are a specific kind of food quality characteristics. (Table 1)

Food Safety	Nutritional	Value	Package
Foodborne pathogens, heavy metals, pesticide residues, food additives, naturally occurring toxins, veterinary residues	Calories, fat & cholesterol, minerals, carbohydrates, proteins, vitamins	Purity, compositional integrity, appearance, taste, convenience, size, style	Package material, information (handling, cooking instructions), labeling (e.g. nutritional)

Table 1. Caswell's Classification of Food Quality Attributes (1998)

Navigating Food Safety Standards and Regulations

In an increasingly globalized marketplace, food safety standards and regulations are vital to the safety and quality of the food supply chain. However, with so many organizations managing these different standards and frameworks, it can be difficult for organizations in the food and beverage industry to know their responsibilities. Indeed, some food and beverage organizations have opted to engage in Multiple Food Safety Management Systems (MFSMS), (Rafeeque & Sekharan, 2018), which, while effective, can also introduce problems like duplication of documentation, the need for increased resources to manage multiple areas of compliance, and never-ending internal audits and reviews.

Table 2 summarizes some of the national and international organizations that oversee standards for food safety. Many of the organizations listed in Table 2 oversee a myriad of standards to which food products in a global marketplace must adhere. Table 3 summarizes some of the most important.

Organization	Description	
FAO (Food and Agricultural Organization)	An agency of the United Nations dedicated to improving policies to end world hunger.	
WHO (World Health Organization)	An agency of the United Nations dedicated to international public health.	
WTO (World Trade Organization)	An intergovernmental organization dedicated to international trade policies and regulations.	
GFSI (Global Food Safety Initiative)	An international consortium that benchmarks food safety standards against their own guidance.	
FDA (Food and Drug Administration)	An American government organization that controls US standards and regulations relating to food safety. The FDA oversees FSMA (Food Safety Modernization Act).	
BRC (British Retail Consortium)	A UK consortium dedicated to consumer protection and the development of global standards.	
SQFI (Safe Quality Food Institute)	An organization that oversees SQF (Safe Quality Food) program to create international food standards.	

Table 2: International and National Organizations Responsible for Food Safety

Standard or Framework	Description	
Codex Alimentarius ("Food Code")	An international collection of food standards and guidelines that guide international best practices.	
HACCP (Hazard Analysis and Critical Control Points)	A systematic approach to food safety and hazards. It is built on seven fundamental principles that form the core of many international standards.	
ISO 22000:2018	An international standard that contains the requirements for an FSMS for organizations in the food supply chain. ISO 22000:2018 is not recognized by GFSI.	
ISO/TS 22002-1	A guidance document that outlines a prerequisite program to prevent contamination of the work environment. ISO/TS 22002-1 is a prerequisite for ISO 22000.	
ISO 9001:2015	A standard for quality management systems that is recognized internationally.	
BRC Global Standard for Food Safety	A private standard that is frequently required in the UK for managing food safety, integrity, and quality.	
FSSC 22000	A private standard for FSMS that incorporates ISO 22000 as part of its requirements recognized by GFSI. Organizations can incorporate ISO 9001:2015 to certify to FSSC 22000.	
Dutch HACCP	A national standard for the Netherlands based on HACCP.	
IFS (International Food Standards)	A group of eight standards dedicated to the food production supply chain. IFS certification is frequently required in EU countries such as France, Germany, and Italy.	
GRMS (Global Red Meat Standard)	A scheme for monitoring food quality in the meat industry.	
SQF	An international program for farm-to-fork food safety.	
PrimusGFS	A food safety audit scheme for the produce industry.	
Various proprietary standards	Some retailers, such as Tesco or McDonald's, maintain their own FSMS for their retailers and suppliers.	
Various traceability standards	There are multiple standards for food traceability relating to humane treatment of animals, fair trade, organic practices, and religious practices.	

Table 3: International Frameworks and Standards

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BY TAKING AN INTEGRATED
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The Important Role of a Digitized QMS

To explain how a cloud-based QMS can simultaneously enable compliance management and quality improvement, Rafeeque and Sekharan (2018) documented a case study in the seafood industry in the Maldives that simultaneously managed to 7 FSMS standards. This geographically distributed organization was governed by a single food safety manual and food safety plan. The organization had to simultaneously manage 91 procedures while keeping 120 different kinds of records. Although some procedures were managed within a single department or functional area, many were spread across different areas and managed by different people. The entire system had gradually evolved over 12 years.

As you might expect, they encountered many challenges:

- When a process or procedure was updated, it was difficult to ensure full coverage, to ensure that everyone was aware of the changes, and to affirm that all operators were trained on the updates if necessary.
- Some processes and procedures in operations would meet the requirements for one food safety management standard, but would not be sufficient to meet the requirements for another, even among standards benchmarked by GFSI.
- Because the FSMS was implemented in a phased fashion over time, there was duplication of effort, as well as significant repetition and rework while producing documents and records.

To manage these challenges, the company created a new department to focus on understanding and maintaining all the management systems. Even with this improvement, they still had a hard time figuring out the exact costs of implementing and maintaining all these management systems, and food safety audits still took 15 to 18 days each year – in addition to other quality and environmental audits. Management reviews were held for each of the various standards because they were unable to determine exactly how similar requirements were being addressed in the processes.

These issues can be substantially alleviated by software systems that address both safety and quality. Disparate systems and data sources, and lack of cross-functional collaboration, are top challenges to performance improvement in this industry.

Many companies still rely on spreadsheets, old databases, and homegrown solutions pieced together over time to maintain their critical quality management programs. Such disconnected approaches to managing quality performance contribute to a lack of standardization and expose companies to increased risk from process breakdowns and management system failures.

Implementing a cloud-based QMS can resolve many of these issues, such as:

- Improved coordination between multiple departments and facilities
- Reduced (or eliminated) duplication of effort, and
- Improved visibility into processes and performance.

More comprehensive EHSQ (Environment, Health, Safety & Quality) systems can provide even more insight. For example, enterprise systems that tightly integrate all aspects of quality management, from hazard identification through risk and performance management, increase visibility by making sure all employees have access to the data they need for decision making in real time. Such transparency is critical for systematic, proactive risk mitigation and serves as the basis for continuous improvement.

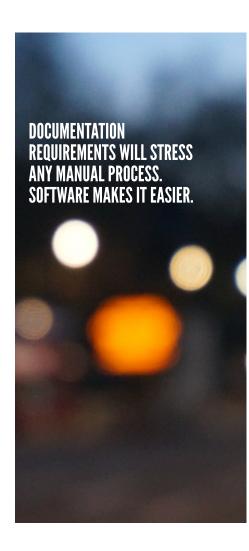
By taking an integrated approach to quality management, and leveraging the right set of software capabilities, food and beverage facilities are better able to ensure compliance and food safety. Without this investment, catastrophic food recalls and damage to the organization's reputation can have a direct and material impact on the business. Simply put, food and beverage companies can't afford to keep their quality management systems on paper and in disparate, disconnected systems. Failure to automate manual processes means failure to keep pace with the industry and competition.

Software Can Support Food Safety Management Needs

A Quality Management System must have the breadth and depth to manage the unique processes of your organization in one integrated platform. In addition, they should automatically work to streamline your health, safety and quality processes from start to finish so that you can:

- Automate quality management processes to ensure consistency and efficiency across multiple facilities and geographic locations
- Establish corrective action procedures (CAPA) with action tracking to mitigate risks
- Connect document control and training processes to ensure that the most up-to-date guidance is always being followed, and increase readiness for inspections and audits, and
- Ensure compliance with the food safety standards and regulations for your organization and jurisdiction.

A QMS should have some specific core applications to meet the unique needs of the food and beverage industry.



Document Control

Document control is a vital component of a food and beverage QMS. FSSC 22000 incorporates the documentation requirements for ISO 22000:2018 and, if the organization is certifying to FSSC 22000 Quality, ISO 9001:2015. Both ISO 22000:2018 and ISO 9001:2015 use the High Level Standard (HLS) for ISO standards dedicated to management systems, which places documentation in the category of *Support* along with competence, awareness, and communication, with additional documentation requirements throughout other sections. The documentation requirements for ISO 220000 include those for statutory, regulatory, and customer requirements, as well as the food safety policy and objectives. Sections 7.5.2 and 7.5.3 have requirements for the identification, description, format, and control of all documents and records, which includes review, updating, and disposition on a regular schedule.

Rigorous document management is therefore a fundamental requirement for food and beverage organizations. FSSC 22000 alone demands a disciplined and detailed approach to documentation, which will only increase for those organizations engaged in MFSMS. Such documentation demands are far beyond the capacity of any manual process, particularly when documentation can mean the difference between compliance and non-compliance.

Audits

Auditing a quality management system requires considerable preparation for any organization in the food and beverage industry. Organizations engaged in MFSMS can expect that preparation to increase as they certify to additional standards that allow them to compete in a global marketplace.

Audits for certification to FSSC 22000 are a two-stage process that incorporates requirements for ISO 22000 and, if selected, ISO 9001:2015 according to the guidelines provided in ISO 19011:2018 for auditing management systems. In addition, the auditing process will consider the requirements for additional sector-specific PRPs (pre-requisite programs).

Audit management is therefore an important element of a QMS, and one that is extremely difficult with manual processes. A software QMS will have automated audit management that provides a detailed account of an organization's audit activity in a centralized location for easy access. It should provide checklists that show progress to completion for each task and a summary of how audits are progressing. Audit management will also allow an organization to create action plans and corrective actions to flag any problems that arise during the auditing process and track identified issues.



Complaints Management

The Voice of the Customer (VoC) is an important element of a modern QMS. Awareness of VoC is vital for customer satisfaction, and attention to VoC messages enable organizations to create products and services that meet customer and market requirements -- and inspire customer loyalty. Customer complaints are the result of internal quality failures that have become external failures. External failures can have significant impacts, as they result in brand damage, decreased customer retention and loyalty, and time spent addressing complaints rather than finding opportunities for growth and innovation.

Customer management is a foundational element of ISO 22000:2018 and ISO 9001:2015. A software QMS should allow an organization to collect, track, and respond to customer complaints by collecting as much information about the complaint as possible. It must also integrate data from complaints into a larger framework consisting of product management, defect tracking, nonconformance reporting (NCR), and corrective action reporting (CAR) to ensure that organizations not only address individual complaints but that they use the data they produce as the basis for organizational learning.

As an example of some of the benefits a software QMS can provide, Table 4 on p. 10-11 summarizes some of the important QMS software components an organization should consider to address requirements of ISO 22000:2018.

Conclusion: Lean on Software to Ensure Food Safety

Very few safety and quality failures will make the headlines like those that involve food. The horsemeat scandal in the EU, the Maple Leaf Foods listeria outbreak in 2008, and the constant notices of lettuce contamination, to name merely a few, are examples of the way in which food safety failures in a global marketplace can lead to widespread health crises, brand damage, and significant financial damage.

Yet our global market means that supply chains in food and beverage are complex and can span many international boundaries, making it increasingly difficult for organizations to navigate the complexity of the regulations and compliance requirements. This is particularly true for organizations with multiple food safety management systems.

A modern food and beverage organization should take advantage of QMS software to manage these increasingly complex requirements. Organizations that continue to manage their processes manually sacrifice vast amounts of time that could be better spent looking for opportunities for growth and innovation. In addition, they may be courting disaster through increased risk of quality failures that could impact both human health and customer loyalty. In this article, we have outlined some of the ways in which QMS software can alleviate knowledge management challenges and reporting burdens in an industry in which complexity will continue to increase.

QMS Component	Description	ISO 22000:2018
QMS component	Bescription	150 22000.2010
Document management	A document management application should have the following features:	Select documentation requirements are found in the following sections of ISO 22000:2018:
		· 5.2 Policy.
	· Supports quality plans, testing documentation, SOPs, pre-audit checklists, quality manuals, safety/defense plans, etc.	· 6.1 Actions to address risks and opportunities.
		· 6.2 Objectives of FSMS and plans to achieve them.
		· 7.1.6 Control of externally provided processes, products or services.
	· Automating routing and approval of documents.	· 7.5.1 Documented information – General.
	· Automated analytics and	· 7.5.2 Documented information – Creating/Updating.
	reporting.	· 7.5.3 Documented information – Control of documented information.
Training and	A training and competency management application	A training management application will support Section 7: Support, including sub-sections:
competency	should have the following	· 7.1.2 People.
management	features:	· 7.1.4 Work environment.
	· Track training assignments and courses.	· 7.1.6 Control of externally provided processes,
	Provide automated email reminders for upcoming and overdue training and refresh training.	products or services.
		· 7.2 Competence.
		· 7.3 Awareness.
	· Progress status on individual training and overall completion rates.	
Nonconformance reporting (NCR)	Nonconformance reporting should have these features:	Nonconformance reporting supports the following sections of ISO 22000:2018:
reporting (New)	· Record and track nonconformances in a centralized, web-based database.	· Section 8: Operation.
		· Section 9: Performance evaluation.
		· Section 10: Improvement.
	· Examine trends over time and provide insights from across the organization.	
	· Assign follow-up corrective and preventative action tasks to specific employees in response to NCR reports.	
	· Option to use 8D problem	
	solving process.	

 Table 4: Examples of QMS Software Applications that Address ISO 22000:2018

QMS Component	Description	ISO 22000:2018	
Customer complaints management	A customer complaints management application should have these features:	Customer satisfaction is integrated into the following sections of ISO 22000:2018:	
	· Automatically assign and schedule follow-up corrective and preventive actions (CAPA) resulting from complaints.	5.1 Leadership and commitment.9.1 Monitoring, measuring, analysis and evaluation.	
	· Track progress of CAPA completion.		
	· Automated escalating email notifications for upcoming and overdue tasks.		
	· Manage complaints along supply chain.		
	· Record complaint type and severity.		
	· Provide data for customer satisfaction analytics.		
Corrective Action (CAPA)	An application for tracking corrective actions and defects should have the	Corrective action supports the following sections of ISO 22000:2018:	
	following features:	· Section 8: Operation.	
	· Record product defects in a centralized software system.	· Section 9: Performance evaluation.	
	· Automated notifications to ensure the correct person is notified as soon as the defect is reported.	· Section 10: Improvement.	
	· Record all details of the investigation of the defect.		
Change Management	A change management application should have the following features:	A change management application supports ISO 22000:2018 clauses:	
_	 Track planned changes through checklists, analysis, and approvals. Implementing and enforcing change management best practices. 	· 6.3 Planning of changes.	
		· 8.2.4 Changes to requirements for products and services.	
		· 8.3.6 Design and development changes	
		· 8.5.6 Control of changes	
		· All sections infused w/ risk-based thinking.	
Audit management	An audit management application should have the following features: · Centralized audit information across departments.	An audit management application will help to manage audit requirements outlined in	
		the following sources: · ISO 22000:2018 – Section 9: Performance	
	· Advanced CAPA functionality.	evaluation.	
	· Automated reporting.	· ISO 19011:2018 Guidelines for auditing management systems.	
	· Standardization of documents and processes.		
	· Automated prioritization of findings.		

 Table 4: Examples of QMS Software Applications that Address ISO 22000:2018

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