The Food Safety & Quality Compliance Storm

And how Safety Chain Management technology can keep you safe

A Position Paper
Barbara Levin, SVP Marketing & Customer Community
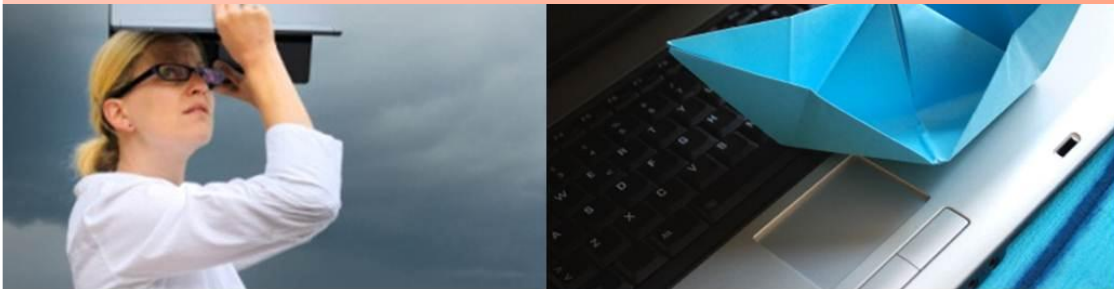**Dan Bernkopf, VP Food Safety & Quality Applications**
SafetyChain Software

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FSMA … HACCP … GFSI … USDA … Customer-Driven Requirements ….

Regulatory, non-regulatory and customer-driven compliance is one of the biggest challenges for today's food safety & quality professionals.

Especially when these requirements change on what sometimes seems like a daily basis.

This paper will cover:

- **Summaries of evolving legislation and mandates**

- **Key information and data management challenges for compliance**

- **How cloud-based, realtime Food Safety Chain Management technologies can keep your customers, brand and market value safe in the compliance storm**

"This is the tool that sets the standard. As the food system becomes more complex, it's more important than ever to use technology that translates information into action. Our customers both demand and deserve this level of protection."

Alice Johnson
Vice President of Food Safety
Butterball

Introduction

In today's world of an ever-increasing global food supply chain, companies who supply, manufacture, distribute and sell food – including both retail and services – face complex challenges when it comes to safety and quality compliance … often getting caught up in a storm of paper and manual processes. To manage these evolving challenges, the industry is adopting technology in growing numbers – looking toward first-in-class solutions that can help manage compliance at every point in the supply chain – from farm-to-fork.

This paper first looks at some of the compelling compliance components of major regulatory, non-regulatory and customer-driven laws, codes and standards – and introduces the concept of food safety chain management. We then examine key information/data management challenges that impact compliance – and how safety chain management technologies help enforce compliance inbound, during production and outbound to keep non-compliant supplies/raw ingredients from coming in – and non-compliant finished goods from going out … keeping suppliers, manufacturers and consumers safe.
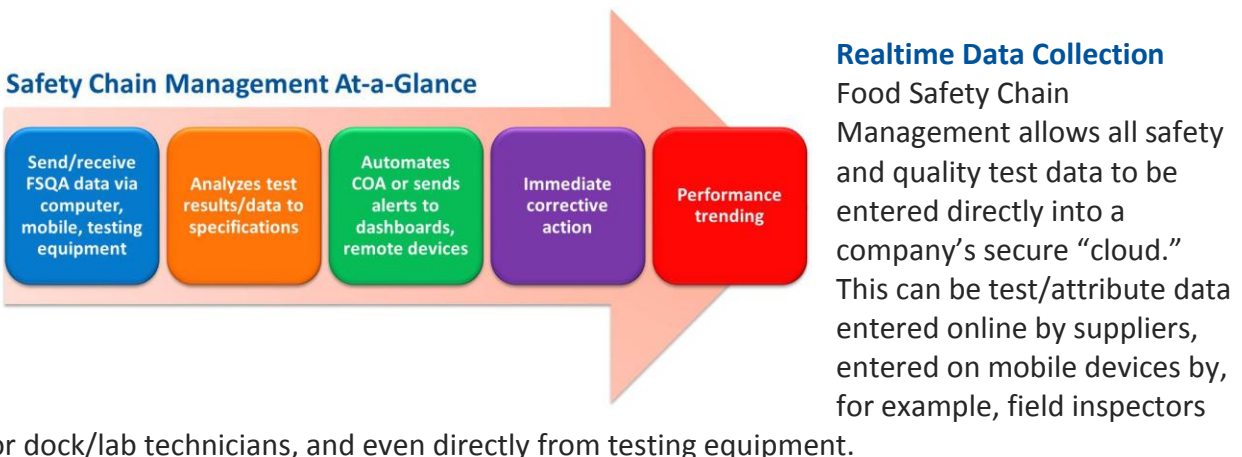
What is Food Safety Chain Management?

Before we summarize the various regulations and standards, such as FSMA, GFSI and HACCP; the information/data management compliance challenges associated with each; and how Safety Chain Management helps resolve those challenges – let's first begin with a high level summary of Safety Chain Management to help put the rest of this paper in context.

Key Concepts of Food Safety Chain Management

The underlying concept of Food Safety Chain Management is to have a single solution that can enforce food safety & quality compliance at every point along a company's supply chain, including:

- Inbound supplies and raw materials

- Production safety and quality requirements

- Compliance associated with customer-driven specifications for outbound finished goods

A key concept of Food Safety Chain Management is that all enforcement is done in *realtime* – promoting *prevention*. Realtime enforcement is the common preventative thread amongst the key components that are the foundations of Safety Chain Management:

Safety Chain Management At-a-Glance

Send/receive FSQA data via computer, mobile, testing equipment	Analyzes test results/data to specifications	Automates COA or sends alerts to dashboards, remote devices	Immediate corrective action	Performance trending

Realtime Data Collection

Food Safety Chain Management allows all safety and quality test data to be entered directly into a company's secure "cloud." This can be test/attribute data entered online by suppliers, entered on mobile devices by, for example, field inspectors or dock/lab technicians, and even directly from testing equipment.

Realtime Analysis

Once data/test results are entered, the food safety chain solution analyzes – again in realtime – all results against regulatory, non-regulatory and customer specifications. When regulations change – or customers add/change specifications – those specs are easily configured and then cascaded throughout the "safety chain" so that compliance can be immediately enforced.

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Automated COAs and Alerts

When results are in compliance COAs are automated and sent to the next point in your chain. When non-compliant results are detected, automatic alerts are sent to the appropriate, identified people who can be any combination of internal/external individuals, such as food safety and quality assurance (FSQA) managers, lab/plant floor personnel, distributors, suppliers, purchasing and more.

Immediate Corrective Action

Because realtime alerts get the right information, to the right people, in the fastest manner possible – immediate corrective actions are facilitated. There are thousands of examples but some simple ones might include: not unloading a shipment of supplies/raw ingredients (or not allowing it to be shipped in the first place); correcting a temperature that has been detected to violate a HACCP Critical Limit; not harvesting a particular field of produce when an alert is received that certain attributes were not in spec; and avoiding sending a customer a shipment that does not meet particular specs – perhaps incorrect fat or moisture content. Think of food safety chain management as a "smoke alarm" in the cloud – preventing bad things from happening in the first place vs. trying to figure out how the fire started and how much it is going to cost to repair the damage.

Performance and Trending

Because all information is time/date stamped and all results/corrective actions are electronically documented, you are able to gain in-depth access and insight into performance by various suppliers, producers and distributors; speed throughput; and be audit ready-on demand for almost any type of compliance audit.

Now that we've provided the "basics" of food safety chain management, let's look at some of the major regulatory/non-regulatory/customer-driven mandates; the key information/data management challenges of each; and how food safety chain management can help keep you safe in the compliance storm… starting with FSMA

FSMA … "the Elephant in the Room"

The FDA's Food Safety Modernization Act (FSMA) of 2011 is mandated for 80% of foods in the U.S. – with more than 50 specific directives aimed at food safety prevention and collaboration between suppliers, producers, federal/state agencies and foreign governments. FSMA's final regulatory rules are still forthcoming – with enforcement expected to continue rolling out in phases – but it is by far one of the most front-of-mind compliance issues for FSQA professionals today.

FSMA impacts the entire food supply chain and is focused on *prevention*, with provisions for:

- Risk-based prevention controls (HACCP-based)
- Performance standards for high-risk foods
- Enhanced tracking and record keeping
- Mandatory recall authority
- Foreign supplier verification
- Import certification
- Prior import shipment notice
- Stricter, on-demand auditing

> *"If we're to have a food safety system that truly prevents food-borne illness, we must all practice prevention"*
>
> *Dr. Margaret Hamburg*
> *FDA Commissioner*

Moving forward, some of the additional mandates we can reasonably expect include:

- Accreditation standards for 3rd party certification bodies with fuller transparency
- Tighter regulations for sanitary transportation
- Enhanced food-borne illness surveillance systems
- Continued focus on regulatory/non-regulatory pathogen intervention
- Paying for FDA regulatory services, such as:
    - ✓ Recall investigation and management
    - ✓ Facility and program deficiency re-inspections
- FDA access to GFSI and other 3rdparty audit reports – and their corrective actions log

Given all of this, it's no wonder that the FDA recognizes that technology – including electronic document and records management – will play a large role in FSMA compliance.

*And with FMSA's focus on prevention – the authors of this paper contend that the technologies required for compliance must go beyond traceability. What is also required are solutions that can **prevent non-compliant supplies and finished goods from coming in or going out in the first place** – which brings us to the next section.*

FSMA Compliance – Information & Data Management Challenges

The challenges of FSMA compliance are quite complex and will continue to evolve for some time to come. For this paper, we will be focusing on the challenges associated with information and data management – which are at the core of all compliance issues; we'll be doing the same for the other regulatory/non-regulatory requirements covered.

For FSMA, the key information and data management challenges include the ability to:

- Manage hazard analysis in the timeliest manner possible

- Create control programs – with realtime records – for inbound, outbound and internally produced ingredients, raw materials, in-process products and finished goods

- Correct insanitary conditions in the most effective and efficient manner possible – and show proof of the correction

- Get on-the-spot notifications from all supply chain points when non-compliant results are detected – and prevent these products from being shipped in the first place, received on arrival, or sent out to the next point in the chain, including failed tests for:

  - ✓ CCP violations, positive pathogen samples, failed product specs and more

- Support throughput for compliant ingredients and products so that, for example, one failed result on a particular SKU doesn't hold up shipment of 100 SKUs that "passed"

- Respond to an on-demand FDA audit without completely disrupting day-to-day business, which is today, often the case

FSMA Compliance – How Safety Chain Management Keeps You Safe

Safety Chain Management capabilities – along with the underlying foundations of realtime data capture, realtime data analysis, automation of throughput documentation, realtime alerts for immediate corrective action, realtime records management and realtime reporting – support FSMA compliance in many different ways:

- Test results are gathered electronically – in realtime – from suppliers, labs, testing equipment and the field, including the ability to take/send digital photos or enter information via mobile forms on smart phones and tablets

- When deviations occur – such as improper refrigeration or insanitary conditions at a plant – alerts are automatically sent to pre-identified decision makers who can respond instantly from anywhere

- Automated alerts allow immediate corrective actions – such as stopping a shipment before it leaves plant if, for example, results show a positive test for a pathogen – or an "after" photo of insanitary conditions brought up to compliance

- On the other hand, if no deviations are detected in safety/quality attributes – from domestic or imported sources – COAs or other documents required for throughput are automated to promote faster shipping to manufacturers

- All data that is captured – including, for example, before/after photos – are date and time stamped, along with electronic signatures where required … and these cannot be altered in any way. Documents are therefore always audit ready for FDA on-demand audits

GFSI, 3rd Party & Customer-Driven Requirements
Including BRC, SQF and Customer Specifications

Today's consumers want access to all types of food regardless of season. And they don't want to pay more for it – resulting in a truly global food supply. This, in combination with a startling statistic from a recent GFSI conference – that by the year 2050 we will need to produce as much food per year as all prior years in recorded history – means that the focus on prevention will be even that much stronger. GFSI and its components, other non-regulatory standards (more on HACCP in the next section) and ever-increasing customer-driven safety and quality requirements translate to:

- Stricter management of suppliers for both branded and private-labeled products

- Increased demand for external audits – *and* audit/auditor qualifications and consistent standards

- More benchmarking and measurement of standards as well as connecting safety & quality communications amongst all stakeholders in a particular supply chain

- Continuous verification

- Customer-mandated hold and release programs to manage microbiological, chemical, physical and other testing

GFSI, 3rd Party & Customer-Driven Compliance – Information & Data Management Challenges

Key information and data management challenges include the ability to:

- Maintain electronic verifications of Standard Operating Procedures (SOP), such as:
  - ✓ Sanitation, master cleaning schedules, product quality audits, allergen control and the required codes/standards of other programs

- Create and maintain electronic reports and trending data of Key Performance Indicators (KPIs), including, for example:
  - ✓ Environmental swabbing, customer complaints, product hold logs, quality attributes and more

- More efficiently organize and cross-reference multiple FSQA programs – including documents, records, data, GFSI codes, verification tasks, customer complaints and training records

- Prevent non-compliant goods from moving to the next point in your supply chain

- Reduce the mountains of paperwork to find the few exceptions that require corrective actions – without holding up all operations

- And of course, be audit-ready at any time – whether it's scheduled or on-demand, such as a GFSI or customer audit

GFSI, 3rd Party & Customer-Driven Compliance – How Safety Chain Management Keeps You Safe

- Safety Chain Management electronically organizes and cross-references SOPs, program information and verification tasks/end results against all 3rd party specifications

- All compliance-related results, records and notifications are tracked against customer or internally mandated finished product hold and release programs

- All documents, records and verifications are time/date stamped, in realtime, and cannot be altered – adding greater efficacy to your records – and therefore also supporting the ability to be audit-ready every day

HACCP – Safety Management from Raw Materials to Consumption

HACCP offers continuous and systematic approaches to assure food safety. In light of high public awareness of recent food-related incidents, there is a renewed interest in HACCP from a regulatory point of view. Both the FDA and USDA will – or have already enacted – regulations that will require HACCP food safety prevention plans, and we anticipate an increase in adoption of HACCP approaches.
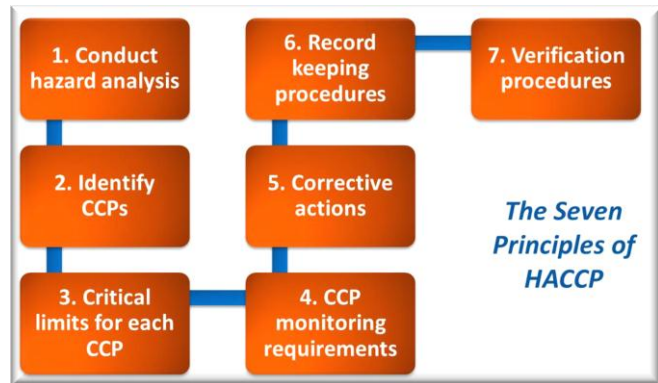
The purpose of this paper is not to cover the seven HACCP principles in-depth – but to highlight some of the key requirements of each principle that pose the most challenges to compliance.

Principle 1 – Hazard Analysis Compliance

- The ability to review every distinct step in each of your processes for food safety risks; risk is assessed in terms of hazard frequency and severity. The higher the frequency and/or severity, the more likely the it must be addressed in HACCP and by an intervention that includes a Critical Control Point (CCP) and its Critical Limit (CL)

    - ✓ For example, E. coli 0157:H7 is a hazard likely to occur in raw and non-intact beef. As a risk, it has a very low frequency but a very high severity rate – loss of life has been associated with this hazard

Principle 2 – Identification of Critical Control Point

- CCPs must be monitored/measured at various points in a food production process – such as cooking, acidification or drying as just a few examples. CCPs are designed to be applied at any step in the production process where a food safety hazard can be prevented, eliminated or reduced to an acceptable level

Principle 3 – Establish Critical Limits

- CLs are determined ahead of time via consultation with competent authorities, and have to be regularly and accurately measured

- When CL criteria are not met, the production process is not compliant with hazard elimination, prevention or control

Principle 4 – Monitor CCPs

- Monitoring CCPs must be a planned sequence of measurements and/or observations to ensure the product and/or process is in control – i.e., CLs are being met

- Compliance depends on the ability to assess trends before a loss of control occurs so that adjustments can be made in the fastest manner possible

- The frequency and measured values of monitoring must be documented

Principle 5 – Establish Corrective Action

- Corrective actions must be pre-planned and documented

  - ✓ For example, if a cooking step must result in a product center temperature of 165° – and the temperature at the time of a test is 160°F – the corrective action could require a second pass through the cooking process with an increase in the temperature of the cooker

- Corrective actions must address the nature of non-conforming events, as well as, preventive measures that result in a permanent solution

Principle 6 – Record Keeping

- The HACCP system requires preparation and maintenance of written HACCP plans together with other documentation associated with the program – including all records generated during the monitoring of each CCP and notations of corrective actions taken

Principle #7 – Verification

- The scientific or technical validity of hazard analysis – and the adequacy of the CCPs must be documented – along with verification of the effectiveness of the HACCP plan itself

- Independent audits are also important to periodically re-validate plan effectiveness

HACCP Information & Data Management Challenges

Again, the compliance challenges of HACCP are many and complex, so we are focusing specifically on those related to information and data management challenges. These include the ability to:

- Gather data in a timely manner, including test results, physical inspection and more

- Analyze and filter data for corrective action in the fastest manner possible

- Access historical documents and records for regulatory, customer and/or 3rd party audits
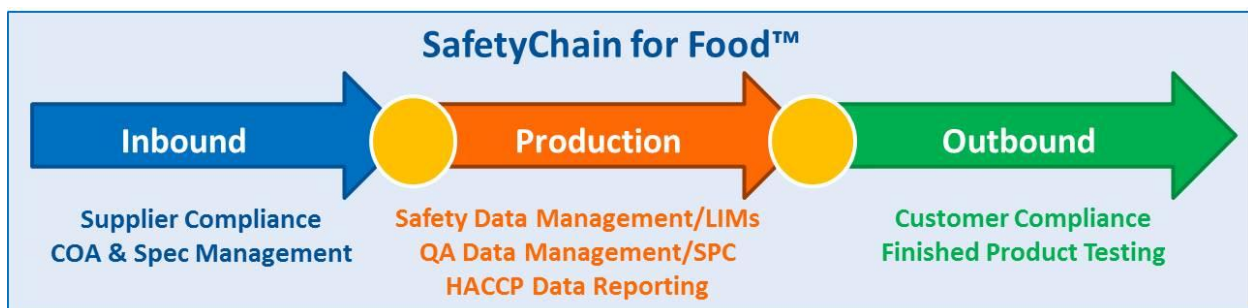
- Easily access and revise, where necessary, HACCP plans and flowcharts for annual and/or mandated reassessments, new regulatory requirements and new or revised manufacturing processes

HACCP Compliance – How Safety Chain Management Keeps You Safe

- Safety Chain Management automates CCP monitoring/verification against established critical limit parameters

- When CLs are within parameters – COAs or other documents are automated to speed throughput

- When there are deviations in CLs, realtime alerts are triggered to promote "moment of detection" corrective actions

- Inbound/production/outbound compliance specifications can be managed from a single console which facilitates centralized safety and quality assurance control

- New and updated requirements are immediately cascaded throughout your food supply chain so that compliance is immediately enforced

- Time/date stamps automatically lock program control verifications

- Because all information is readily available – there is complete audit transparency, which can eliminate the need for regulatory and non-regulatory audit preparations

SafetyChain for Food™ is the Pioneer in Food Safety Chain Management

SafetyChain for Food™

Inbound	Production	Outbound
Supplier Compliance COA & Spec Management	Safety Data Management/LIMs QA Data Management/SPC HACCP Data Reporting	Customer Compliance Finished Product Testing

Key Features Include:

- Realtime data capture from all participants in the supply chain

- Realtime analysis

  - ✓ Automatic COA/CCP tracking when results are within parameters

  - ✓ Realtime smart alerts for non-compliant results

- Easy-to-use dashboards for a central look at safety and quality performance along the entire chain

SafetyChain for Food™ is delivered as a flexible, secure, Software-as-a-Service (SaaS) solution – designed for rapid deployment and rapid return on investment

- We do the "heavy lifting" to configure, test, train and deploy SafetyChain for Food – including coordination to bring suppliers and third-party labs on board

- SafetyChain for Food is completely configurable – with unlimited specs for different customers and the ability to add specs "on-demand"

- SafetyChain for Food features SOA (Service-Oriented Architecture) web service connectivity with internal, shared, and external systems including ERP, PLM, WMS, QMS, LIMS, Document Management Systems and more

About SafetyChain Software™

SafetyChain provides realtime safety and quality compliance management. Our innovations in the area of Food Safety Chain Management™ take food safety and quality initiatives to a new standard by preventing losses in realtime to:

- *Enforce* food safety and quality compliance
- *Eliminate* manual processes and errors
- *Prevent* recalls, retrievals and rejections
- *Protect* market value/brand

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About the Authors

Barbara Levin is SafetyChain Software's Senior Vice President of Marketing and Customer Community. As a frequent speaker and publisher in the ERP and Software-as-a-Service communities, she is best known for working with customers to increase understanding of the role technology plays in meeting strategic business initiatives. At SafetyChain, she is focused on building awareness, throughout the food safety and quality community, of how innovations such as Food Safety Chain Management help companies stay ahead of the growing complexities of global enforcement of food regulations and requirements.

Dan Bernkopf has spent more than 30 years as an innovator in the food safety & quality industry, with extensive front-line experience leading integrated safety and quality assurance initiatives. Dan has worked as both a consultant to – and executive with – leading food producers and manufacturers, including a division of Tyson Foods, Farmington Foods and Marel. His areas of expertise include SQF certification, HACCP certification, 3rd party audit preparedness and lean manufacturing principles. At SafetyChain, he serves as the Vice President of FSQA Applications – focused on helping participants in the food value chain build business cases for new technologies, and for helping shape technology innovations to keep up with the ever-evolving safety and quality needs of a global food supply chain.

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