



Are You Ready for an Audit?

How Technology Can Improve Audits and Supply Chain Controls

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Supply chain threats and supplier issues are an unavoidable part of doing business in the food, beverage, and dietary supplement industries. For many companies, supply chain hazards represent their biggest safety and regulatory vulnerability. Trying to identify and control those risks remain an ongoing battle.

Even the highest-performing quality and regulatory teams can still come up short, exposing themselves to safety and brand risks, legal liabilities and expensive product recalls. These failures seem to make headlines at least once a week – whether it's a blanket ban on romaine lettuce because of E. coli or a single incident, such as a choking hazard recall due to plastic accidentally entering the food in the processing environment.

When preventive controls fail, resulting in a recall, costs can skyrocket. Food and beverage recalls are up roughly 10 percent over the last five years, with each one incurring an average of \$10 million in direct costs to the company involved, according to a joint study between the Food Marketing Institute and the Grocery Manufacturers Association. This doesn't even include indirect costs such as lost revenue and tarnished brand reputation.

According to FDA Commissioner Dr. Scott Gottlieb, the increase in outbreaks can be attributed to, at least in part, technology. In a statement regarding the romaine lettuce outbreak, for example, he said, "What's happening is that our ability to identify outbreaks has dramatically improved due to new information technologies and laboratory techniques. This is a view that we share with other experts, including the CDC, who have indicated that as these new methods are employed to protect the public from outbreaks, paradoxically the number of outbreaks may increase since we are now able to identify problems that had previously been invisible to us."¹

Interestingly, just as there has been an increase in outbreaks, the number and types of audits also have jumped dramatically due to changing regulatory and voluntary standards. When the Global Food Safety Initiative (GFSI) began nearly 20 years ago, one of the goals was to help solve the audit fatigue problem, but audits have instead been on the rise. More outbreaks, more regulation, and more audits haven't solved the problem, so TraceGains set out to plug the industry into a common technology platform to improve auditing, recordkeeping, and other supply chain controls.

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¹ June 28, 2018, statement from FDA Commissioner Dr. Scott Gottlieb, on developments in the romaine outbreak investigation, recent outbreaks and the use of modern tools to advance food safety <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm612187.htm>

According to the auditing, consulting, and certifying body FoodChain ID, there were 13,387 documented food safety issues in 2018. These incident reports cover nearly 600 food commodities from more than 180 countries, including:

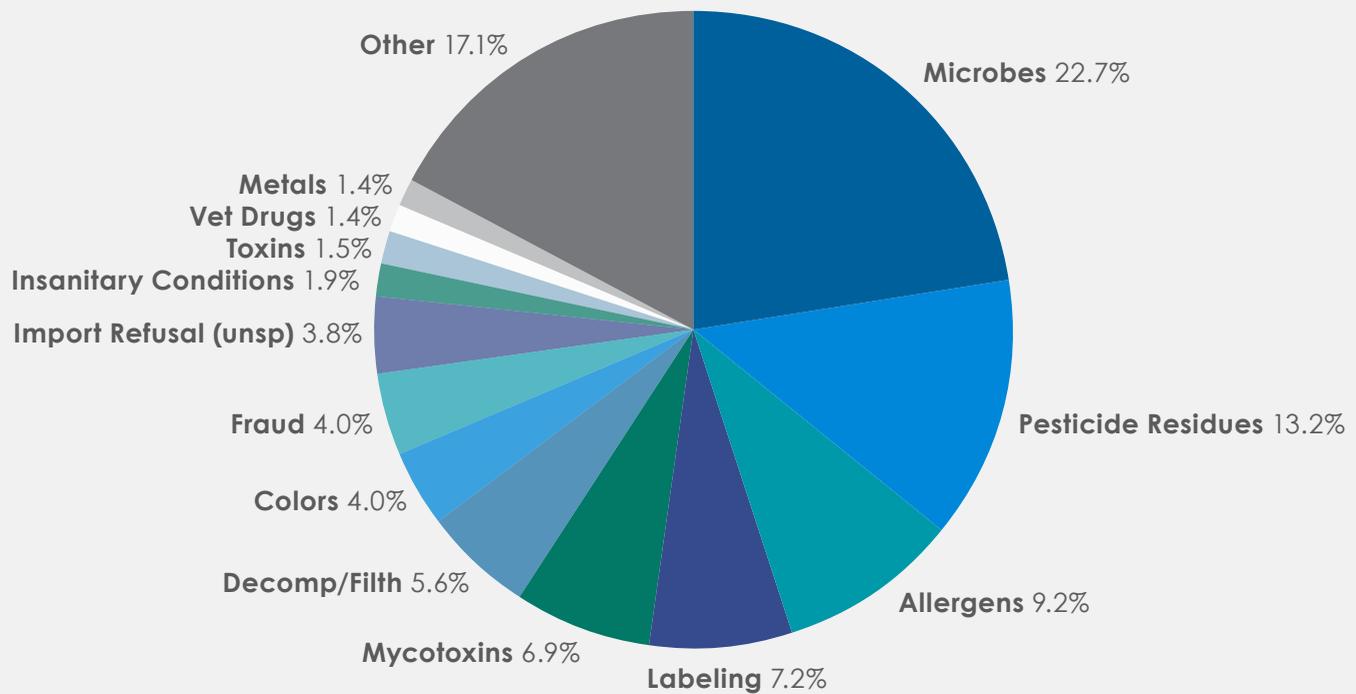
1. Microbes
2. Pesticide residues
3. Allergens
4. Labeling
5. Mycotoxins

Many of these incidents emerge as a failure of basic good manufacturing practices. But it doesn't have to be that way, especially if you have a world-class internal and external audit program driven by data that identifies the most critical risks.

This guide highlights some reasons why so many companies struggle and explains how technology solves these common problems and produces better audit results.

Global Food Issues 2018

13,381 Documented Issues from HorizonScan™



Source: "HorizonScan™ - Distributed by FoodChain ID" (www.foodchainid.com)

Lack of an Audit Plan

Every food, beverage, and dietary supplement company should have a formal, updated audit plan. Those who fall short of that not only risk the future of their business but the safety of their customers. These plans should include steps such as:

- Planning.
- Execution.
- Corrective and Preventive Action.
- Verification.
- Audit Evaluation.

The audit plan also should address the following questions:

- Who – the auditors who will perform the audits at all internal and external sites;
- What – the products or items to audit;
- Where – the geographies where auditors will be dispatched;
- When – the schedule for all internal and external audits;
- Why – the risks or threats to be addressed and
- How – the audit type and format.

TraceGains' suite of software solutions are designed to help manage supplier relationships, track compliance, manage internal quality processes, and schedule, conduct, and manage audits in the cloud.

TraceGains Audit Management solution automates and streamlines the entire audit process while providing instant access to anyone who needs it – especially auditors and their supervisors. Customers can pair Audit Management with TraceGains' other solutions to maintain complete facility records in one place, including a world-class audit plan.

Alternatively, Audit Management can operate as a standalone auditing tool.

Data-driven Auditing Decisions

Manufacturers simply can't audit every supplier, facility, or warehouse every year, so management needs to prioritize which internal and external sites to audit based on risk. Understanding and tracking how facilities and their items are performing is essential to audit planning. Most companies think they're strategically selecting the facilities they'll audit, but without data to back up those choices, critical threats could be overlooked.

Audit Types

Audits generally fall into one of three categories:

First-party audits, also known as self-assessments, are conducted to confirm procedures and management strategies reflect the requirements of meeting various safety and quality standards.

Second-party audits, or proprietary audits, are those manufacturers perform on a supplier or contractor.

Third-party, or independent, audits are conducted by outside inspectors, typically in pursuit of an external certification.

TraceGains **Supplier Management** offers automated trend analysis, reporting, and risk scoring that can help customers scorecard their suppliers, showing them which suppliers might require frequent, or aggressive auditing. Leveraging supply chain information already collected in TraceGains Network from 7,000 suppliers in 17,000 locations, auditors can quickly identify and prioritize suppliers, facilities, or warehouses with the highest risk and preview key documents such as previous audits and corrective actions. With all information centralized on a single platform, manufacturers have a 360-degree view of the health and risk of their supply chain.

Connected network data helps highlight risk by supplier, item, and geography, identifying the most critical threats. Scores might be higher for a foreign supplier or an item or ingredient that is known to be at risk for economically motivated adulteration like spices diluted with cheaper material. TraceGains proprietary algorithms can be used to assess risk or it can be customized to match the manufacturer's unique requirements. The scores measure inherent risk as well as a facility's performance. These scorecards are updated nightly, so users have a real-time view of supply chain risk.

Supplier Management, along with Audit Management, offers customers easy access to a wealth of information that provides deep data insights and analysis to inform the audit planning process. Data helps substantiate audit plan development and why certain audit sites were chosen.

Complex Scheduling

Once your organization has identified which facilities need audits, it's time to assign the inspection responsibility to internal staff or an outside contractor. Scheduling and managing the responsible teams is deceptively complex because the criteria and frequency of audits vary widely, and assignments need to match the auditor's qualifications.

TraceGains centralizes audit management so users can quickly schedule, conduct, and monitor audits on a single platform using any web-enabled device. Supervisors can easily assign tasks, track progress, and oversee the entire process. When an audit supervisor can see the audit sites, schedule, and auditor capabilities with just a few mouse clicks, it streamlines the scheduling process. Geolocation capability also helps supervisors group audits together to reduce travel and expenses.

Outdated Audit Tools

It's 2019. Nearly everyone walks around with a super computer in their pocket or purse. Wireless internet is available – for free – at most coffee shops. Yet, most food, beverage, and dietary supplement companies still rely on outdated tools such as email, clipboards, and three-ring binders filled with paper forms to conduct audits. At best, some use antiquated spreadsheet software to create their audit plan and track findings. The problem with performing paper-based audits or only partially electronic audits is that they lead to data entry errors and there's lag-time in updating records. When audits are completed, they're filed away and the data can't be mined for business insights such as risk profiling, trending, training, performance reviews, and other analysis.

Audit Management eliminates paper audits so the auditor can leave the clipboard behind. The system comes with pre-loaded templates or customers can easily configure custom templates and standardize them across the operation.

Audit Management can be used to conduct audits of any kind, including GFSI, FSMA, cGMP, HACCP, and brand standards. Auditors can take a tablet on the plant floor and their electronic checklist will be at their fingertips. The same tablet or phone can be used to easily take photos or record observations. If an audit site isn't connected to Wi-Fi, or there are restrictions due to the nature of the processing environment, users have the choice to conduct audits using remote data collection that syncs with the system later.

Auditors often spend a lot of time during on-site audits examining required documentation. Without pre-audit records access, time is wasted finding and reviewing documents. TraceGains' cloud-based visibility empowers detailed pre-audit review of key documents including previous audits and corrective actions. This access means auditors can plan their inspections more effectively because they're better informed before going on site.

Neglecting the Audit Data Trail

Controlling supply risk is not only a newer requirement under the Food Safety Modernization Act (FSMA), it's an important part of brand protection. When non-conformances are identified, they need to be recorded, addressed, and corrected. Every observation should be recorded because these are rarely fluke incidents and could be symptoms of a larger problem. Failing to document these failures over time puts the company at greater risk of future failures. A robust data trail can not only address systemic issues but can better prepare companies for future audits.

Post-Audit Communication

After the failures or errors are recorded, there are several important steps before the auditor's work is done. An exit meeting is essential to recap the audit outcomes and compliance activities for with the relevant people involved. Auditors use this opportunity to discuss what went well and highlight area for improvement. Overall performance and findings should be discussed with everyone, including senior management and line workers. When technology can play a role in post-audit communication, everyone wins. It can be as simple as using a projector or screen casting device at the exit meeting to display photo examples of non-conformances on a big screen so everyone can see for themselves. It's also possible to simplify communication using an online platform to exchange information and immediately update the audit record.

GMP Issues

When GMP issues are identified, the auditor should take a photo to include with the audit documentation. These photos can be particularly helpful to demonstrate the behavior or conditions that need to change. When the GMP issues are rectified, a photo also can be loaded into the system. The photos can be organized as a before-and-after example to support the corrective action process. When an auditor is using Audit Management, they can take photos with the same device they're using to conduct the audit, so the photos can be automatically connected to the correct section of the audit record. No uploading or dragging and dropping is necessary.

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Education and Training

Even if no non-conformances are identified, auditors should still use the opportunity to re-educate or retrain workers. This training can be provided as part of the audit debrief and recap. Any GMP photos taken can be shared and also serve as a great education tool across the organization.

Audit Documentation

There can be a tremendous amount of documentation generated during the audit process, especially when it's been for multiple days. If folders, binders, and paper documentation is involved, the staff of the audited site will need to return all documents and records back to their storage location. Companies that use TraceGains to manage supplier and quality recordkeeping can avoid this step because their documentation is all in the cloud and concluding the audit can be as simple as closing a laptop.

Similarly, when an auditor uses Audit Management they don't need to do data entry back at their hotel room overnight, because they used the system to conduct the audit.

Grading & Results

Grading systems for audits can vary depending on the audit standard. With TraceGains, grading and results are also fully configurable. Some companies might use a numerical value that's calculated at the end for an overall score, while some companies use letter grades, and some might elect to use a Pass/Fail designation. TraceGains can denote Critical, Major, and Minor failures and auto-calculate what constitutes an audit failure based on each company's acceptable thresholds.

CARs Preparation

Corrective action requests (CARs) will need to be completed for all non-conformances identified. Initiating CARs immediately after the audit can help resolve them quickly and ensure companies don't exceed the allowable CAR close out time frame. Audit Management can generate a CAR that will automatically inherit the results of the audit and gives the auditor the ability to input instructions for the recipient. The software has a CARs tab to give auditors a dedicated section to track these corrective actions, including producing trending data around how long these take to resolve as well as which sites have the most CARs. The system also can print or publish the results.



When an auditor uses TraceGains Audit Management they don't need to do data entry back at their hotel room overnight, because they used the system to conduct the audit.

Informed Business Decisions

Audit supervisors need better visibility into the process so they're not waiting around for final reports. Seeing all the data at a granular level empowers Audit Management users to immediately access findings, and in some cases can reduce audit time from days to hours. Automated notifications, workflows, and task assignments help track the progress of audit teams, and real-time reporting flags key findings and corrective actions.

Reports can demonstrate trends historically to illuminate auditor competency issues. Are they regularly making the same findings? Are some auditors more productive and efficient than others? Reporting metrics are helpful identifying training opportunities. In addition, management can compare multiple facilities for risk analysis and continuous improvement efforts.

One of the more powerful aspects of TraceGains Audit Management solution, however, is that the auditing functionality is contained in the same platform where TraceGains users are managing suppliers and compliance. That means that because the system can share data attributes between different solutions, an external audit score could become part of a supplier's overall record and even calculate it directly into a supplier scorecard. Users can set up a business rule that flags a supplier for needing a follow-up onsite visit if they failed an audit. It also means the system can easily communicate to a quality team receiving COAs or a receiving dock worker that the incoming products are from a site that failed an audit and might require additional processing or attention. Companies can set up a workflow to automatically disqualify a supplier or put a facility on probation immediately after a failed audit. This type of real-time consequence of a failed audit is virtually impossible with outdated audit tools.

TraceGains has created a platform that saves time and helps avoid the manual errors that often occur during conventional auditing operations. When audits are completed, they're too often just filed away. Within TraceGains, however, risk assessment factors are data mined as an essential element of audit management. This allows companies to quickly identify areas that pose the highest operational threats and mitigate them proactively.

TraceGains Audit Management is scalable and affordable for small and large operations alike. Product demonstrations can be done online with a TraceGains account executive individually or for the entire audit team.

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