

Managing Risk in the Global Supply Chain



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The COVID-19 pandemic forced the CPG industry to confront the glaring vulnerabilities in the global supply chain, particularly those that rely on Chinese suppliers. And that's no small segment of the business. According to Deloitte, more than 200 of the Fortune Global 500 firms have a presence in Wuhan, China, the province where scientists figure the outbreak originated.

"A decades-long focus on supply chain optimization to minimize costs, reduce inventories, and drive up asset utilization has removed buffers and flexibility to absorb disruptions – and COVID-19 illustrates that many companies aren't fully aware of the vulnerability of their supply chain

relationships to global shocks," Jim Kilpatrick, Deloitte's Canadian Consumer Products Industry Leader wrote. "Fortunately, new supply chain technologies are emerging that dramatically improve visibility across the end-to-end supply chain, and support companies' ability to resist such shocks."

Organizations that miss critical supply chain weaknesses face quality and safety issues that threaten the brand and its bottom line. Without a clear view of the supply chain, managing risk is challenging in today's environment, if not impossible. It's a lot like playing Whac-A-Mole blindfolded.

Growing Supply Chain Threats

But new supply chain threats are emerging, some of which are close to home, such as:



A Lack of Understanding

The pandemic has exposed just how little most companies understand about the intricacies of their supply chain. To navigate future disruptions, organizations need a much deeper understanding of all the moving parts of their supply chain.



Limited Supplier Networks

Historically, economies of scale have compelled companies to rely on a limited number of suppliers. It's a glaring vulnerability that's shown that future supply chain security rests on a broader network of suppliers.



Data Overload

While advancements in technology and big data have made it easier to do business, all that information presents its own set of challenges. Companies struggle to keep up with the constant flow of data from increasingly tech-savvy suppliers.



Demanding Consumers

Consumers have emerged from the pandemic with higher expectations and a deeper understanding of what they're buying – and what they want to buy in the future. That puts increased pressure on an already strained supply chain.

Assessing Risk

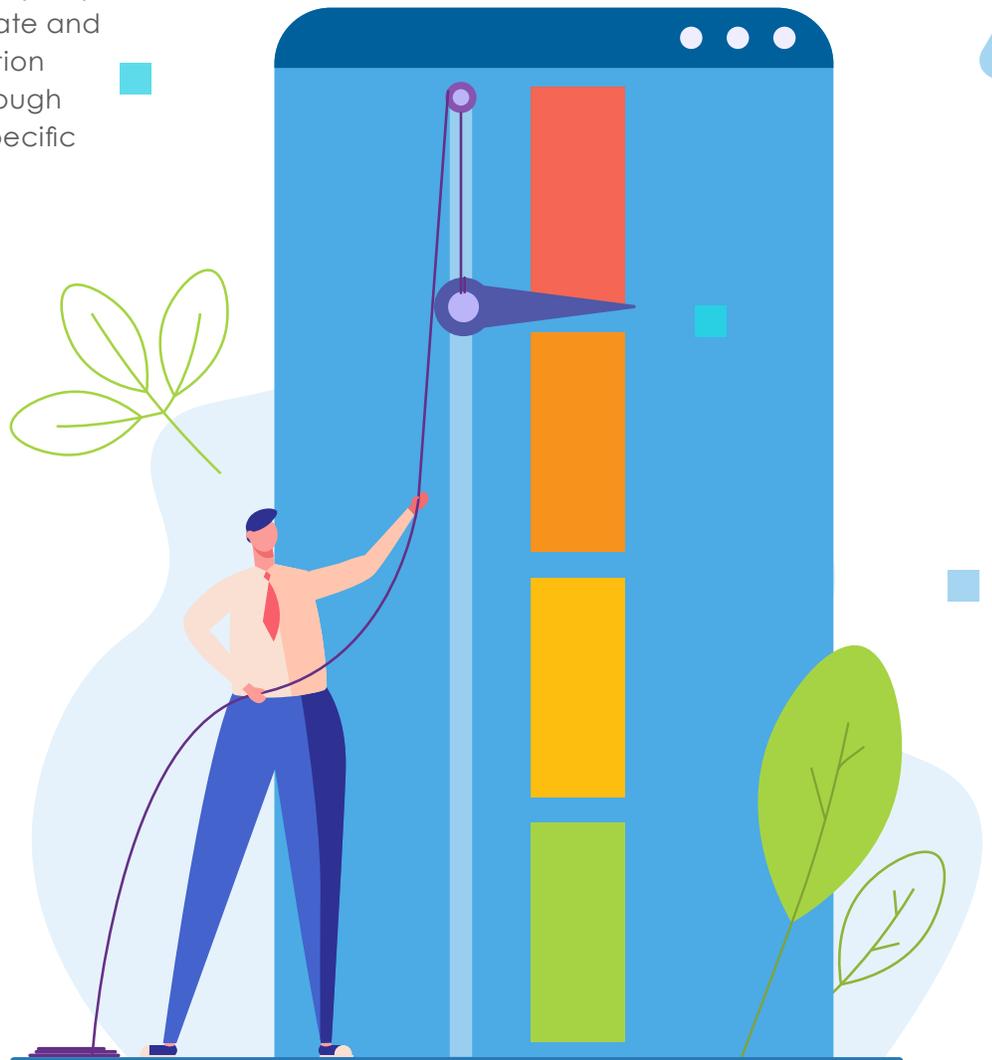
Risk assessments remain vital to evaluating raw materials, suppliers, and supply chain protocols. But complex supply chains, a lack of uniform standards, and non-integrated systems make a difficult task even more challenging.

Properly evaluating risk is critical for effective supply chain management and ensuring the safety of sourced ingredients. It's also an integral part of food safety management systems. The U.S. Food Safety Modernization Act (FSMA) and Global Food Safety Initiative (GFSI) certification programs require supplier approval and monitoring programs to safeguard the safety and authenticity of materials. Material and supplier risk assessments form the backbone of critical approval, monitoring, and verification activities – the gatekeepers of the food supply chain.

Supply chain risks lurk throughout the supply chain, especially when it comes to:

- The composition and origin of sourced material.
- The production methods and supplier infrastructure.
- The materials in the finished product.
- And the length and complexity of the supply chain.

The Food and Drug Administration's (FDA) quantitative risk assessments estimate and compare reductions in contamination and/or illness that would occur through specific interventions applied at specific points along the supply chain.



Material/Ingredient Risk vs. Supplier Risk

Two overlapping systems exist to isolate supply chain risk: material (or ingredient) risk and supplier risk.

When researching vendors, companies must evaluate both the materials and suppliers for hazards and vulnerabilities. Most manufacturers perform at least one assessment to determine the risk level of sourcing material from any given supplier. They use that to employ the appropriate supplier approval, monitoring, and verification activities.

These supply chain management tasks are highly interdependent, mandating greater visibility, enhanced supplier relationships, and ongoing supply chain improvements.

The quality of risk assessments and, by extension, the effectiveness of mitigation, monitoring, and verification relies on the right combination of qualified personnel and effective systems to support those efforts. Supply chain management software solutions that include risk assessment functionality tied to compliance and monitoring criteria are invaluable.



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Material/Ingredient Risks

The CDC estimates that produce causes nearly half of contamination incidents in the United States, while beef and poultry are responsible for almost a third of food-related deaths. Industry players must combat both public perception and safety issues to compete effectively.

Material risks are abundant and include threats from raw agricultural commodities (RACs), animal products, ingredients, processing aids, and packaging. The composition and geographic origin of materials are critical risk level factors, as are production methods. Both hazard analysis and vulnerability assessments are vital tools to determine material and ingredient risk.

These questions help determine the risk of a material or ingredient:



Composition

- Does the material's composition protect against pathogen growth?
- Is the material intact with a natural barrier — like most whole fruits — or are cut surfaces exposed, increasing the likelihood of contamination?
- Is the material's texture homogeneous, like ground spices, providing more opportunity for the addition or substitution of non-authentic ingredients?



Material Used in the Finished Product

- Will the manufacturer use the material in a formula that can serve as a medium for pathogen growth? If so, will the final product be pasteurized?
- Does the final product contain unique claims or disclosures that are regulated?
- Is the consumer responsible for controlling the hazards associated with the product and, if so, what is the risk of the consumer not following the "intended use" instructions?



Origin and Production Methods

- Is the material's country of origin in a developing region where supplier infrastructure might be at greater risk for contamination or spoilage?
- Is the material derived from a region with political unrest, possibly subject to disrupted transportation routes and threatened security?
- Do supplier production methods contain appropriate controls to prevent, eliminate, or reduce identified hazards to acceptable levels?

Questions like these form the basis for determining a material's risk level, and the hazard analysis and vulnerability assessments are essential resources for this task.

Hazard Analysis

Hazard analysis refers to evaluating risks and conditions to determine those significant for product safety. Companies should address these threats in the Hazard Analysis and Critical Control Point (HACCP) plan, which includes an evaluation of upstream and downstream activities and extend beyond the manufacturing plant and include raw material production methods, post-harvest handling and storage, transportation, and distribution.

GFSI-benchmarked certification programs are based on Codex methodology for the development of food safety plans. These require a hazard analysis, which evaluates and ranks potential hazards according to their likelihood of occurrence and severity across the entire process, from primary production to distribution. Manufacturers evaluate materials for hazards by analyzing the procurement and receiving steps. But there's no requirement for an in-depth evaluation of all raw materials. FSMA's Preventive Controls and Foreign Supplier Verification rules extend HACCP expectations by requiring that the hazard analysis evaluate each material and process step.

The HACCP plan controls reasonably likely hazards, such as:

- **Biological:** harmful bacteria, viruses, or parasites (e.g., salmonella, hepatitis A and trichinella).
- **Chemical:** compounds that can cause illness or injury due to immediate or long-term exposure.
- **Physical:** foreign objects in food that can cause harm when eaten, such as glass or metal fragments.

Vulnerability Assessments

Vulnerability assessments address weaknesses in the supply chain that can expose suppliers to fraud, intentional adulteration, or contamination.

In the food business, vulnerability assessment refers to a risk-assessment-style evaluation of a food's vulnerability to food fraud. This evaluation pinpoints sensitive materials and supply chain events. Identifying material vulnerability goes beyond evaluating potential biological, chemical, or physical hazards to paint a complete picture of the risk associated with a material's authenticity, safety, and legality.

Supply chain flaws that can lead to fraud or intentional adulteration include:

- Insufficient or uncontrolled recordkeeping.
- Offline labeling practices or the absence of label-check procedures.
- Incomplete or missing documentation.
- Unsecured storage areas or loading docks.

Where someone identifies a vulnerability outside the manufacturer's control, the company must consider mitigation measures to ensure product authenticity and safety. A robust supplier approval and monitoring program can achieve this.

The quality of risk assessments and, by extension, the effectiveness of mitigation, monitoring, and verification relies on the right combination of qualified personnel and effective systems to support those efforts.

Material Risks and Supply Chain Management

Material risk evaluations build on the hazard analysis, vulnerability assessment, and other related risk analysis to combine potential hazards and threats into a single risk profile for a given material.

Companies face many challenges when completing and updating material risk assessments. A recent General Society of Surveillance (SGS) survey found that nearly 75% of businesses worry their supply chain risk management and mitigation efforts aren't enough.

The survey revealed several key obstacles to effective supply chain management, including:

- A lack of knowledge about existing and emerging risks.
- Underestimation of the potential impact of supply chain risks.
- Inadequate technology to monitor and manage the supply chain.
- Missing supplier performance indicators and metrics.

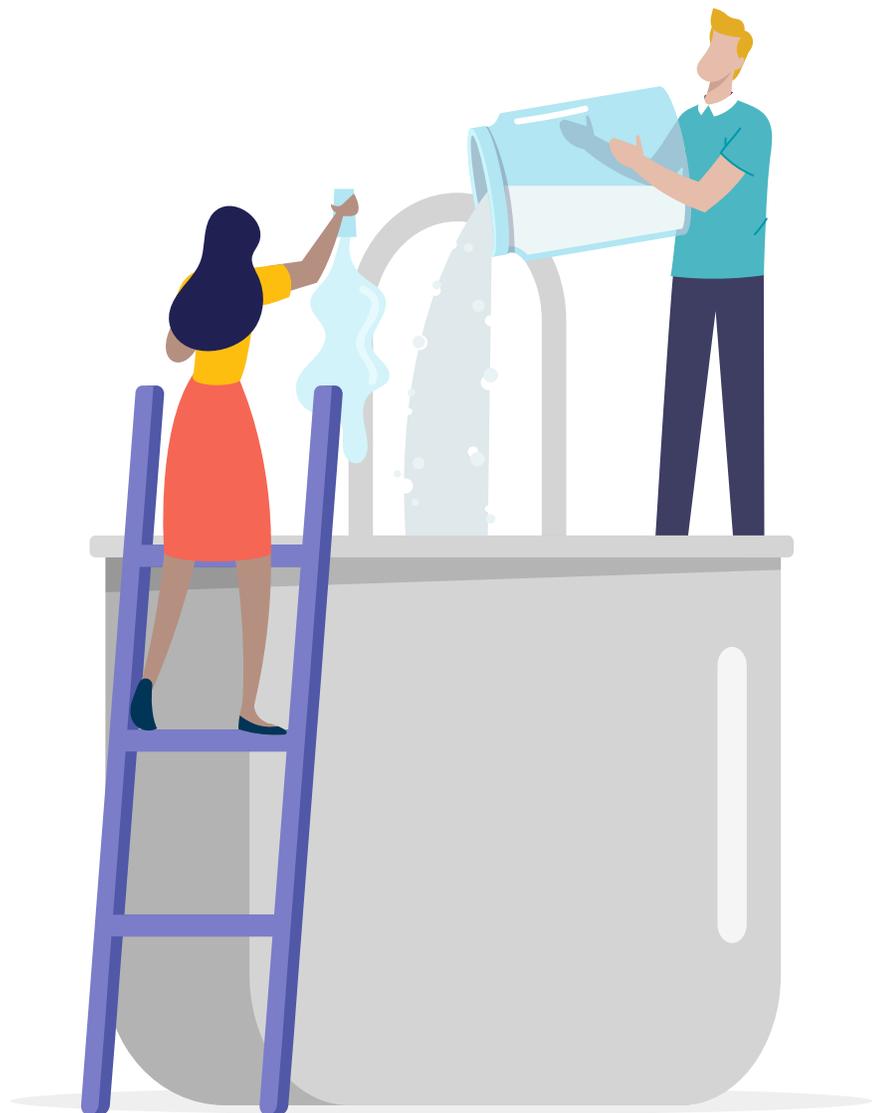
Material risk assessments remain the foundation for determining material acceptance criteria, such as certificates of analysis (COAs), testing, and inspection. Companies should combine this with supplier risk assessments to determine appropriate supplier approval, monitoring, and verification criteria.

Understand Raw Materials

Before a company completes a risk assessment, it's essential to understand the raw materials involved. Key attributes include the ingredient(s), country of origin, allergens, packaging, storage conditions, and shelf life. Once a company identifies all the potential hazards, the next step is to assess the likelihood each will occur and the consequences, which generates an overall risk score for the raw material.

In keeping with food safety HACCP compliance, it's essential to document the assessment to:

- Provide proof during the audit process.
- Show the justification for the risk ratings.
- Inform companies about their raw materials and the impact they have on business operations.

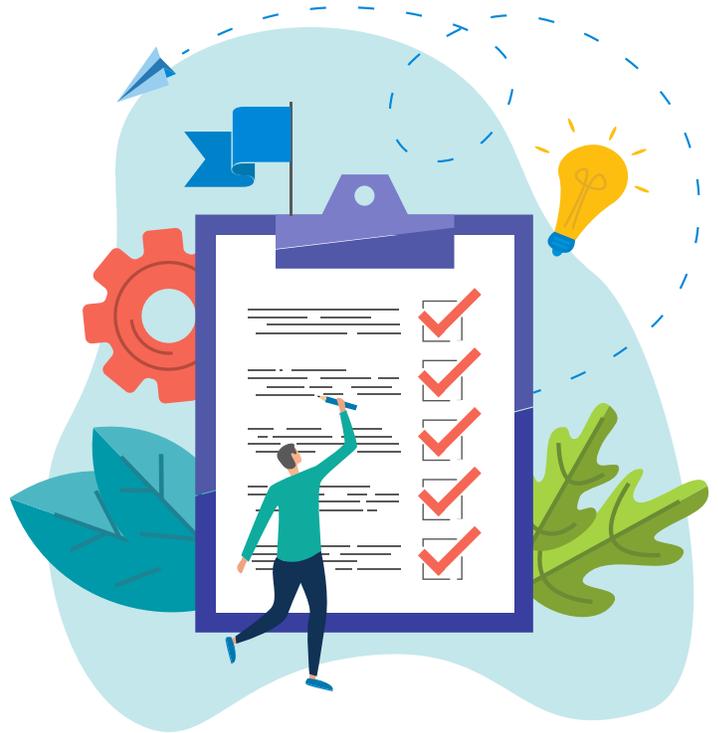


Supplier Risks

Supplier risk assessments frequently overlap with material risk assessments. Additional factors shared between material, and supplier risk assessments include supplier geography, storage and transportation methods, and the chain of custody.

However, the supplier risk assessment should also examine internal factors, such as the supplier's performance history, and external factors, such as economic, environmental, and geopolitical disruptions. External interruptions such as labor shortages, natural disasters, and export restrictions can cause widespread harm when combined with existing supply chain vulnerabilities. Companies can factor these variables into the supplier risk profile.

Manufacturers use supplier scorecards to measure key performance indicators (KPIs) critical to the materials' safety and quality. Supplier scorecarding increases visibility and drives approvals, renewals, and supply chain improvements.



Geography is a Factor

Today's food supply chain is a growing global network. Experts figure that about \$14 trillion worth of food makes its way through the world's supply chain annually.

Regional considerations for identifying and prioritizing supplier risk include evaluating production factors, infrastructure components, security, and communication resources.

For example, clean water is critical for production and postproduction. Water scarcity or contamination is always a potential risk for a supplier, depending on geography.

Similarly, pesticide use for crops or veterinary supplements can create supplier risk where there's potential for using chemicals or hormones not approved in the receiving country.

Several infrastructure-related supplier risks exist, including utilities, buildings, equipment, and roads. There might be risks associated with poor water quality, inadequate air handling, and dust control because of a lack of facility enclosure, unsanitary equipment design, or damaged roads caused by weather, natural disasters, or political conflict.

Furthermore, the increased geographic distance between suppliers stretches the supply chain, clouding transparency.

Risks associated with increased geographic distance between suppliers and customers include:

- Multiple partners improved handling and delays.
- Export and import restrictions.
- Sub-contracting, which can hamper visibility.



Storage and Transportation

Storage and transportation operations create additional risk factors, including pathogen growth from temperature abuse, product adulteration through cross-contamination or cross-contact, and opportunities for the supply chain's criminal elements.

Logistics present some of the most significant supply chain risks in developing countries – due primarily to an inability to maintain cold chains, poor material container hygiene, and segregation methods, insufficient training, and a lack of coordinated logistics management.

Container hygiene and segregation are also paramount to logistic operations for preventing cross-contamination from pathogens or other containers. Adequate container sanitation and product segregation during storage and transportation mitigate these risks; however, consistent implementation can be challenging, based on regional resources.

It's also critical to identify the highest risk areas of the cold chain so that controls can mitigate them. For example, in most cold chains, the highest risk areas are product handoffs or transfers, including ports, transfer facilities, and distribution centers. Multi-stop transit generally presents control risks as well. Once companies identify other threats, they should draft a plan for addressing them and general cold chain performance. This strategy includes handling policies, exception protocols, critical control points, and workflows.

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Chain of Custody

Chain of custody is the unbroken path a product takes from raw material through production to the customer. Many complex supply chains include more than 100 links, complicated by companies that outsource manufacturing to other countries.

A well-documented chain of custody is essential to ensuring a material's safety, legality, and authenticity in a complex network. This assurance supports supply chain transparency and protects a company's brand.

According to Inbound Logistics, "ensuring food safety and integrity is no longer an issue of what happens inside the manufacturer's walls. Instead, all players in the country's food supply chain must be able to quickly trace where they received a food product and where they sent it."

There are six steps to managing the chain of custody:



Key control points Review the manufacturing process to understand each production stage where products are combined.	Uniform marking system The marking system must be evident throughout every process, from raw material to the finished good.	Recordkeeping and document management Maintain detailed records down to the lot, batch, and minute of the manufacturing process.	Assign ownership Assign qualified employees with knowledge, accountability, and authority to design and implement the chain of custody.	Conduct audits Chain of custody is insurance. Audits ensure the chain of custody operates effectively, so it works when it has to.	Integrate chain of custody throughout the supply chain Supply chain managers bear the burden of ensuring the chain of custody program operates effectively.
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Managing Risk is an Ongoing Process

Once companies identify the risks associated with ingredients and suppliers are approved, it's essential to verify supplier compliance with ingredient specifications and food safety standards.

Companies can accomplish this with two processes:



Certificates of analysis (COAs)

With each shipment, the supplier's QA department issues a COA, confirming that each regulated ingredient or product meets specifications.



Inbound material inspections

The second verification method is to inspect inbound materials from suppliers. Depending on resources, the initial ingredient hazard analysis should guide the frequency of inspection required.

When received material doesn't meet specifications, a corrective action report, or CAR, is sent to the supplier outlining the details of the non-conformance. By maintaining a log of supplier CARs, companies can measure supplier performance.

Not only are these processes time-consuming and error-prone when completed manually, but there's also often not enough time or resources to be consistent. Technology is integral to supplier approval and monitoring programs, providing tools that extend beyond electronic data management. Supply chain management software solutions, which operate from a supplier-network base and incorporate risk management intelligence and modeling features, can help companies close supply chain transparency gaps. These solutions prioritize risk assessment and track supplier compliance against critical metrics directly correlated to the nature and level of the risk. Leveraging technology with full-scope transparency offers enhanced supply-chain visibility, consistently linking chain of custody to the final product and giving real-time notifications when material results and supplier documents don't meet specified criteria.

TraceGains Can Help

With TraceGains, you can transform a tangled web of manual and disconnected suppliers, sourcing, quality assurance, specification, development, and document management steps into a highly automated and orchestrated digital workflow tracked for supply chain transparency and a complete audit trail.

Sourcing

Evaluating materials and ingredients for hazards and vulnerabilities is a tall order for most teams. Because ingredient qualification and approval are often manual processes, companies expose the business to tremendous risk.

TraceGains Market Hub is a robust sourcing directory for items, packaging, service providers, and more. Powered by TraceGains Network, manufacturers and brand owners can procure new items or ingredients and automatically collect supporting quality and regulatory information and documentation from an ever-growing library.

When teams search for ingredients with Market Hub, TraceGains Smart Alerts provides visibility into supply chain threats and regulatory risks for existing, experimental, and alternative ingredients and raw materials across suppliers and geographies. Fulfilling FSMA's requirement for manufacturer and brand owners to continuously monitor suppliers and ingredients for risk,

TraceGains also tracks reported events throughout the supply chain. Food and supplements companies can pinpoint risk by ingredient, additive, flavoring, substance, contamination, etc. Companies can also receive advisories on adulteration risk, USDA, side effects/ interactions, adverse events, Prop 65, among others.

All this data integrates seamlessly with TraceGains Supplier Management, highlighting risk by supplier, item, and geography, allowing your team to identify and eliminate the most critical threats.

Hazard Analysis

The potential risks associated with food safety hazards extend well beyond the manufacturing floor and are vital to a company's HACCP plan. TraceGains Quality Management minimizes the risk of production operations, as unexpected equipment failures, maintenance issues, and product defects can bring production to a standstill, damage your brand, and even worse, harm consumers. The software drives continuous improvement by storing and analyzing quality control and safety data in a single system, providing immediate insight into plant floor and quality operations. Teams electronically submit forms on the plant floor, and the software compares them with compliance standards and critical benchmarks in real-time. When issues arise, the system triggers notifications instantly, empowering employees to act. Corrective action requests (CARs) are generated quickly and are immediately visible to stakeholders. Easily accessible and comprehensive quality data means a more efficient plant floor, less work, and instant response times to demanding audits.



Vulnerability Assessments

Too often, periodic vulnerability assessments reveal long-standing biological, chemical, or physical hazards throughout the supply chain. Unfortunately, these vulnerabilities cause immediate risk for companies relying on newly compromised suppliers or ingredients. By delivering targeted market intelligence relevant to companies' supply chains, TraceGains Smart Alerts gives teams focused, daily alerts segmented by geography, supplier, item, and ingredient and access to industry-related regulatory, safety, incident, and fraud information daily.

Smart Alerts strategically exposes relevant incident and alert information tied to specific ingredients to food safety and regulatory teams so they can mitigate them. Comparatively, typical supply chain alert systems populate stand-alone incident libraries and deliver disjointed email alerts to subscribed users. An individual alert for an item or ingredient is essential and is often the inception point for developing a comprehensive audit verification or remediation initiative.



Supply Chain Management

Supply chain risk and hazard incidents are often captured as data points and stored in silos, inaccessible across departments. A company's inability to effectively centralize its supply chain data and extract useful information is the primary reason teams lack the knowledge, level of impact, and resolution methods necessary to reduce supply chain risk properly.

TraceGains Supplier Management streamlines supplier qualification and sourcing by collecting, centralizing, and digitizing supplier documents, extracting the relevant data and arranging it into performance dashboards and reports. Teams can choose standard or custom dashboards to evaluate risks for mission-critical data. Suppliers receive automatic alerts when documents are missing, incomplete, or about to expire, ensuring everything stays up to date.

Audits are crucial for ensuring supply chain compliance and managing risk. With TraceGains Audit Management, companies can automate and streamline the entire audit process to schedule, conduct, and track audits within a single

platform using a desktop or mobile device. Teams can customize audit checklists or use pre-loaded templates with notifications, workflows, and task assignments to track progress.

For companies manually formulating new or reformulating existing products, insufficient visibility into the upstream and downstream consequences of supplier updates to ingredients and other formula components can put the business at serious risk. TraceGains Formula Management allows teams to create and manage formulas and recipes while collaborating across departments and suppliers or co-manufacturers. Network connectivity gives teams instant access to millions of supplier-provided documents and information, enabling rapid digital prototyping using real ingredient and supplier data to achieve ideal product criteria faster. TraceGains reduces the risk of creating new or enhancing existing formulas and substantiating label claims. With TraceGains, all changes are tracked and instantly available to everyone on the team.



Supplier Risks

Often reliant upon manual processes, quality teams can struggle to manage their supplier and ingredient compliance programs. As supplier shipments are received, essential factors like shelf life, moisture content, production date, lot number, and more need to be compared against specifications to ensure the items and ingredients fall within your acceptable production guidelines. To make matters worse, CoAs can arrive in various formats, including email, fax, and post, and sometimes do so after receipt of the items or ingredients to the dock.



Depending on the number of ingredients and materials required, the process of determining if supplier shipments adhere to specifications can be nearly impossible to implement manually. Most teams don't have time to read and compare hundreds or thousands of CoAs to material specifications. And, even if they do, human error often leads to product variability, rework, customer complaints, and recalls.

When supplier non-conformance problems arise, the process used to create, track, and report the status of Supplier Corrective Action Requests (SCARs) is often decentralized and disconnected. This approach limits the visibility teams have into the performance and compliance of their suppliers and makes it challenging to hold suppliers accountable.

TraceGains Supplier Compliance evaluates supplier product performance, lot by lot, from purchase order to production, extending inventory visibility to the shipping dock. Teams can scorecard, measure, and rank suppliers by risk category, providing an intuitive, visual overview of supplier performance.

Operating as a virtual early warning system, the software automatically identifies issues with incoming shipments before they enter production, reducing out-of-spec inventory, cost, and risk. Downstream issues like customer complaints and plant floor problems are traced to specific supplier lot shipments, enabling supplier chargebacks and rapid replacement. Compliance data is centralized, allowing teams to review specifications, track CoA trends, and run reports on any critical data with one click. With Supplier Compliance from TraceGains, teams gain the visibility and control needed to meet the product quality, regulatory compliance, and financial requirements that today's global supply chains demand.

About TraceGains

Founded in 2008, TraceGains connects people and information so teams can work smarter. As a global technology company, TraceGains provides networked innovation, quality, and compliance solutions to consumer brands that want to reduce supply chain risk, speed up business processes, and take control of data. On average, companies find 80% of their suppliers already on TraceGains Network, allowing them to connect and collaborate instantly.

Learn More

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