



TRACEGAINS

Managing Risk in the Global Supply Chain

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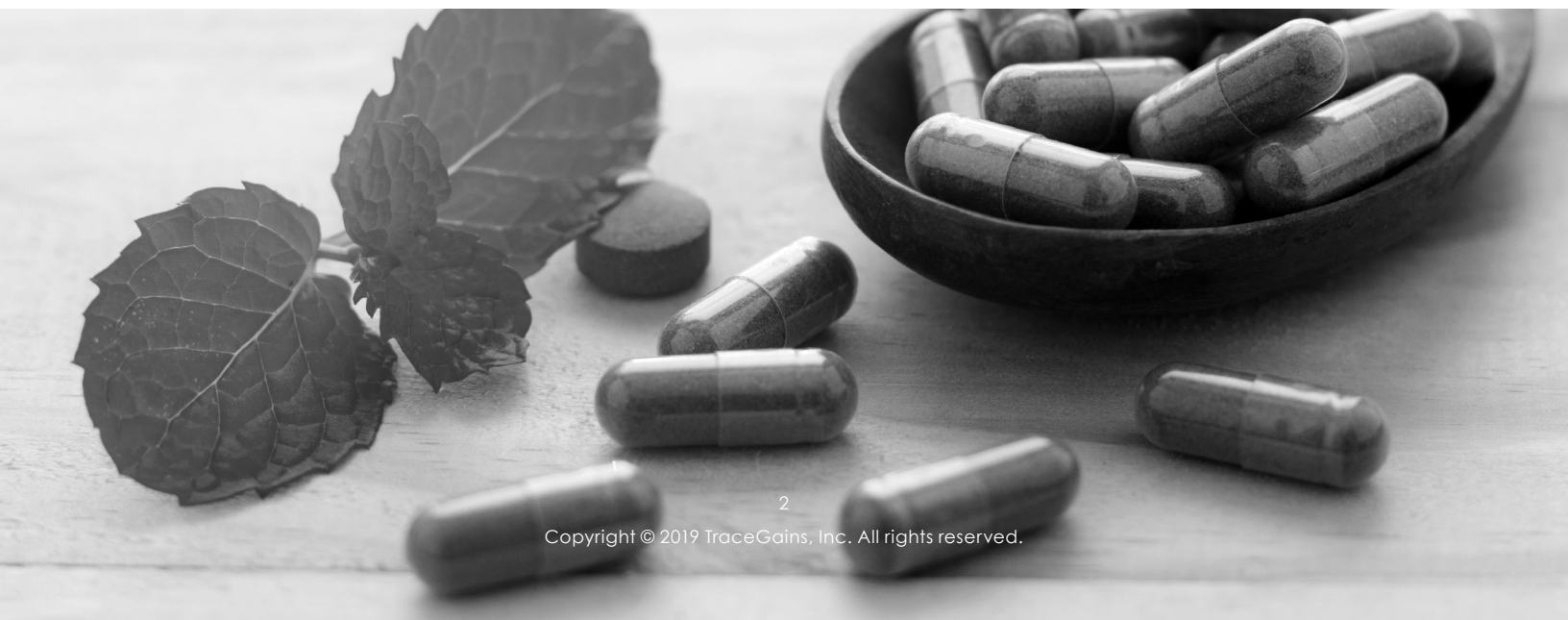
While the adage insists that the only sure things in life are death and taxes, the food, beverage, and dietary supplement supply chains face an additional grave certainty: risk.

Risk assessment is vital throughout the supply chain to evaluate materials, partners, company processes, and consumer uses. But identifying, managing, and applying findings from these assessments becomes exponentially more complicated with global supply chains and non-integrated or non-standardized systems.

Properly evaluating risk is critical for effective supply chain management, transparency, and for ensuring the safety of globally sourced materials. It's also an integral part of food safety management systems complying with Global Food Safety Initiative (GFSI) or the U.S. Food Safety Modernization Act (FSMA). GFSI-benchmarked certification programs and FSMA regulations (including Preventive Controls and Foreign Supplier Verification rules) require a supplier approval and monitoring program to ensure the safety and authenticity of materials. Material and supplier risk assessments form the basis of critical approval, monitoring, and verification activities, which are the gatekeepers of the food supply chain.

Supply chain risks hinge on several factors, but most consider:

- Composition and origin of sourced material.
- Production methods and supplier infrastructure.
- Material in the finished product.
- Length and complexity of the supply chain.



MATERIAL RISK VS. SUPPLIER RISK

Two overlapping systems exist for consideration when identifying supply chain risk — material risk and supplier risk.

When researching prospects, manufacturers 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 a material from any given supplier. That's then used 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.

Most importantly, these tasks rely on the appropriate personnel and technology. The quality of risk assessments and, by extension, the effectiveness of mitigation, monitoring, and verification relies on resources, knowledge, and data.

This means a supply chain management software solution that includes risk assessment linked to compliance and monitoring criteria is the best tool to make the most of company resources, manage data, and increase transparency.

Did you know?

TraceGains' **Supplier Compliance** and **Supplier Management** software solutions incorporate risk determination into approval and monitoring criteria. TraceGains' SC module allows users to apply a risk level to a material or supplier and to set business rules for auto acceptance or rejection of materials based on the supplier's compliance standing within the context of an associated risk score.

This feature, along with email notifications and real-time alerts for non-compliant materials or suppliers, improves the safety of sourced materials and increases supply chain visibility within an automated framework.





MATERIAL RISKS

Potential risks for materials are plentiful. These include risks from raw agricultural commodities (RACs), animal products, ingredients, processing aids, and packaging. The composition and geographic origin of materials are key determinants in risk level, as are production methods and the use of the material in a finished product.

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 with ground spices, providing more opportunity for the addition or substitution of non-authentic ingredients?

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?

USE

How will the material be used in the finished product? Will the material be used in a formula that serves as a medium for pathogen growth? If so, will the final product be pasteurized? Does the final product contain special claims or disclosures and are these regulated? Is the consumer responsible for the control of hazards associated with the product and, if so, what is the risk of the consumer not following the intended-use instructions?

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

HAZARD ANALYSIS

Hazard analysis refers to the evaluation of hazards and conditions to determine those significant for food and supplement safety and, therefore, should be addressed in the Hazard Analysis and Critical Control Point (HACCP) plan. In HACCP methodology, this includes an evaluation of upstream and downstream activities, which extend beyond the walls of the manufacturing site, and include raw material production methods, post-harvest handling and storage, transportation, and distribution.

GFSI-benchmarked certification programs are based in 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. In Codex methodology, materials are evaluated for hazards through the analysis of procurement and receiving steps, but a requirement doesn't exist for an in-depth hazard analysis of all raw materials or material groups. FSMA's Preventive Controls and Foreign Supplier Verification rules extend the expectations of Codex HACCP by requiring that the hazard analysis evaluate each material and process step.

VULNERABILITY ASSESSMENT

Vulnerability assessments generally refer to the evaluation of weaknesses in the supply chain, which can expose suppliers to fraud and intentional adulteration or contamination. Vulnerability assessments within the food and supplement safety management systems identify susceptible materials and supply chain events. Identifying material vulnerability goes beyond an assessment of potential biological, chemical, or physical hazards to provide a complete picture of the risk associated with a material's authenticity, safety, and legality.

Examples of supply chain weaknesses, which provide opportunities for fraud or intentional adulteration include:

- Insufficient or uncontrolled recordkeeping.
- Offline labeling practices or the absence of label-check procedures.
- Incomplete or missing documentation, which cuts chain of custody from the supplier to the end-user.
- Unsecured storage areas or loading docks.

Once a supply chain vulnerability for a given material is identified and ranked, the result is factored into the material risk assessment. Where vulnerability is identified outside the control of the manufacturer, mitigation measures within the supply chain must be sought to ensure product safety, authenticity, and consumer protection. This could be realized through the supplier approval and monitoring program.



MATERIAL RISKS AND SUPPLY CHAIN MANAGEMENT

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

Companies face many challenges when completing and updating material risk assessments, largely stemming from the vast number of materials, global sourcing issues, knowledge gaps, and inadequate resources.

A recent SGS survey found that nearly 75 percent of businesses worry their supply chain risk management and mitigation efforts just aren't enough. Furthermore, the survey revealed several key obstacles to effective supply chain management, including:

- A lack of knowledge about current 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 are the foundation for determining material acceptance criteria such as certificates of analysis, testing, and inspection. They should be combined with supplier risk assessments to determine appropriate supplier approval, monitoring, and verification criteria.

SUPPLIER RISKS

To some extent, supplier risk assessment overlaps with material risk assessment when considering hazards and vulnerabilities associated with the supplier's production methods and infrastructure.

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

Findings from material and supplier risk assessments support criteria used for initial and continuing approval of suppliers. Examples of supplier approval criteria include review of a supplier's history and financials, submission of standard compliance documents, a satisfactory second- or third-party audit, self-assessment questionnaires, and testing against the material specification. Supplier scorecards are frequently used to measure key performance indicators (KPIs) critical to the safety and quality of the materials. Supplier scorecarding increases visibility and drives approvals, renewals, and supply chain improvements.

Did you know?

TraceGains' risk assessment functionality applies algorithms for quantitative-based risk levels per material group to ensure a systematically automated approach.

TraceGains' analytics also supports frequent updates to material risk profiles as new and emerging risks are identified.

TraceGains' SC and SM modules automate supplier approval and monitoring activities through notifications and business rules. These modules can issue notifications to inform suppliers of required information, digitize returned documents and records to extract data, manage this data, and apply business rules to automatically determine compliance. This not only eases the burden on personnel for collecting and managing large volumes of data, but also improves the efficiency and accuracy of compliance.

Additional supply chain factors shared between material and supplier risk assessments include supplier geography, storage and transportation methods, and chain of custody.

GEOGRAPHY AND SUPPLY CHAIN COMPLEXITY

In a global supply chain, a material's source has a large effect on its safety, quality, and authenticity. Cultural practices, resources, and geopolitical factors vary greatly across material-sourcing regions.

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

For example, sufficient hygienic water is critical to many production and post-production activities. Water scarcity or contamination can be a potential risk for a supplier depending upon geography.

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

Numerous supplier risks exist with respect to infrastructure and range from utilities, to buildings, equipment, and roads. There might be risk associated with poor water quality, inadequate air handling, and dust control due to a lack of facility enclosure, unsanitary equipment design, or damaged or rough roads due to weather, natural disasters, or political conflict.

Furthermore, the increased geographic distance between suppliers often increases the depth of the supply chain, decreasing its transparency.

RISKS ASSOCIATED WITH INCREASED GEOGRAPHIC DISTANCE BETWEEN SUPPLIERS INCLUDE:

- Multiple partners (increased handling and delays).
- Export and import restrictions.
- Sub-contracting (reduced 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 criminal corruption of the supply chain.

Moreover, logistics presents some of the greatest supply chain risks in developing countries with respect to contamination and loss. This is largely due 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 of materials from pathogens or cross-contact from containers carrying allergenic materials or materials with identity preservation (IP) status. Effective container sanitation and product segregation during storage and transportation mitigates these risks; however, consistent implementation can be challenging depending upon regional resources.

CHAIN OF CUSTODY

Chain of custody refers to documentation for a material or product that connects all handling, production, and distribution activities for a specific lot or batch. But documentation that accurately records key information at critical tracking events is a known transparency gap. Robust supply chain management software can bridge this gap.

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

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CONCLUSION

Prioritizing risk at both the material and supplier level is essential for effective supply chain and safety management. However, numerous barriers still exist to accurate and complete risk assessment—namely, risk intelligence, personnel, and technology. To overcome these difficulties, technology is increasingly becoming 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, are well-positioned to help companies close supply chain transparency gaps. This can be achieved not only by prioritizing risk assessment, but also by tracking supplier compliance against key metrics, which directly correlate to the nature and level of the risk.

Technology focused on full-scope transparency provides enhanced supply chain visibility, consistently linking chain of custody to the final product and providing real-time notifications when material results and supplier documents do not meet specified criteria.

ABOUT TRACEGAINS

TraceGains delivers cloud-based supplier compliance and quality management solutions for the food, beverage, and supplement industries.

At the heart of TraceGains is an advanced network platform that allows companies to automate and streamline their processes through instant information sharing and collaboration throughout the supply chain, fueling digital transformation and product innovation.

**TraceGains Network
provides immediate
access to:**

7K+

SUPPLIERS

95+

COUNTRIES

700K+

DOCUMENTS

100K+

SOURCEABLE ITEMS

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