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Managing Risk, Recalls, and Traceability in the Food Industry

eBook

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Elevating Food Safety Using Enterprise Risk Management Principles: A Primer

BY MELANIE NEUMANN J.D., M.SC AND MARTIN WIEDMANN PH.D., D.V.M.

One of the daily challenges for food safety professionals is being viewed as a cost center (or, as the joke goes, the "profit prevention center"). If you are in a food safety role, you know that nothing could be farther from the truth. If we are viewed as "blocking" or "preventing," it is because our role is much like an offensive line protecting its quarterback—we defend and protect our company's customers, brands, and bottom line in nearly everything we do. Then why is it so challenging to obtain a meaningful budget to procure the right equipment to protect those key players? Is there another way to position ourselves and our requests for resources to enhance our food safety game?

The short answer is yes. It is an approach called enterprise risk management (ERM). Unbeknown to many, publicly traded companies are required to manage enterprise risks that may have a material impact on their balance sheet or long-term survivability. What higher risk does a food company have than food itself?

You may be asking whether your company should start integrating your food safety management program into your ERM strategy. We will address three questions to help you give ERM the consideration it deserves.

What Is Enterprise Risk Management?

There are several definitions for enterprise risk management, all of which reflect ERM as a vital risk management process.

As alluded to above, for virtually any food company, food safety should be considered one of the leading, if not the top, enterprise risks. But before we can chastise a company for not having food safety at the top of its playbook, we should acknowledge that this tool is relatively new to food companies.

ERM doesn't have the same shared, industry-adopted, common definition attached to it, like Hazard Analysis and Critical Control Points. This is at least partially because food safety traditionally speaks in terms of managing *hazards* (e.g., *Listeria monocytogenes*), not risk (e.g., the risk of a recall due to *Listeria*). For food safety to get its legitimate place among all enterprise risks, it is important that a food safety team can discuss risk, and one effective way of doing so is to provide estimates of the likely financial impact of food safety incidents. For example, according to a survey administered by the Consumer Brands Association, the average food recall costs $10 million.[1] Have you run a financial simulation to determine what the cost could be to your company on your highest-selling product if you can't produce it or have to recall it if there is a food safety issue? This exercise is particularly important to level the playing field for budgetary as well as financial impacts of other enterprise risks that can often be estimated more easily.

A leader in defining and shaping this ERM is a group known as COSO—the Committee of Sponsoring Organizations of the Treadway Commission.[2] COSO created a management system called ERM that addresses material financial risk out of the wake of financial scandals in 2001 and 2002.

COSO describes ERM as:

- An ongoing process
- Applied in strategy setting and across the enterprise
- Designed to identify potential events that, if they occur, will affect the entity in a material way
- A process to manage risk within an organization's risk appetite
- Providing reasonable assurance regarding the achievement of business objectives

COSO summarizes ERM as:

A process to assist resource allocation-based decision making designed to **identify** potential events (*risks*) that may affect the enterprise; **manage** risks to fall within the identified *risk appetite*; and **provide reasonable assurances** that such risks are being *managed* and the organization's objectives are being achieved (*metrics*) (*words in parenthesis and emphasis added by the authors*).

While there are other working definitions and ERM frameworks, virtually all can be summarized in the following definition that reflects our proposed definition for the food industry: *ERM is the discipline, culture, and control structure an organization has in place to continuously improve its risk management capabilities in a changing business and risk environment.*

Photo courtesy of Getty Images.

In addition to food safety, other enterprise-level risks are often found to "compete" with food safety for resources and priority. Cybersecurity is a good example of this. If your company is subject to a material data breach or hacked and held hostage by a ransomware attack, this could present a material balance sheet risk to your organization and potentially cripple or even bankrupt your company. Other enterprise-level risks often offer a similar competitive challenge when food safety is vying for finite funds in budget planning and boardroom requests. See "Other ERM Risks in Food Companies" for additional examples.

Other ERM Risks in Food Companies

- Regulatory Noncompliance
- Data Breach
- Advanced Detection (e.g., Whole-Genome Sequencing)
- Major Workforce Injury
- Fraud
- Intentional Adulteration
- Natural Disaster
- Strike
- Inability to Obtain/Retain Critical Talent

Why Do Companies Identify and Manage Food Safety Risks as Enterprise-Level Risks?

If you are publicly traded, you need to. If you are privately held, you will still benefit.

Publicly traded food companies may be more familiar with ERM as a consequence of the accounting scandals at Enron, Arthur Andersen, etc., resulting in billions of dollars in corporate and investor losses.[3] More specifically, due to these scandals, the Sarbanes-Oxley Act of 2002 was born (often referred to as "SOX" or "Sarbox"). The act was expanded by the Dodd-Frank Act of 2010.

This regulation requires public companies to manage, document, and report material enterprise-wide risks to their financial health. It deals with financial governance and accountability, including the need for internal controls to reduce these risks, with a goal "to protect investors by improving the accuracy and reliability of corporate disclosures."

Penalties for noncompliance with SOX are set forth in various SOX sections and can include fines, removal from listings on public stock exchanges, and invalidation of D&O (Directors and Officers) insurance policies. Per Section 906, CEOs and CFOs who willfully submit an incorrect certification to a SOX compliance audit can face fines of $5 million and up to 20 years in jail.

For food companies, examples of specific enterprise risks include highly visible foodborne disease outbreaks linked to a company's product, food fraud events, and large recalls that may include temporary or permanent facility shutdown. Yet you may still be asking: What food safety risk could rise to the level of an enterprise risk that could materially impact the financial health of a company, to the point it may risk its overall survivability? You may be surprised. See the *Listeria* case study in the next question.

Ultimately, SOX requires a set of good practices to identify and manage risk. It requires covered companies to identify and disclose material financial risk, to implement internal controls to reduce that risk in an integrated framework that manages risk within the company's risk appetite, and to report the risks to its board and other impacted stakeholders.

Isn't this what we do in food safety risk management every day? So, whether your company is public or private, you will benefit from tying food safety risk management with your overall corporate risk management approach to more formally and effectively manage enterprise risks.

How Is ERM Applied to Food Safety?

Very carefully—but do not be intimidated; it's not rocket science.

As you can see, ERM is both an art and a science. But there is one aspect that is critical to understand. That is, the results of an ERM assessment are relative; each risk should be compared and ranked *relative* to all other identified enterprise risks.

While a food safety professional may believe that food safety should be at the top of an ERM list, there is the potential that food safety may not be recognized and classified as a top enterprise risk. There may be legitimate reasons for this—for example, if a company produces very low-risk food products, such as canned products or certain dry or low-water-activity products. However, in many cases, a challenge may be that the food safety team may not be able to effectively communicate why food safety is a major enterprise risk. This is at least partially because food safety traditionally manages hazards, not risks. Below is an example of this "hazard" versus "risk" concept with an illustration of how to present a hazard in terms of risk, particularly financial risk.

A Food Safety Enterprise Risk Case Study:

In addition to the general calculations offered regarding recall risk/cost quantification, consider another example of how you can quantify food safety risks in a way that your C-suite will better understand. Let's say you have identified *Listeria* spp. in your environment for the first time. As part of your hazard analysis and risk assessment, you determine that the facility is aging, and the area where the environmental samples were taken shows sign of wear, crevices, and cracks that are ripe for microbial growth. You determine infrastructure improvements are needed to reduce the risk of a larger problem. It is likely that in your conversation with the CEO, you may request resources for infrastructure improvements to eliminate *Listeria* in this part of the facility. This is a classic example of trying to manage a hazard and positioning your request as a hazard, not in terms of risk. A better way to address the same issue with the CEO may be to estimate the risk of a recall, perhaps something like: "*With our current aging infrastructure and based on our environmental monitoring program, we estimate that FDA would likely find* Listeria *in our environment if they were to perform a swab-a-thon; we estimated the chance of a swab-a-thon happening in a given year is 20 percent, the likelihood of a positive sample as 90 percent, and the likelihood of follow-up investigations by FDA leading to a recall as 25 percent; therefore, under our current system, there is an estimated 4.5 percent risk of a recall in a given year* (0.2 × 0.9 × 0.25 = 0.045). *Per industry studies, the average cost of a recall is estimated to be $10 million; with a 4.5 percent chance our company could have a recall in a given year, this could be seen as representing an annualized financial risk of $450,000.*" Using this as a starting point, one can then estimate the risk reduction that can be achieved by an infrastructure improvement (e.g., reducing this risk of a positive sample from 90 percent to 10 percent, and the likelihood of follow-up investigations by FDA leading to a recall from 25 percent to 10 percent).

Run the numbers; it's the C-suite's vocabulary for understanding food safety's need for resources.

There are other examples of financial costs that impact food safety risk prioritization. A few more are listed below, which is not an exhaustive list:

- Production Downtime (to perform root-cause analysis and corrective actions)
- Product Replacement (producing new, safe product to replace the adulterated product)
- Product Disposition (the costs associated with destroying impacted product; with non-impacted product also being returned or destroyed by your customers)
- Loss of Corporate/Brand Reputation (consumers/customers lose faith, reduce, or cease purchasing impacted product, and worse, non-impacted product)

Conclusions

Leveraging ERM is an extremely effective strategy to ensure an all-hands-on-deck, cross-departmental approach to food safety. It is a tool that creates a "push" and "pull" effect, increasing visibility and importance of food safety from the top down and the bottom up, in turn increasing the likelihood of long-term success of ERM-based food safety management programs.

All this said, ERM is not the magic bullet. It is one tool among many in your food safety toolkit. It also runs a risk of being performed in a manner that stops short of its intended outcome. ERM is a risk *management* tool. If we stop at *identifying and assessing* risks without implementing effective controls to *manage* those risks, and to *reduce* them to acceptable levels, then ERM is not being optimized.

Enterprise risk management, performed right, is integral to strategy setting and the identification of risk and opportunities to manage it in a way that creates efficiencies and protects enterprise value.

Keep watch for our second and third articles!

A Final Question to Ponder

We leave you with a question to ponder as you finish this article and await the next two articles in this series (the second on the role that testing and advanced testing methods such as whole-genome sequencing play in an ERM approach to food safety, and the third discussing the use of simulations to identify and characterize enterprise-level food safety risks).

It is increasingly recognized that robust food safety programs require a strong food safety culture. If this is the case, can ERM become the tool to help effectuate and indicate behavioral changes needed to enhance food safety culture? As food safety programs become more integrated into ERM programs, will this require the food industry to reevaluate how we define and assess food safety culture? For example, does relative importance and integration of food safety in an ERM program indicate the maturity of a food safety culture? Let us know your thoughts at melanie@neumannriskservices.com, and a summary of these insights will be shared in subsequent articles in this series.

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Supply Chain Verification to Improve Product Recall and Crisis Management Plans

BY SHAUN KENNEDY

Bagged spinach, chocolate, pet food, peanut butter, pot pies, canned chili, ground beef, tomatoes, jalapeños—and more—food system companies have faced a string of foodborne illness outbreaks and associated recalls. This has, at times, both strained the food safety system and also demonstrated how effective it is. Each food or food ingredient presents different challenges when it comes to how to handle a suspected foodborne illness outbreak or product recall. The genesis of a recall adds its own unique challenges. A company that identifies a potential contamination problem through regular quality/safety testing and rapidly issues a targeted recall is in a much different position than a company that is caught up in a commodity wide recall due to a public health investigation. Since a company's brand and consumer confidence is on the line every time its recall and crisis management plan is called into action, efforts to further strengthen such plans are worth considering. A robust supply chain verification program is one such approach that is consistent with the FDA's Food Protection Plan.

Supply Chain Verification

All food system companies employ some level of quality assurance and supply chain verification—from HACCP plans to a bill of lading. Fewer companies, however, go beyond the one-step forward, one-step back record keeping required under the 2002 Bioterrorism Act to require source identification, quality assurance, food safety, food defense, and related requirements from retail to the farm. Having standards is a step forward, ensuring that those standards are consistently met is what supply chain verification really means. At its core, supply chain verification can be thought of as management by objectives brought to bear on a company's supply chain. The objectives are relatively straightforward:

- All ingredients or products are as intended, with no accidental, intentional or economic adulteration.
- Ingredient or product handling, transportation and processing maintain product quality and safety.
- Every product or input can be rapidly traced back to its source.

These may sound like "food system for dummies" requirements, but it is how the objectives are translated into sensible and verifiable measures of system performance that they form a more robust approach to crisis prevention and preparedness. The extent that a food firm can drive these objectives and, importantly, the performance measures, all the way through their supply chain will dictate how prepared it is to prevent, and if necessary respond to, accidental or intentional food contamination.

Avoiding Adulteration

Wheat gluten, sunflower oil and infant formula economic adulteration events illustrate how quality standards can apparently be met while still exposing consumers to potential risk. The wheat gluten contamination is a particularly challenging example as the product still met the protein content quality standard because the method generally used is an indirect measure of protein content. The Kjeldahl method specified for apparent protein content measures total nitrogen, so the melamine contaminant enabled the product to meet that standard to the economic gain of the supplier. In some cases, this type of contamination can be anticipated by prior events, but having a quality assurance test protocol that verifies the absence of anything that isn't supposed to be there isn't realistic. Until a "Star Trek Tricorder" is available, having the user of the product verify that their supplier is operating in a manner that will yield the desired product is the only reasonable approach. This includes objective measures of food quality and safety, but it is not limited to those.

Third-party inspections/audits are invaluable, but not infallible. If a retailer requires the supplier to undergo unannounced third-party audits, they may very well catch any issues before they cause a problem. If that supplier, however, receives input material that is adulterated, then the audit might not find it until the product has quality or safety issues in the marketplace. One frequent concern with audits is their proliferation rather than their absence, with firms having to undergo multiple audits to meet customer demands. There are efforts underway to come up with coordinated approaches to supplier auditing to help reduce the burden of audits while increasing their utility. Examples include the Global Food Safety Initiative (GFSI) and GMA-SAFE. Participation in these programs will need to increase, however, to meet consumer expectations on the safety of the food supply while also managing the cost of audits given that GMA-SAFE includes 2,103 plants (five inspected in 2007) and GFSI membership is at 415 companies, with only three in China and over 150 of them retailers.

For something like the wheat gluten contamination, periodically conducting more detailed product analyses could also be part of the program. This is especially true if there is information indicating that there have been problems with that supplier or that type of product in the past, as was the case with the contaminated wheat gluten. It may also be appropriate to conduct more detailed product analyses if supply situations require sourcing a product outside of a company's normal supply chain.

Photo courtesy of Getty Images.

Preventing System Failure

The Castlebury, Cadbury, and Peter Pan foodborne illness events are examples of product processing failures leading to consumer illness. These represent a different type of challenge in that a supply chain verification program, even with third-party inspections and related food safety performance requirements, may well not uncover the issues until the product is already in consumers' hands. From what has been made public of the three events, the challenge here was accepting results from quality assurance as being still quality product, when in fact there was enough unusual data to suggest that a more detailed investigation for potential food safety problems was warranted. When a system is at that point— it has already failed and the consequences are just waiting to roll in. If neither the company nor their supplier emphasizes the importance of food safety and the need to invest in it, efforts are unlikely to yield acceptable results.

In some cases, part of the problem is the cost and reputation penalty of dealing with what may appear to be minor processing or related problems. To borrow from Rudy Guliani's approach to crime reduction in New York City, if you focus on and fix the small problems that occur regularly (broken windows), you can reduce the possibility of bigger problems in the future (felony crimes). An active supply chain verification program is similar—by identifying and resolving the small quality or other issues that occur randomly, the overall supply chain is increasingly strengthened to avoid food safety issues. These actions also improve the company's ability to avoid or respond to food defense concerns. While there is always going to a cost associated with an actively managed supply chain verification program, it may often be offset by more favorable insurance rates. More importantly, its utility in allowing a firm to more rapidly respond to an event will reduce the much larger costs associated with an accidental or intentional contamination that does get through. Maple Leaf Foods estimated that the recent recall due to *Listeria* contamination was going to result in direct costs to the company of over $20 million. The shareholder costs are even greater with its stock price having dropped by over 20% by the end of August since the announcement of the recall, a shift of over $200 million.

Rapid Traceability

The complexity of the recent tomato and pepper recalls and tracebacks demonstrate the challenges in rapidly tracing back certain food items given the nature of the supply chain. The current food system has been optimized for cost, quality and availability of items year round, including things that are either not available year round or are not naturally available. In these cases, systems that enable a company to rapidly reach as far back in the supply chain as is necessary need to be developed. Some companies have already developed systems to allow traceability for certain commodities all the way back to the farm, but there is a cost associated with such approaches and for some items, it isn't practical. In those cases, supply chain verification may include conducting mock recalls to ensure that, in case of a problem, every participant in the supply chain is able to communicate quickly to get the information from farm to end use.

It is important here, however, to make a distinction between the ability to identify a product or ingredient and recall it and the ability to traceback the source of a foodborne illness outbreak. Outbreak traceback to the food that is the vehicle for the pathogen starts with the uncertainty of the patient interviews and the case control investigation conducted by public health officials. If the bag of spinach associated with an ill person is in their refrigerator, the specificity of the product code on the bag can make both traceback and recall happen quickly. If the only thing that the epidemiological investigation can confirm is that it was ground beef, then the traceback is at a roadblock and the recall choices facing the company or agency are recall everything, or in some cases effectively recalling nothing since there often isn't any implicated product left in the supply chain by the time the investigation has hit a dead end.

Looking Forward

Supply chain verification isn't a new concept, but it is more relevant in today's food and agriculture system than ever before. As the food system continues to globalize and supply chains continue to optimize, being able to verify the reliability of the supply chain back to agricultural inputs is perhaps the most cost-effective way of ensuring the quality and safety of the products that we eat. Because of the constantly evolving and innovating food and agriculture system, a flexible concept like supply chain verification has a better chance of meeting the needs of the consumers than new regulatory frameworks. Efforts such as the GFSI are one approach to drive toward the goal of a reliable food safety system in a cost-effective manner by reducing the cost of maintaining an effective third party audit system but much more work is needed. New technologies and new supply chains will present both opportunities and challenges, but since the consumer no longer can realistically know every farmer, supply chain verification is here to stay.

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To Solve Contaminated Food Crises, Information Management Is an Unsung Hero for the Food Supply Chain

BY SHAKIRUL ALOM

Each year, the U.S. Centers for Disease Control and Prevention estimates 48 million people in the United States alone get sick from contaminated food,[1] and data from its Foodborne Disease Outbreak Surveillance System displays the alarming trend of outbreaks steadily increasing since 2001.[2] As a result of this impact, the U.S. Department of Agriculture (USDA) estimates associated illnesses tend to cost the economy more than $15.6 billion annually.

Following the introduction of the U.S. Food and Drug Administration Food Safety Modernization Act (FSMA) in 2011, it became increasingly important for food manufacturers and distributors to proactively ensure contaminants in the food supply are prevented. These types of regulations continue to undergo updates to ensure the purity of the food supply, such as FSMA's new guidance on food defense and adulteration, as well as the president's proposal to consolidate federal food safety under USDA.

Despite these stringent efforts, new food contaminations seem to happen every few weeks. To date, 19 outbreaks of *Salmonella* and *Escherichia coli* in 2018 have impacted fresh and packaged foods, the economy, and ultimately, lives.[3] In addition, allergens remain a leading cause for market withdrawals.

A common point of these contaminations stems from the distribution chain, identified post-outbreak through a comprehensive record review.[4] So, if regulations on the front-end of the food supply can't identify food contamination before it gets distributed to consumers, what can be done?

The answer is surprisingly simple—food suppliers must ensure they have an information management system in place that can comprehensively and easily track all records on the back-end.

Intelligent information management is especially crucial for food manufacturers and distributors to maintain high-quality products—as well as a good reputation and track record of trust with suppliers and customers.

Case in Point

At Farbest Brands, we've held this track record with our global network for more than 60 years. Our strategy to ensure food safety and quality is no different than any other organization in this industry—it's crucial for any supplier and customer to frequently endure mandatory qualification processes. Part of this process involves a thorough review of documentation—including product specifications, nutritional information, risk assessments, sensitized ingredients, product labels, and safety data sheets.

These resources must be readily available, especially depending on the amount and type of documents needed based on a supplier's risk level. After all, food manufacturers and distributors aren't only in the business of food ingredients—we're also in the business of information management to maintain our core principles of quality, truth, and service.

Throughout the industry, it's not uncommon to track documents and business processes manually in a spreadsheet, with files saved across multiple network folders. Remember, contamination stems from the distribution chain. If documents, resources, and processes aren't easily accessible and referenceable, the challenges of ensuring food safety increase significantly.

At Farbest, we realized a more automated system was needed to manage the increase in the amount of documentation needed to meet FSMA's standards, as well as future standards with regard to food safety and quality. To solve this challenge, we identified workflow management as the most important element to ensuring quality products. This meant several crucial questions needed to be answered, including:

- Could any document be found easily, regardless of where it's stored?
- Could it protect sensitive information while being readily accessible to the right people at the right time?
- Can critical supplier qualification tasks be defined in a workflow, preventing the approval of a supplier until a complete evaluation has been performed?
- Can these review tasks be set to recur at defined intervals, to ensure that the supply chain is periodically (and thoroughly) reviewed?

With an intelligent information management solution implemented throughout our quality, documentation and product management departments, we've been able to process requests much faster

by gaining visibility to the process. There is now no need for us to maintain a separate spreadsheet on the process; we're able to get all requested, up-to-date information available into our customers' hands. For expiring documents, we have visibility into when they expire, and can take a proactive approach to renewing the information.

While workflow was our primary focus, other important information management elements weren't—and should never be—neglected, including security, automation, and reducing regulatory risk. These details can make or break your customer and suppliers' trust and should be carefully considered when thinking through organizing one's resources.

In short, you may be wondering, "Is proper information management the answer to preventing future food contamination?" While most recalls are a result of poor food safety practices that occur in the distribution chain, it's difficult to say it'll be fully stymied, especially following the food preparation phase. However, every food processing organization has the option to do its due diligence to protect the population from devastating nationwide foodborne illnesses. By implementing an intelligent information management system on the back-end to proactively and automatically handle time- and information-sensitive documents for suppliers and customers, we'd all be one step closer to saving the food industry, economy, and, most importantly, lives each year.

Illustration courtesy of Getty Images.

Shakirul Alom *in the Quality Assurance & Compliance manager for Farbest Brands.*

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Creating a Paper Trail That Works

BY JOHN E. RUSHING, PH.D.

As the practices of food safety and food regulation move into a new era, we can expect to see changes in many of the things we now do as a matter of course. While many government committees are attempting to hash out these changes, it is difficult to predict what the new requirements will be. However, one thing is for sure. Processors will be even more dependent on accurate and properly maintained records and documentation for all parts of their operations.

In addition to the usual records maintained by any enterprise, many other types of records and documents are maintained in a food processing operation. Some records are the documentation of standard procedures and some are records of testing, while other records document the history and disposition of products and ingredients. There are still other records that are specifically required in government regulations, and others that are implied by requirements to comply with certain procedures.

Records, Records Everywhere

While the variety and types of records can vary considerably depending on the kind of food processing operation, records can be grouped into several different categories and range from the simple to the complex. Records development can be as simple as reviewing and logging or filing incoming documents, such as supplier guarantees, or certificates of pest control treatments. Some records are automatically generated by equipment, such as in the case of temperature control charts or tanker wash charts. Management also produces and requires records, as in assignment of duties. Other records may document calibration of equipment or the results of tests required for quality control. We maintain records of processes and registration of facilities.

With all these documents for so many purposes and from so many sources, it is necessary to have a record control plan. Recently, a good friend let me in on his record control and retention plan. He said, “I just never throw anything away.” Everyone seems to have had the experience in which they have discarded something seeming unimportant just to need it shortly afterward. So, how best should organization be handled to maintain an effective record control plan? Not being an expert in this field, I canvassed several sources to glean basic rules and found some consensus in formulating a plan:

1. Have a specific purpose for every record your company generates or for each document it collects.
2. Realize and plan for some records that have only short-term value or usefulness, while others are to be maintained for extended periods.
3. No document should be filed without review to make sure it is complete and any action required to complete its purpose has been initiated—and documented, of course.
4. Records do not always need to be printed or copied. Electronic retention often fills the bill.

5. Electronic records must be backed up and protected from unauthorized changes.
6. Related records, for instance all ingredient, processing and shipping records for a particular batch or lot, must have a method for linking them together. Give each record and document generated by your company, a unique name and a form and version number. All documents produced should be dated.
7. A record retention plan should be formulated and address all records that are maintained by a company.

Whatever the type of record, filing and maintenance should be in accordance with the company's record control plan to ensure they can be easily stored, identified and retrieved. Each record should have a unique title, should be dated, and should identify who completed it. There should be space to record the lot or batch number, time, appropriate data, comments or corrective action, and verification by a representative of management.

Records and Recalls

With all the rules and suggestions above, an obvious question is, "How do I know that my record-keeping is effective?" It can be a sobering experience when a recall is announced by a company for a few defective lots initially but then is very quickly expanded due to inadequate records documenting ingredients, processes or lots. This can result in a devastating, and probably unnecessary economic hit to a company.

Since recalls test a company's recordkeeping in a very profound way, a "mock recall" is a common tool used to test the effectiveness of the company's recall plan and the effectiveness of its record-keeping system. The mock recall is an exercise which assumes a recall of a particular item or group of items based on an ingredient or processing deviation. This exercise can either be a "tabletop" exercise for a particular lot, or a full-blown test of the system with a large number of key employees involved.

Kinds of Records

In general, records should be maintained that document a processed food's safety and compliance with the regulations. In addition, records should be maintained to assist in decision-making about particular lots of products and ingredients, such as might be needed for a recall.

What follows is an attempt to classify records by type in such a manner that a processor could use this information to help decide the breadth of records that should be maintained for his particular company. The following is a list of typical records needed:

Registrations. Documentation of registrations with government agencies or other process authorities is useful when a company is required to show proof of registering for mandated programs. These may include:

- Copy of the facility's registration under the Bioterrorism Act
- Copy of establishment registration with FDA (required for low acid and acidified foods processors)
- Copies of filed processes and letters from the process authority (required for low acid and acidified foods processors)
- Copies of supplemental processes from equipment manufacturers to supplement the filed processes

Management and Personnel. It is critical to maintain updated records pertaining to employee qualications, certifications and chain of command responsibilities, including:

- Documentation which clearly assigns compliance with the regulations to qualified supervisory personnel
- Records of assignment of qualified supervisor(s) for overall sanitation of the plant
- Records of training for supervisors and employees which document competency to identify sanitation failures or food contamination
- Certificate of supervisors' successful completion of Good Manufacturing Practice (GMP) schools under 21 CFR 108 (required for low acid and acidified foods processors)

Procedures. These types of records form the bulk of the basic documentation from an operations standpoint:

- Personnel procedures for hygiene and proper food handling
- Cleaning and sanitizing procedures
- Quality control procedures
- Allergen control procedures
- *Listeria monocytogenes* control plan
- Recall procedures
- Hazard Analysis and Critical Control Points Plan

Supplier Guarantees. A product's life cycle through the supply chain should be documented to enhance traceability in the event that a contamination problem arises, and should include records for:

- Raw materials, packaging materials and ingredients
- Cleaning and sanitizing materials
- Records of pest control measures and treatments
- Water safety and testing documentation
- Boiler and gasses indirect additives

Quality Control and Testing. With increased demand for test results that document that quality control measures are effective, the list of possible records is lengthy and will likely include one or more of the following:

- Records documenting compliance with written procedures
- Measuring instrument calibration records
- Records of inspection of incoming raw materials, packaging materials and ingredients
- Records of sanitation testing and allergen testing
- Records of testing for aflatoxin and naturally occurring toxins (if needed)
- Records of testing for unavoidable defects (if needed)
- Records of inspection and control of physical hazards
- Records of validation of preventative controls
- Monitoring of final control parameters such as pH and A_w

Production. These day-to-day records must be updated and maintained with as much accuracy as possible:

- Batch control records identifying ingredients
- Records of batches, lots, and coding
- Records of in-process controls of critical parameters, including storage temperatures
- Records of reconditioning and rework
- Distribution records
- Pre-shipment or pre-distribution records verification
- Non-carrier source of ingredients and transport records
- Transportation and initial distribution of finished product

While this is neither an exhaustive list of records that might be required under federal regulations, nor are all the records listed required to be maintained in all circumstances, this list gives processors a guide to evaluate what kinds of records should be maintained in light of their particular operation.

Some Other Rules to Consider

Data should be recorded at the time the observations or measurements are made. The person producing the record should certify this record with their initials or signature, and the record should be reviewed before the product leaves the control of the facility. Files of records should be stored for ready access. Records of perishable products are usually maintained for one year after the end of shelf life, nonperishable products for two years, and records of acidified and low-acid canned foods for three years.

Good records can be one of a company's greatest assets—like a friend in times of need. Inaccurate or incomplete records can only be a liability and lead to problems. As the regulation of this nation's food supply continues to move toward increased documentation, sound record policies and accurate records will take on an increased importance to food processing companies.

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Managing Risks in the Global Supply Chain

BY DAVID ACHESON, M.D., F.R.C.P.

The supply chain for food and beverage companies has grown to be truly global and interconnected. To offer customers exciting new flavors, products, and ingredients, many businesses have expanded their geographic reach of sourcing ingredients and materials.

Entering into this vast network of different suppliers means companies could be opening themselves up to more risks. The U.S. Food and Drug Administration (FDA) recognized these complexities and possible problems in the supply chain when developing the Food Safety Modernization Act (FSMA). As a result, regulators are now requiring companies to take increased measures to ensure the safety of their food.

However, food and beverage businesses still must control costs to stay competitive, making maintaining the efficiency and performance of their supply chain also crucial. The entire end-to-end process must be strategically planned and systematically managed with an acute emphasis on mitigating any risks from suppliers. The following are some best practices food and beverage companies can use to better protect themselves from any food safety and quality incidents.

Identifying Supply Chain Risks

Companies must start with evaluating their current processes to manage supply chain risks. For instance, are audits relied upon to verify their suppliers have appropriate food safety practices in place? Or are second- or third-party audits conducted? Is the testing program in-house? Are certificates of analysis (COAs) relied upon? Where and how is that information collected and tracked? What departments and staff are in charge of the supply chain—R&D, finance, operations, QA, etc.?

Taking a critical look at supply chain management will not only allow risks to be identified but will also unlock the ability to differentiate which risks have the greatest potential impact. Oftentimes, food and beverage companies wonder whether they should devote more resources to managing high-risks areas than low-risk areas, and the answer is yes. Nearly everything food companies do today must be risk based.

FSMA and Supply Chain Control

Because FDA recognized that supply chain control is critical in terms of managing food safety risks, it developed two key rules under FSMA to address this area—the Preventive Controls rule and the Foreign Supplier Verification Program (FSVP).

Food and beverage manufacturers subject to the Preventive Controls rule must assess supply chain risks and then verify that the risks are being controlled. If it is determined that the supplier is responsible for controlling the risk, the purchasing company must be able to verify that the supplier is doing so effectively.

FSMA's FSVP is very similar to the Preventive Controls rule, with the exception that it shifts the burden of ensuring safe food to importers. It is therefore FDA's expectation that importers will have assessed

risks in the supply chain and subsequently have verified that risks are being controlled.

While these rules are conceptually simple, many companies still face confusion around their implementation. Here are some steps that will help ensure companies are compliant with the regulations:

1. Perform a Hazard Analysis: Look at hazards presented by the materials sourced in all three areas: ingredients, products, and packaging.
2. Evaluate the Risks: Identify the types of risks posed, including whether they are microbiological, chemical, or physical. The next step is to identify who is responsible for controlling the risk: the supplier, the processor, or the end customer. FSMA requires a letter of assurance from any customer assuming responsibility for controlling the risk.
3. Supplier Verification: If it has been determined that the supplier is controlling the risk, this will need to be verified.
4. Use of Approved Suppliers: FDA can request to see companies' lists of approved suppliers and the method used to select and approve suppliers.
5. Corrective Actions: If there is a problem with a supplier, corrective actions must be carried out appropriately and thoroughly documented.
6. Build a Program and Keep Records: Detailed recordkeeping

is a common theme across many aspects of FSMA, so confirm that records are updated regularly and are well organized.

Developing a FSMA Approach to Risk Management

When beginning a practical implementation of a FSMA approach to supply chain risk management, create a list of all ingredients used as well as products and primary packaging. Next, perform a Hazard Analysis and document the results in records that can be presented to FDA. Finally, assign responsibility to who will control the risks identified.

To begin a supplier verification program, compile a list of all suppliers and their manufacturing sites. For all Class 1 risks being controlled by the supplier, an onsite audit will be needed from each site sourced. Many companies rely on third-party audits to satisfy this requirement, but proper documentation should be put in place.

Because Global Food Safety Institute (GFSI) standards are well-aligned with FSMA, GFSI certification appears to satisfy FDA requirements. If an onsite audit for Class 1 risks is not able to be conducted, documentation will be needed of the explanation for this as well as how the risk will be controlled through an alternative method, such as a testing program.

Some companies use COAs to control other risks from their suppliers, but accurate understanding of each COA is necessary. If an ingredient poses a high risk, make sure the COA is strong and reliable. For instance, is the testing method an approved one? Does it test adequate amounts of the product? Is the lab that is being used an accredited one? While it is not necessary to look at COAs quite this closely for every ingredient, be sure to do so for those deemed most important.

Assessing Existing Suppliers

Not all suppliers present equal risks. How, then, should these risks be evaluated? Companies must first determine which risks are most significant and then dedicate the most resources on the areas of greatest risk. There are multiple factors that can impact risks, which can be categorized into three main areas:

1. Ingredient Risk: This refers to the inherent risks posed by the ingredient itself, including a recurring history of problems, country of origin, and so forth.
2. Supplier Risk: Supplier behavior, including the degree to which they control risks, should be factored into the risk assessment.
3. Use of the Ingredient: Ingredients used in all products versus a select few pose a higher risk. Likewise, the ingredients used in high-profile products—or most associated with a company's brand—should also be considered a greater risk.

Next, companies should begin to rank supplier risks by collecting information about their qualifications and certificates, onsite audit results, any prior history of problems with the supplier, and regulatory actions.

Then, understand how and where an ingredient is used in the product production process. How many products are affected by this ingredient? Are these flagship products or strongly linked to a brand identity? What is the financial impact of a recall? All this information will help define the risk-based strategy of a food and beverage company.

This ranked risk approach allows companies to not only protect themselves, but optimize resources. The same amount of

resources can't be used to prevent risks for every supplier and ingredient. However, identifying which entities pose the greatest threats will help ensure risk management dollars are truly being spent based on an accurate and thorough risk assessment.

Working with Suppliers

To some extent, the effectiveness of your supply chain management lies in the ability to collaborate seamlessly both externally with the supplier as well as internally. When new products are in development, make sure that all teams involved are collaborating to ensure that potential risks are identified proactively—not reactively. This may mean that in addition to R&D, procurement, and supply chain personnel, a food safety manager might also need to be involved in the early phases of product development. The company must understand both the ingredient risk and the supplier risk. If it is deemed that the ingredient poses a high risk, it may require a change or a new process for controlling risks.

One area in which many companies fall short is tracking the performance of existing suppliers. The emphasis is typically on innovation—which is why new suppliers are so thoroughly vetted—but to ensure safety at every level of the supply chain, companies must also monitor current suppliers.

Develop a process to track and trend performance data, which could include timeliness of deliveries, how well specs are being met, COAs, corrective actions, and so forth. Keep thorough records and analyze them frequently to look for warning signs that a supplier's performance needs to be addressed.

While transitioning supply chain management activities towards a more risk-based approach may require an initial investment of time and effort, it will help companies take a more proactive stance on food safety. As a result, it could be the very activity that helps a brand succeed even in the face of increasing supply chain complexity.

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