PACKAGING WORLD

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education for packaging professionals

2015-2016 EDITION

FOOD SAFETY PLAYBOOK

BEST PRACTICES FOR SAFE PACKAGING AND COMPLIANCE WITH GLOBAL STANDARDS AND FSMA, THE U.S. FDA'S FOOD SAFETY MODERNIZATION ACT

- Exclusive survey results on food company compliance
- Where to find and control hidden packaging risks
- How to automate food safety from plant to supply chain
- Tables, downloads, and management planning resources

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Special thanks to these industry organizations for their contributions:

FSAP FOOD SAFETY ALLIANCE FOR PACKAGING

Institute of Packaging Professionals

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We gratefully acknowledge the expertise of these supplier contributors: EtQ, Inc., GE Intelligent Platforms, and Safety Chain Software

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Expert advice—from incoming materials to packaged goods

BY BOB SPERBER,
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Packaging World
Food Safety Playbook

As this updated and expanded edition of the *Packaging World* Food Safety Playbook goes to (electronic) press, the U.S. Food and Drug Administration (FDA) has finalized rules on pieces of the Food Safety Modernization Act (FSMA). These include facility registration; hazard analysis and risk-based preventive controls; accreditation of third-party auditors and labeling. Additional, proposed rules are subject to rolling deadlines stretching out through May of 2016.

"All told, an estimated 57% of the law's provisions are in effect, depending on where your company lands, risk-wise, in the farm-to-fork food chain," says William Kanitz, president of ScoringAg, whose global database tracks agricultural and food safety compliance.

Rather than implementation dates, however, the goal of the Food Safety Playbook is to foster industry compliance with all likely scenarios. Toward that end, we're pleased to report that our panel of food safety experts has returned to offer updated insights for this new e-book edition. These include **David Acheson,** former FDA "food czar," whose work has served as the basis for significant portions of what has become the FSMA; **Wynn Wiksell** of General Mills and ex-chair of the Food Safety Alliance for Packaging (FSAP); **Jeff Barach, Ph.D.**, FSMA expert, leading advisor to industry organizations, and developer of FSMA training materials; and attorneys **Elizabeth Fawell** and **Eric Greenberg**, who return

continued
Expert advice—from incoming materials to packaged goods

with updated articles on working with packaging suppliers and complying with FDA laws. Additionally, industry veteran and consultant **Gary Kestenbaum** joins our virtual panel with critical news of a chronic documentation shortcoming that you'll want to address "ASAP."

Significant updates to this Playbook include all-new articles, from those written with industry input from food company and supplier experts, to the results of our survey of food companies on their FSMA compliance, and a new section of articles on IT and automation strategies to help you in your compliance efforts, from sensor to supply chain.

What impact does the law have on you?

If your company is like most, you're already compliant with much of the law, even in its present work-in-progress form. Because even with its broad, new oversight powers, the FDA has been crafting the law with industry input and based on standards and practices already in place.

The most obvious example is Hazard Analysis & Critical Control Points (HACCP), a cornerstone methodology of today's food safety standards, introduced in the 1960s when Pillsbury used it to supply meals for the first manned U.S. space flights. Standards built upon HACCP matured further in 2008, when mega-retailer Walmart announced it would require suppliers to be certified by a safety program accepted by the Global Food Safety Initiative (GFSI). As other large retailers followed suit with similar requirements, such food safety standards, while technically voluntary, became requirements for all food and beverage manufacturers and marketers seeking entry into the mainstream.

continued

Expert advice—from incoming materials to packaged goods

Now, practices set down by such standards don't just seem to carry the full force of law; they're becoming law. This will most affect less-sophisticated companies operating without sophisticated food safety management programs, or serving customers who themselves lack such standards.

It's important to note that FSMA's goal is to create a level playing field for all companies by weeding out potential "bad-apple" operators and not overburdening smaller operators. As one company told us, "We are a small manufacturing facility, so implementing the new rules will not be a more time-consuming effort than an actual procedural process...we've been doing 99 percent of these 'new rules' forever."

While FSMA may be a catalyst for significant reassessment and shoring up of your existing systems, it's likely that your company is like most, and your compliance effort will go smoothly.

This document can help in that effort. The insights in these pages are designed to be read on-screen or printed out and—above all—shared with others on your cross-functional food safety team. Additionally, at the bottom of every page you'll find buttons to forward and/or add a comment to ease that sharing.

Simply put, we hope that your reading, referencing, and sharing insights from this e-book will contribute to your food safety and compliance success. ◆

FOOD SAFETY PLAYBOOK SURVEY 2014

FSMA compliance soars for those who meet existing standards

Survey Methodology
To gather responses for this *Packaging World* Food Safety Playbook survey, we sent three e-mail invitations to professionals with packaging-related purchasing or decision-making influence at U.S. food and beverage facilities. The survey was conducted in the first quarter of 2014. Respondents who identified themselves as working for suppliers, or companies in any other industry, were filtered out of the survey, resulting in a net total of 38 qualified readers completing the survey.

New industry regulations can be the source of fear and trepidation, particularly in the case of the U.S. Food and Drug Administration's Food Safety Modernization Act (FSMA), for which many details and guidances have yet to emerge.

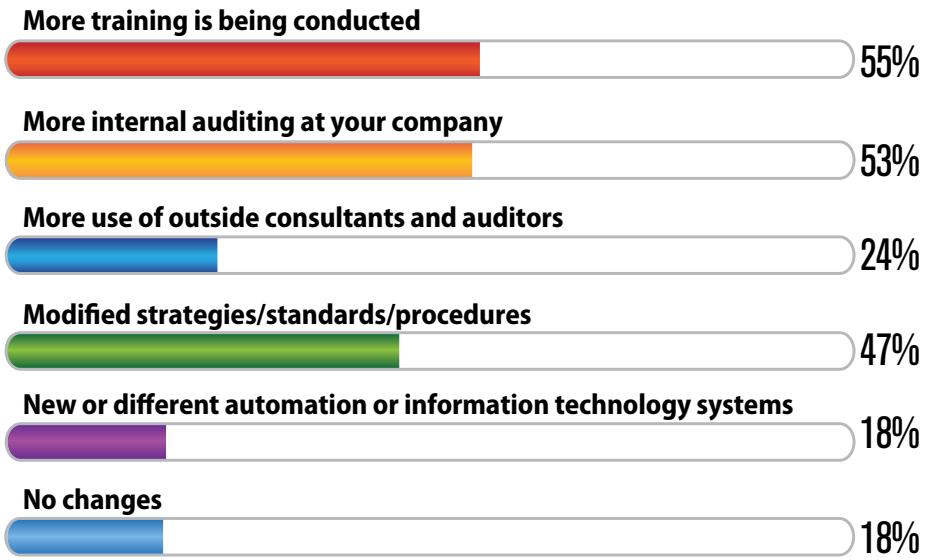
Still, in the first quarter of 2014, when we surveyed production and packaging professionals at U.S. food and beverage facilities, the results painted a more optimistic picture of industry compliance. A large majority reported that they have already completed the law's key requirements. And an overwhelming majority incorporate packaging into their food safety plans, or will in the coming year despite a historic paucity of specific standards or compliance tools to aid in this effort.

The findings, while representing only a snapshot of a cross-section of companies, echo this view by industry experts: The FSMA, while a catalyst for reviewing food safety management practices, is consistent with existing market requirements, and should not cause management or operational upheavals for firms that already follow accepted food safety standards and procedures.

continued

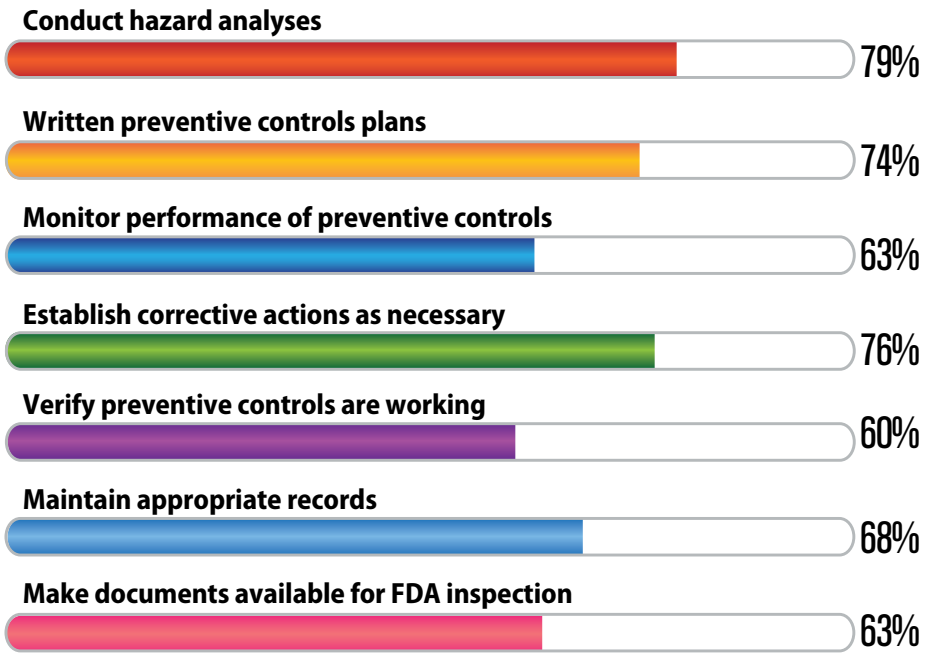
FSMA compliance soars for those who meet existing standards

Effects of FSMA on food and packaging safety



FOOD SAFETY TRAINING AND INTERNAL AUDITING activities have risen for a majority of food companies, albeit a small majority. Likewise, a large majority have modified their overall food safety strategies, but this does not translate into a significant rise in the use of outside consultants or upgrades to automation or IT systems that may improve track/trace and enhanced recordkeeping as the industry awaits the emergence of final provisions and guidance documents.

Level of completion for major FSMA requirements

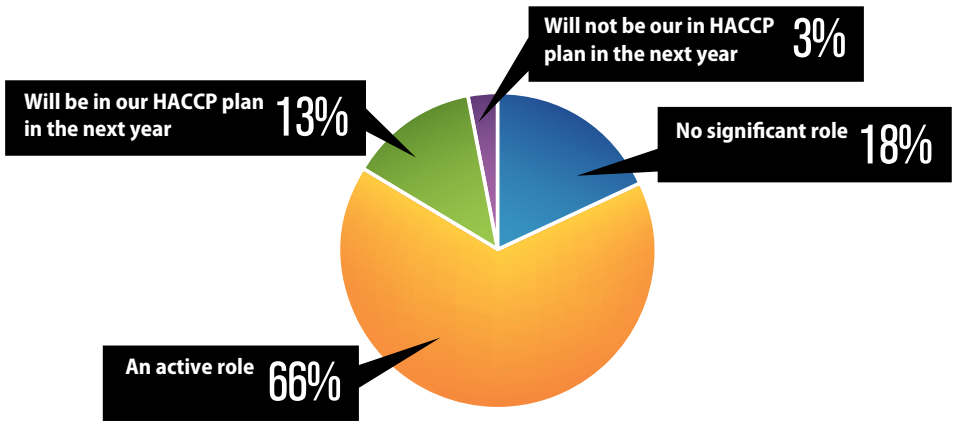


A HUGE MAJORITY OF COMPANIES report full completion and implementation with the seven major requirement areas of FSMA as summarized by the Grocery Manufacturers Association—first and foremost in the areas most deeply embedded in the industry's long-standing practice of Hazard Analysis & Critical Control Points (HACCP) programs. While a strong majority reports compliance across the board, areas for additional activities tend toward "meta" considerations involving verification, validation, and recordkeeping.

continued

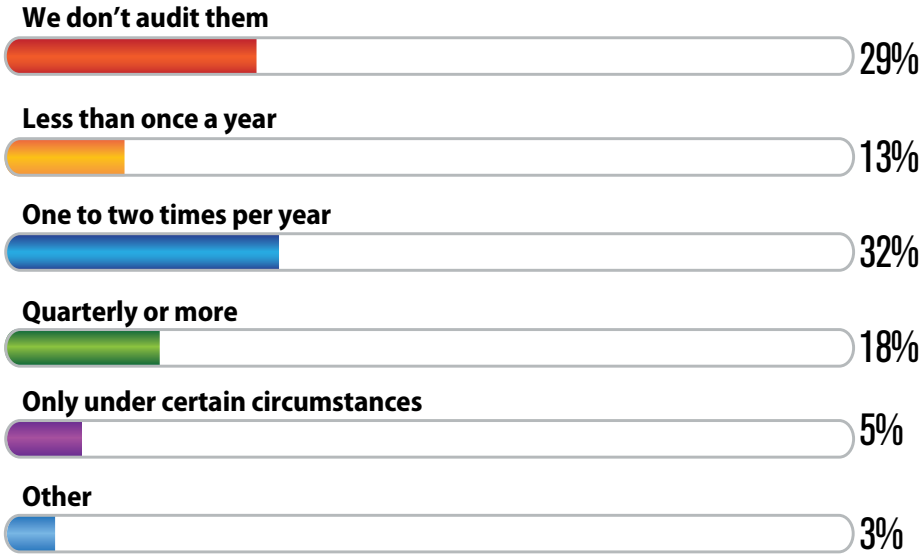
FSMA compliance soars for those who meet existing standards

What role does packaging play in your HACCP plan?



DESPITE A HISTORIC PAUCITY OF GUIDELINES and standards specific to packaging materials, it's somewhat surprising that nearly 80% of respondents indicate that packaging considerations are already part of their HACCP plans, or will be in the next year. While general standards lack specificity, standards such as IFS PACsecure and organizations such as IoPP's Food Safety Alliance for Packaging are addressing them, and equipment sanitation can follow guidelines for processing equipment. (All of these are addressed in this Playbook.)

How often do you audit your packaging material suppliers?



FOOD PACKAGERS ARE HELD RESPONSIBLE for risks stemming from hazards caused by their suppliers. Most respondents report having some form of plan in place to audit their packaging material suppliers in accordance with FSMA and standards. This area is likely to get a closer look and will likely become more clear as standards and FSMA mature.

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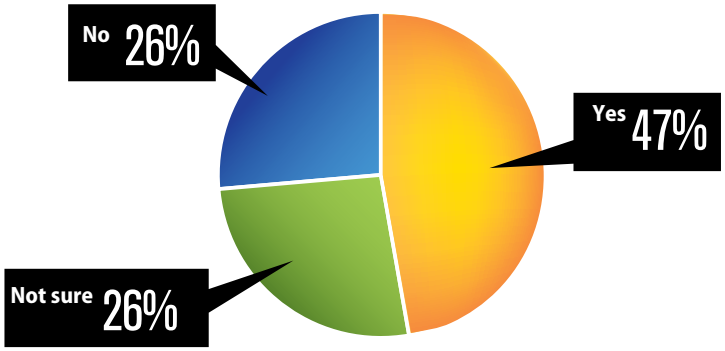
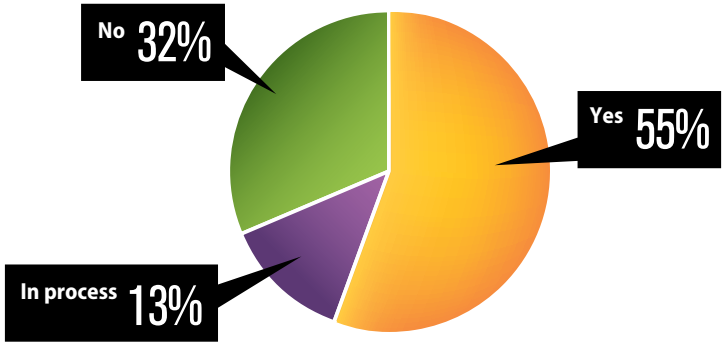
FSMA compliance soars for those who meet existing standards

Will FSMA spur more frequent packaging supplier audits?



NEARLY HALF OF RESPONDENTS EXPECT an increase in the frequency of packaging supplier audits under FSMA. Besides regularly scheduled updates for recordkeeping purposes, supplier audits may be triggered by changes in packaging, in supplier practices, or in the food or beverage company's own risk analysis or assessment practices.

Percentage of facilities certified to a GFSI-accepted standard



WALMART DECLARED IN 2008 that it will require suppliers to be certified by a safety program accepted by the Global Food Safety Initiative (GFSI), such as the predominant U.S.-based Safe Quality Foods Program (SQF). That declaration, echoed by leading retailers worldwide, has had the practical force of law. FSMA will carry the actual force of law, and is particularly targeted at those who do not follow GFSI.

Recordkeeping is key to the new era of prevention

BY DR. DAVID ACHESON
President and CEO,
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In addition to his role as CEO of The Acheson Group, the author has served as Associate Commissioner for foods at the U.S. Food and Drug Administration and as Chief Medical Officer for the FDA's Center for Food Safety and Applied Nutrition.

A primary goal of the Food Safety Modernization Act (FSMA) is greater prevention. While this has always been a general goal of food safety practices industry-wide, the new requirements are designed to mandate for all companies what many of the leading companies consider best practices today.

In doing so, the FSMA represents a major effort to establish a risk-based and global systems approach that takes prevention to the next level.

We now have seven proposed rules issued by the FDA, and one common theme among them all, aside from prevention, is the need to keep records. The FDA essentially has the approach that "if you didn't document it, you didn't do it." Thus, many companies will have to significantly upgrade their ability to document production, from processing and packaging to their and their partners' supply chain activities. Recordkeeping is central to food safety efforts and now the law. It leads the list of these aspects of the law implemented since its 2011 enactment:

- **Inspection of records:** These include manufacturing records; raw materials (ingredients and packaging) receipt records; product distribution records; product inventory records; test records; recall records; reportable food records; customer distribution lists; and records of complaints and adverse events. It is important to remember that the FDA has the authority today to look at records.

continued

Recordkeeping is key to the new era of prevention

The FDA has gained greater power to inspect records from manufacturing and raw materials (including packaging) through distribution and customer complaints.

• **Mandatory recall authority:** The FDA gained authority to mandate a recall, something it could only do for infant formula until FSMA. This would be based on a reasonable probability of serious adverse health consequence or death.

• **Authority to suspend the registration of food facilities:** This applies when food manufactured, processed, packed, received, or held by a facility is found to have a reasonable probability of causing serious adverse health consequences or death to humans or animals. This can effectively shut down a facility by halting imports or exports into the U.S. as well as domestic interstate or intrastate commerce.

• **Administrative detention of foods becomes effective:** The FDA can and already has put a hold, or Administrative Detention, on shipments using a new, lower threshold. Detention can now be based on a "reasonable belief food is adulterated or misbranded." Prior to FSMA, the standard was based on "credible evidence that food presents a serious adverse health consequence."

Additional items enacted in 2011 include an FDA Food Defense Mitigation Strategies Database; authority to require import certificates; passing of an Interim Final Rule on Criteria for Administrative Detention; and an FDA/Department of Homeland Security Joint Anti-Smuggling Strategy.

The 2014 agenda is ongoing, with comment periods still open for some of the proposed rules, but it is closing fast. We can anticipate some portion of preventive controls to come around later in 2014 for another round of comment, but we need to be looking toward mid-2015 for all these proposed rules to be final.

continued

Recordkeeping is key to the new era of prevention

The Foreign Supplier Verification Program (FSVP), an all-new consideration in the area of preventive controls, is going to have a massive impact on food companies and their suppliers, which will have to keep records that demonstrate control of risks in order to gain entry to the U.S. market.

Traditionally, FDA regulators have focused on maintaining the safety of spot-checking food from any of more than 250,000 global sources as it arrives at a port of entry. But they inspect only about 1% of foods, and have cause to actually test only a fraction of that. The FSMA now shifts the burden from the regulator trying to catch the "bad stuff" to the importer to take responsibility for demonstrating that the food was produced safely and in compliance with the law.

The need for better documentation

The need for greater FDA access to records is illustrated by an outbreak of botulism several years ago, when botulinum toxin was found in canned chili produced during two days on two of 12 cooking lines. At the time, the FDA had authority to request records for only the two lines in question on the two days the botulism was tested and found present. The FDA then had to invoke laws from the Bioterrorism Act, and this led to a much larger, massive recall of that and another canned product, because the FDA didn't have jurisdiction to inspect records for another product produced on the same lines during the same work week.

Just as with domestic product tracking requirements, global supply chain realities are driving the need for better preventive controls by importers. The deliberate export of melamine-tainted pet food, which resulted in several animal deaths in 2007, illustrates this need. This event was a game changer that drove this need, because if this event were to happen again, this time in products for human consumption, such an incident could be catastrophic.

continued

Recordkeeping is key to the new era of prevention

While companies will be subject to considerable documentation requirements under FSMA, many of the requirements are already being met, including the "one-up, one-back" product tracking standard many companies practice in meeting their large retailers' requirements. But there is no doubt that the new, mandatory requirements will be a challenge for many companies in the high-volume, low-margin food industry.

Traditionally, the industry has done everything possible to deal with outbreaks and recalls, but there are limits to what is practical and affordable. The cost of a product tracking solution, however, is difficult to know; it will be largely determined by a company's current

Implementing a food safety plan under FSMA requires continual documentation of ongoing activities, which enhances a company's preparedness to minimize the impact of a food safety incident.

level of risk and what kind of product tracking it already has. An automated system might cost $10,000 or hundreds of thousands of dollars. At the same time, the law does not mandate automated systems.

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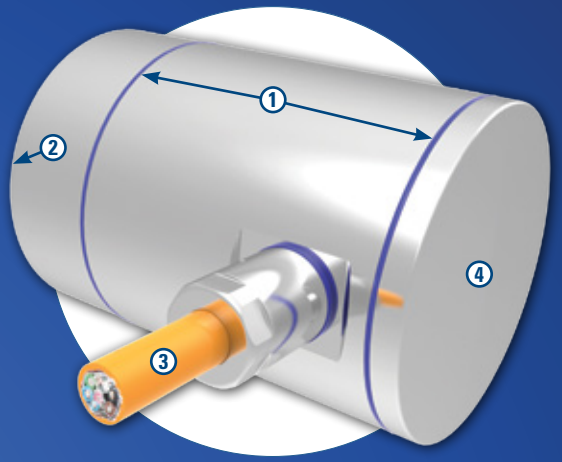

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continued

Recordkeeping is key to the new era of prevention

One of the new proposed rules is on third-party audits. For for the first time, the FDA is establishing a program to use data from third-party audits. There are strict requirements for accreditation of auditors, and there is some direct reporting of findings to the FDA. But this is a major change for the regulators, and is appropriately leveraging private-sector auditing capabilities.

By keeping records, and knowing when a process deviates to threaten not just quality, but also safety, companies that lead in compliance can quickly identify and destroy product if needed, protecting the public and significantly reducing financial risk.

Complying with FSMA's data collection and documentation requirements will be a struggle for many companies, but the requirements will make it significantly easier for companies to reduce food safety incidents or at the very least their impact and scope should one occur. This "carrot" is far preferable to facing the "sticks" of noncompliance. ◆

Packaging-specific requirements for documentation, materials disclosure, and 'FDA Letters'

BY GARY KESTENBAUM
Senior Food Safety Packaging Consultant, EHA Consulting Group, Inc.

Kestenbaum brings 37 years of food and packaging experience from National Starch, General Foods, Kraft Foods, and EHA, where his consulting spans best practices, crisis management, technology, litigation, specifications development, and process/packaging safety.

Mandatory and effective procedures are at the core of every successful food packaging (and materials) safety program. In years past, less-stringent documentation standards were accepted as sufficient, because neither the FDA nor the vast majority of end users (food manufacturers) were focused on packaging, material safety, or collateral documentation. However, this has changed under the Food Safety Modernization Act (FSMA).

Large retailers require all of their food and beverage suppliers, and these, in turn, must require their packaging suppliers, to have significant programs in place that include detailed data documentation. Depending on the relationship, a partner at any point in the supply chain may require full transparency and disclosure.

Fortunately, the documentation, disclosure, and events that I've encountered over the years have led me to adopt the attitude that "there are always multiple ways to accomplish an objective." There is one constant, however: All information, including how it's captured and displayed for a particular item/event, must 1.) be clear so that all readers can make sense of it, and 2.) act as irrefutable documentation (and evidence) in the event of a crisis or question of quality, legal, or regulatory event.

continued

Packaging-specific requirements for documentation, materials disclosure, and 'FDA Letters'

The Packaging Materials Disclosure 'Checklist'

Solid communication between packaging vendors/suppliers and their food manufacturing customers is a primary element in attaining excellence in documentation. All vendors must be vetted for best practices, and as part of this, both vendor and customer must maintain detailed, comprehensive, and precise specifications. This includes having technical and procurement personnel collaborate to develop vendor/customer relationships that foster an attitude of disclosure, cooperation, and security.

Beyond good intentions, the packaging customer should spell out the expectations for the documentation and details the vendor should disclose. This is done in a Packaging Materials Disclosure Form (PMDF), or an equivalent variation of one that has been established. If written properly, the PMDF acts as a "checklist" for vendor disclosure. It is within the best interests of any end user to know who is manufacturing his packaging materials goods; where they are manufactured; whether the manufacturing facilities are audited and certified (and by whom); and to what extent the goods are certified and tested against meaningful standards, and validated as safe, suitable, and authorized for the intended use as food packaging.

Following disclosure of these basics, a comprehensive PMDF begins to ask specific questions that get to the heart of suitability and compliance with specific properties, regulatory compliance, and quality of an item. Areas for request of disclosure include material composition, allergens and additives, physical and chemical properties, and microbiological susceptibility. Sustainability, processing aids, handling, shipping, safety, and other categories also should be included in any PMDF.

continued

Packaging-specific requirements for documentation, materials disclosure, and 'FDA Letters'

Write a better Letter of Regulatory Compliance

Within the PMDF, an often under-considered document to be included in any vendors' disclosure to the end user is the "Letter of Regulatory Compliance," sometimes referred to as an "FDA Letter." By any name, this letter, whether you are the user or the vendor, is of high value to all—but only when properly written and validated. On the other hand, it can be a detriment when the letter is vague, inaccurate, or poorly constructed.

The key required deliverables in a well-written Letter of Regulatory Compliance are as follows:

- It must be written on vendor letterhead, dated, and signed by an individual with knowledge and authority to understand the details of that which is being certified.

- It must be addressed to the customer or converter.

- It must reference the exact material(s) or item(s) by name and vendor code that it is describing, as opposed to acting as a blanket statement representing multiple unspecified products.

- It must acknowledge the use type by the customer. Also, as a best practice, it should include the category of food system and manufacturing process as specified in applicable regulatory documents such as contained in the Code of Federal Regulations (21CFR), the Food Chemicals Codex (FCC), the United States Pharmacopeia (USP), or other reference documents embraced by the scientific and regulatory communities. To clarify "food systems" and "processing methods," consider:

continued

Packaging-specific requirements for documentation, materials disclosure, and 'FDA Letters'

A) Examples of food systems include non/high/low-acid products, emulsions, dry solids, bakery products, fats and oils, and others.

B) Examples of processing methods include high-temperature heat-sterilized, aseptic, hot-fill, cold-fill, refrigerated, etc.

• The exact names (generic at least; trade and generic both as best practices) of all layers, components, materials, processing aids, coatings, and additives must be listed separately in a table adjacent to the referenced regulation(s) or other applicable monograph number(s) under which the item is being certified for approval.

• Specific, unambiguous descriptions of limitations or exclusions from the certification.

• Specific, unambiguous descriptions of circumstances, limitations, or exclusions from any guarantees based on use, handling, or other actions specified by the vendor.

Often, vendors will include regulatory references in other "file" documents submitted to customers, including technical service bulletins, product data sheets, vendor specification sheets, and Material Safety Data Sheets (MSDS). It is wise for food companies to review these ancillary documents in the event that any regulatory references and use information could be in conflict with the regulatory letter. The need for food companies to do this should be obvious: In the event of a crisis where component or material quality or conformance is called into question, the vendor certifications and regulatory guarantees will be called into question and examined by many.

continued

Packaging-specific requirements for documentation, materials disclosure, and 'FDA Letters'

It is in the best interest of all involved that the customer clearly describes (with examples) the disclosure information required in the vendor letter of regulatory compliance. Of equal importance is to verify that the vendor is willing to make mandatory disclosures *in advance* of (you) testing and validating the packaging goods in order to avoid commercialization and sale of goods not supported by the detail required by your company's quality and food safety program. ◆

Food safety powers you might have forgotten about

BY ERIC F. GREENBERG
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The author, Principal Attorney of Eric F. Greenberg P.C., has been practicing food and drug law, packaging law, and commercial litigation for 31 years, is author of the pioneering Guide to Packaging Law, has contributed a monthly column for Packaging World magazine since 2006, and has been a prominent columnist and seminar/conference speaker since 1989.

Like a public relations rep for a forgotten celebrity, I sometimes find myself reminding people about the Reportable Food Registry (RFR). The Food Safety Modernization Act (FSMA) may be the latest shiny new toy in town, grabbing all the press, but the RFR continues to chug along, burdening the food industry with important and strict reporting obligations. The RFR was put in place starting in September 2009, a little over a year before the new food safety law was passed, and plays an important role in preventing food safety problems from causing damage, and that includes problems caused by packaging or labeling mishaps.

Food companies or government officials who discover food in commerce that has a reasonable probability of causing serious adverse health consequences or death have 24 hours in which to report to the FDA through a special RFR Internet portal.

These companies, referred to as "responsible parties," commit a violation of law if they fail to make the required report. Both animal and human foods are covered by the requirement, but dietary supplements and infant formula are not (they each have separate reporting obligations), and meat and poultry are not.

Because the RFR places reporting obligations on essentially everyone who discovers a potentially dangerous food, it's common for an initial report to be made by one company, and many subsequent reports to follow from their customer companies or suppliers.

continued

Food safety powers you might have forgotten about

The Reportable Food Registry program predates FSMA, and has already helped food companies achieve some of the newer law's goals.

The FDA reported recently on the data from the third full year of the RFR's operations.

The total number of RFR submissions was up a bit in the third year, from 1,153 to 1,471, though the number of primary or initial submissions was almost the same—225 in the second year, 224 in the third.

What hazards are inspiring the RFR reports? More than a third are undeclared allergens on labels (37.9%), almost another third are *Salmonella* (28.1%), followed by *Listeria monocytogenes* (21.4%). Other lesser causes include nutrient imbalance, uneviscerated fish, sulfites undeclared on labels, *E. coli,* and foreign objects. The food products involved in the reports were quite varied, including products such as produce, animal foods, baked goods, seafood, spices and seasonings, dairy products, and others.

The FSMA is regularly described as designed to prevent food outbreaks before they occur, and most but not all of its provisions target that goal directly, by, for example, requiring HACCP-like risk control programs and foreign supplier certifications. The RFR, by contrast, is designed to limit the damage that problematic foods can cause. Because it requires essentially immediate reports about potentially dangerous foods, the RFR provides "early warning about potential public health risks" and allows industry and government to "remove hazards from the marketplace" more quickly, says Michael R. Taylor, FDA Deputy Commissioner for Foods. And what it requires is immediate and detailed reporting by food companies of sensitive information. The RFR is a very real and present burden that often inspires companies to take remedial actions, whereas some of the FSMA obligations might not apply to every food company, and in any event, are not yet fully phased in.

continued

Food safety powers you might have forgotten about

In fact, the FSMA gave the FDA new powers to order responsible parties to give the FDA consumer-oriented information about reportable food, which the FDA can easily summarize and publish, and sets forth procedures for grocery stores to publish it.

Regulators like multiple arrows in their quivers, and food safety is an important priority, but still, it's useful to ask whether the RFR's requirements and the FDA's enforcement powers end up being a little redundant. The RFR is essentially a loud and widespread alarm about a potentially harmful food, and it puts pressure on companies to recall or take other remedial actions when the food they package or handle is associated with such a report. So, despite all the attention being paid to the FDA's new powers under the FSMA to order food recalls, detain foods, and suspend facility registrations, the RFR program might have been achieving many of the same goals that are behind provisions of the FSMA. We'll have to see future annual reports about the program to identify any patterns that differ before and after the implementation of FSMA. Until then, someone get the RFR a new PR firm. ◆

Key implications of FSMA for food packaging suppliers

BY ELIZABETH BARR FAWELL,
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As Associate in the Food and Agriculture Group at the law firm of Hogan Lovells US LLP in Washington, DC, the author has significant experience with the development and implementation of the FDA Food Safety Modernization Act (FSMA).

It has been more than three years since President Barack Obama signed into law historic food safety legislation—the FDA Food Safety Modernization Act (FSMA). The law has two major themes: prevention and accountability. Prevention means that food companies need to have controls in place during manufacturing to assure the safety of their products and to prevent problems (not just react to them after the fact). Accountability means that food companies are accountable to the Food and Drug Administration (FDA) to help ensure that their suppliers are making safe ingredients.

Although the law primarily has significant implications for food manufacturers, importers, and the fresh produce industry, it also affects the food packaging industry. Importantly, not all provisions in FSMA apply to food packaging in the same way. Some provisions of the new law make food packaging manufacturers accountable to the FDA, while other provisions make food packaging manufacturers accountable to their customers. In order to help keep everything straight, I encourage you to think about a few key principles as you read on.

- First, who does the legal requirement apply to? Some requirements apply to "food" as defined in the Federal Food Drug and Cosmetic Act (FFDCA), and others apply to "registered" food facilities.
- Second, where is your business in the supply chain? Are you acting as a seller or as an importer/buyer?

continued

Key implications of FSMA for food packaging suppliers

• Third, who cares about your activities? Is it the FDA or your customers (or both)?

There are two major provisions in FSMA that are particularly relevant to food packaging manufacturers and their relationships with their food-industry customers: Preventive Controls and the Foreign Supplier Verification Program. Third-party certification is a tool that may help ease compliance for food packaging companies.

Preventive Controls

The Preventive Controls provision is found in Section 103 of FSMA (FFDCA Section 418). It requires all registered food facilities to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, to identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards, and provide assurances that the food is not adulterated and does not contain any undeclared allergens.

As stated above, this requirement applies to all food facilities registered as required by Section 415 of the FFDCA. By regulation, the FDA has exempted food packaging companies from the registration requirement (it defined "food" to exclude "food contact substances" for registration purposes). This means that these companies are exempt from the legal requirement to comply with the Preventive Controls provision—meaning such companies are not accountable to the FDA. But in practice, they are still accountable to their customers.

Although food packaging manufacturers are exempt from the Preventive Controls provision, in all likelihood their customers—food facilities that use packaging materials to wrap

continued

Key implications of FSMA for food packaging suppliers

FSMA's Preventive Controls and Foreign Supplier Verification provisions are of particular relevance to food packaging suppliers.

or package foods—are subject to these new preventive controls requirements. And it is important to understand that one of the preventive controls that we expect the FDA to require registered food facilities to have in place is a supplier verification program. Because food manufacturers will be required to verify that their suppliers are making safe packaging materials, they may very likely require their packaging suppliers to have preventive controls in place so they (the food manufacturers) can meet their legal obligations to the FDA.

Remember two of our key principles from above: Where are you in the supply chain? To whom are you accountable? In this case, if you are selling food packaging materials to food manufacturers, the FDA will not require you to have preventive controls. Nonetheless, because food manufacturers (your customers) are accountable to the FDA, you will be subject to your customers' oversight. And your customers will require you to convince them that you have procedures in place to assure them of the safety and quality of your packaging materials.

The Foreign Supplier Verification Program

The second major provision in FSMA is called the Foreign Supplier Verification Program (FSVP) (FSMA Section 301; FFDCA Section 805). This provision applies to all importers of "food" and requires them to perform risk-based verification activities to ensure that the food they import is produced in compliance with the Preventive Controls provision (if applicable) and is not adulterated or does not contain any undeclared food allergens. There are two definitions that are critical to understanding how this provision may affect your business:

- First, FSMA defines "importer" as "the United States owner or consignee of the article of food at the time of entry of such article into the United States" or the U.S. "agent or representative of a foreign owner or consignee of the article of food at the time of entry."

continued

Key implications of FSMA for food packaging suppliers

- Second, for purposes of this section, "food" includes food packaging materials (i.e., food packaging is not exempt here as it was for purposes of facility registration/preventive controls described above).

Therefore, if you are an importer, and you import food packaging materials, FSMA will require you to have an FSVP. If this is confusing, let's look at our principles again. Who does the legal requirement apply to? Unlike the Preventive Controls provision, which applies to registered facilities, the FSVP applies to all importers of food, whether they are registered or not. Under the FFDCA, the term "food" includes food packaging materials.

Although the FDA exempted food packaging materials from the definition of "food" for purposes of facility registration, that exemption only is an exemption from registration. The basic definition of food in the statute remains.

It is possible the FDA may grant an exemption from the FSVP for importers of food packaging materials in the regulations implementing the provision, as a coalition of trade associations related to the packaging industry has requested of the agency. Specifically, as of this writing, the FDA wrote a proposed rule implementing the FSVP and accepted public comment through January 27, 2014. This provided an opportunity for food packaging manufacturers to comment on the proposed rule to the FDA expressing their support for an exemption. Although the FDA did not propose an exemption in the proposed rule, it is possible that the FDA may grant an exemption in the final rule. So stay tuned.

continued
Key implications of FSMA for food packaging suppliers

Third-party certification

Furthermore, there is a tool at your disposal that may help you comply with the FDA's requirement that you have an FSVP and/or your customer's requirement that you have preventive controls in place. The tool is third-party certification.

If you are an importer, you can use third-party certification as a verification activity. That is, you can require your suppliers to get certified. Then, meeting the FSVP requirement is much easier. If you are a supplier, you can use third-party certification to show your customers you have rigorous programs in place to ensure safety and quality. You can show your customers you are certified, and then they can more easily satisfy their obligations under FSMA. (Please keep in mind that you are not legally required by the FDA to use third-party certification. I am merely suggesting it as a potential tool for your consideration.)

Conclusion

In the end, the passage of FSMA means that big changes are coming for food companies everywhere, and that applies to makers of food packaging as well. As you think about what you need to do to prepare to come into compliance with the law, be sure you:

- Understand which provisions apply to registered food facilities (Preventive Controls) and which apply to importers of food (FSVP).

- Think about what activities you need to engage in to satisfy the FDA (FSVP), and what you need to do to satisfy your customers (Preventive Controls).

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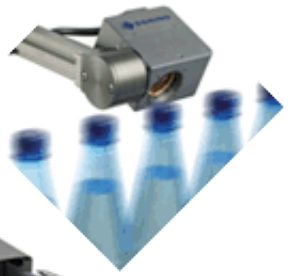

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continued

Key implications of FSMA for food packaging suppliers

- Think about whether third-party certification makes sense to satisfy both FDA (if applicable) and customer requirements. ◆

For more information, fact sheets, and FSVP process flow diagrams, visit the FDA's web page,
FSMA Proposed Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.

Food safety factors driving equipment upgrades

BY DR. DAVID ACHESON

Many factors are driving change in the food industry, not the least of which is impending new regulatory requirements that are part of the Food Safety Modernization Act (FSMA). However, food companies are currently being driven by a whole lot more than compliance with new regulations.

Pressures that food manufacturers and producers need to pay attention to are legion, including:

- Reliance on a global food supply chain
- Changing science that is connecting illness with foods more than ever before
- Consumers who expect great quality at low price with zero risk
- The propensity for both mainstream and social media to weigh in on food issues
- Increased threat of legal action
- New regulatory requirements

These are among some of the major factors driving upgrades in food processing and packaging facilities. Let's take a closer look at these factors:

continued

Food safety factors driving equipment upgrades

Reliance on a global food supply chain:

In the U.S. alone, there are more than 170,000 food manufacturers, processors, and distributors, about 2 million farms, and about 1 million restaurants and foodservice outlets. Every one of them is driven by safety, quality, and compliance. The FSMA is only the latest regulatory "stick" in a long progression of technologies, standards, best practices, and a mix of mandatory and voluntary guidelines.

In the U.S., 15% of the food consumers eat is imported from more than 150 countries and territories. This includes about 80% of seafood and more than half of the fresh fruits and vegetables. Import shipments of FDA-regulated products, for instance, have been growing at 13% annually. The country is dependent on imports, not because it has lost the skill to produce these foods domestically, but because it's more cost-effective to import them.

Changing science that is connecting illness with foods more than ever before:

The science of food safety is changing. There are some who hold views like the small business owner who says, “I don’t need to worry. We’ve been making this product the same way for 50 years, and I’ve never had a problem.” Just as likely, he’s never had a problem because he’s never gotten caught. Times—more properly, science—have evolved to uncover sources of risk.

continued

Food safety factors driving equipment upgrades

For example, 2007 marked the first *Salmonella* outbreak linked to peanut butter in the U.S. The product was found to have heightened risk in the post-processing stage, after roasting and grinding and prior to packaging. Advances in science have identified many more sources of risk. In addition to peanut butter, these also "low-risk" foods have been linked to new U.S. outbreaks of foodborne illness since 2006:

- Bagged spinach
- Carrot juice
- Raw cookie dough
- Canned chili sauce
- Broccoli powder on snack food
- Pot pies
- Dog food
- Hot peppers
- White pepper

How has the science of food safety advanced? Recent years have given rise to the use of molecular tools and modern genetics to "connect the dots" between multiple reports, and to link illnesses with their causes and sources. Along with this capacity has come a greater ability to measure lower levels of chemicals and pathogens; greater fidelity of epidemiology to understand the characteristics, causes, and distribution of food safety incidents; and improvements in genetic testing.

In turn, Class 1 food recalls—defined by the FDA as having "a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death"—were reduced for *Salmonella* from 43% in 2010 to 21% in 2011. However, allergens remain in the industry's and regulators' crosshairs as an area of much attention.

continued

Food safety factors driving equipment upgrades

Industry measures to prevent incidents and to promptly address them once they happen are critical in risk reduction. One of the critical factors in achieving such results is the development of new and better equipment systems and automation applications.

Consumers who expect great quality at low price with zero risk:

Consumers expect top quality at low prices with zero risk, and demand that supermarkets, which stock tens of thousands of SKUs, deliver that variety of foods all year round, without regard for the seasonality that once governed food choices. They have zero tolerance for unsafe food and place primary responsibility for safe food on the producer.

The propensity for both mainstream and social media to weigh in on food issues:

From traditional print and TV outlets to Internet outlets such as social media, reports of recalls reflect consumer concerns and amplify them. The media tend to focus on food safety, partly because of consumer concerns and partly because recalls present a readily available source for stories. As a result of media reports and public awareness, a food safety incident has great potential to damage a brand.

Sometimes, the media and the "blogosphere" can take food safety concerns to an unfair extreme. The scare over "pink slime," for example, was purely a media creation. This was simply a meat protein processed to separate out the fat, used for many years for products including hamburger patties. The product and process were safe—arguably safer than other meats for

continued

Food safety factors driving equipment upgrades

the heat process used—but the term went viral, and consumer pressure effectively resulted in the 2012 shutdown of several plants producing it.

While it's impossible to eliminate all irrational fears and sensational headlines, it is possible to reduce them by stepping up efforts to prevent brand damage, and greater food safety is the primary way to do this.

New regulatory requirements:

Ensuring food quality, food safety, and compliance go hand in hand to help companies protect the public as well as their brands. New regulations play a key role in driving food companies to upgrade their equipment.

As food companies step up their efforts, the additional regulatory oversight and authority granted to the government adds additional pressure to ensure the safety of the food supply.

The increasing number of recalls for allergens and the rising numbers of warning letters from the FDA are testimony to both new recognition of problems and ramped-up enforcement actions. Some of the key areas that are creating concerns for the manufacturing and processing industry that can be addressed by equipment and packaging manufacturers include:

continued

Food safety factors driving equipment upgrades

- Environmental contamination
- Challenges with cleaning equipment
- Allergen concerns
- Labeling issues—especially for allergens
- Product tracking

Failure to pay attention to controlling risk around these critical issues can and does result in significant negative brand impact, which has to be protected by balancing safety, quality, and compliance. ◆

The key role of equipment and packaging in food safety

BY DR. DAVID ACHESON

As food companies are constantly looking for ways to control food safety risks, they increasingly recognize the need to ensure that their processes are fully validated and verified on an ongoing basis to do what they are supposed to do to control risk, and that they must control environmental risk and especially allergen risk.

Below are some of the key areas food production and packaging professionals should expect their equipment and packaging manufacturers to focus on in order to help production and packaging facilities maintain leadership in Food Safety Modernization Act (FSMA) compliance:

Design equipment that is focused on 'built-in FSMA compliance needs.' Considerations include:

- Systems that can be easily validated
- Systems that provide the key monitoring data that will determine the verification of validated systems as they operate to control risk
- Systems that allow the electronic capture of data for the ongoing new recordkeeping requirements
- Systems that can be built into product tracking systems

continued

The key role of equipment and packaging in food safety

Ensure that equipment can be readily cleaned to avoid environmental contamination concerns. Considerations include:

- Being sensitive to the growing need to address allergens. This includes features for easy equipment cleanup (dry or wet), as well as fail-safe mechanisms to ensure the correct label is applied.
- Designing systems that facilitate the gathering of ingredient and finished product information to ensure accurate and easy capture of product tracking data
- Having a comprehensive understanding of the regulatory requirements around food packing and Food Contact Substances defined as:

"Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

"Examples of food-contact substances include polymers (plastic packaging materials), pigments and antioxidants used in polymers, can coatings, adhesives, materials used during the manufacture of paper and paperboard, slimicides and biocides (antimicrobial agents), and sealants for lids and caps."

Packaging and equipment companies that are sensitive and knowledgeable about the current pressures on food companies will have a market advantage in this growing area of complexity and the need to protect brands. ◆

How companies can tap their machinery suppliers for FSMA compliance

BY JEFFREY T. BARACH,
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The author, with Barach Enterprises, is former Vice President of Science Policy for the Grocery Manufacturers Association, is currently the FSMA expert for The Association for Packaging and Processing Technologies, and is a participant in in the FDA-sponsored Food Safety Preventive Controls Alliance, to develop FSMA training materials.

In general, food companies affected by the Food Safety Modernization Act (FSMA) would be wise to call upon their equipment suppliers, which can be a great resource when they:

- Become more familiar with the principles of Hazard Analysis & Critical Control Points (HACCP), because this will improve supplier knowledge of the impacts of FSMA.
- Consider current and future equipment improvements toward enhancing sanitary design.
- Work collaboratively to mitigate potential hazards through better control and validation of current Good Manufacturing Practices (cGMPs), which in practice take the form of HACCP Prerequisite Programs (PRPs). PRPs are preventive control measures needed for food safety systems, because they lay the groundwork for safe food production.
- Develop science-based validation information on processes and equipment performance.

More specifically, there are several areas where processing and packaging professionals seeking FSMA compliance assistance would do well to enlist the knowledge and services of their equipment suppliers. Some areas are direct (think sanitary design features), while others that are operational may not be as obvious.

continued

How companies can tap their machinery suppliers for FSMA compliance

Equipment such as this horizontal form/fill/seal machine, which is designed to meet USDA meat, poultry, dairy, and 3-A Sanitary Standards, has a head start in FSMA compliance because the underlying best practices are the same under the new FDA law.

Photo: Pro Mach/Ossid

Allergen management: Equipment and also material suppliers such as labeling sources can be of great assistance to food companies seeking to prevent allergen hazards. Some individuals are highly sensitive to certain foods or ingredients (e.g., peanuts, dairy, wheat, etc.) and can develop serious allergic reactions after consuming allergens. The main defense an allergic person has against allergen exposure is to have properly labeled products. Companies should maintain allergen management programs to control allergens that may include validation of cleaning procedures, prevention of cross contact, and product label review.

Environmental monitoring: Suppliers can likewise help their food plant customers in developing an effective food facility environmental monitoring program for potential foodborne pathogens. Such a program plays an important role in the production of low-moisture, refrigerated, and frozen, ready-to-eat foods. This program will help ensure that hazardous microorganisms are not transferred into the product stream by testing, finding, and eliminating real or potential pathogen harborage sites. The program should include a list of objectives, monitoring and verification procedures, a corrective action process, a root cause analysis, and provisions for recordkeeping and review.

Employee training: Proper and adequate employee training is absolutely essential for cGMP implementation. Without effective training, safe production of foods is jeopardized. Training should focus on assuring that the knowledge and expertise necessary to produce safe food products are provided. The training content, comprehension, and classroom attendance should be documented.

continued

How companies can tap their machinery suppliers for FSMA compliance

Validation considerations: Food companies should call upon their machinery suppliers when they seek help in determining the effectiveness of elements within a food safety program, such as establishing the validity of the critical limits for specific critical control points. Equipment design also plays a role in easing this aspect of a food safety plan, because good sanitary (or hygienic) design reduces risks as well as the complications of ensuring a safe environment.

Sanitary equipment design challenges: Food company personnel should bring equipment suppliers into a collaborative, organized problem-solving program to discover the root causes of potential hazards and develop new sanitary design options to mitigate these hazards.

Such collaborations are well established in helping food plants operate more safely and deepen the effectiveness of customer-supplier relationships. Equipment suppliers have been known to work on their customers' behalf through stewardship programs. Collaborations exist with customers as well as with the USDA and with the independent, nonprofit 3-A Sanitary Standards, Inc., and have led at least one prominent supplier to make design changes in its bagging machinery. These changes in design guidelines included the elimination of "sandwiched" metals (caulked, welded, or gasketed surfaces); the elimination of aluminum components (film cage, film rollers) in certain areas; reductions in hard-to-reach crevices in metal surfaces; and the elimination of flat or horizontal surfaces where potential hazards can develop.

continued

How companies can tap their machinery suppliers for FSMA compliance

There are many aspects of sanitary design criteria for food production and packaging equipment. Some key items include:

- Minimizing the amount of surface area that must be cleaned.
- Making parts and assemblies easy to access and inspect. Remember: If you can't see it (or access it), you can't clean it! (Note the prevalence of see-through panels on many packaging machines today.)
- Simplifying disassembly so actions can be completed with simple tools or by hand.
- Establishing cleaning and sanitizing procedures that are easily repeated by all employees.

Sanitary design improvements are a critical area where supplier-customer collaboration can improve food safety and efficiency. One of the best starting points for those interested in more detail is a list of The 10 Principles of Sanitary Design, which follows in this Playbook. ◆

Don't panic; the FSMA is 'just' HACCP on steroids!

BY JEFFREY BARACH

Whenever a new regulation is released—especially one as significant as the Food Safety Modernization Act (FSMA)—there's bound to be a sense of information overload, perhaps accompanied by misinformation, panic, and a supply of parties who will provide "quick-and-easy" solutions that are neither of those things. Good advice for food companies and their equipment supplier partners is: Take a deep breath and get prepared for FSMA!

The best way to prevent a sense of panic is to realize one basic fact: FSMA is about 85% Hazard Analysis & Critical Control Points-based.

Hazard Analysis & Critical Control Points, or HACCP, has long been the foundation of food safety best practices and prevention of food safety problems—just like the FSMA, which will encompass it. HACCP has been a cornerstone of food safety best practices and regulations since its inception in the 1960s as a collaboration between Pillsbury, the U.S. Army's Natick Laboratories, and NASA to produce safe foods for the U.S. space program.

FSMA, while complex, can be seen as a kind of "HACCP on steroids," in that it will apply to all FDA-registered facilities, which means all companies, domestic or foreign, engaged in manufacturing, processing, packing, or holding food for consumption in the U.S.

continued

Don't panic; the FSMA is 'just' HACCP on steroids!

HACCP is a methodical and systematic application of science and technology to plan, control, and document the safe production of foods. The FSMA's requirements are largely based on the same preventive controls, and in practice, can be likened to "HACCP on steroids."

Source: Robert Gravani, Professor, Department of Food Science, Cornell University

An HACCP primer

For those not on the front lines of HACCP, it can be broadly defined as a systematic approach for the identification, evaluation, and preventive control of food safety hazards. The primary focus is on preventing problems that could lead to foodborne illness or injury, and it is commonly applied across many food plants as well as supply chains, from farm to table. This is done by analyzing hazards and defining the critical points to control them, and following up with corrective action, and of course, the associated documentation. This well-established discipline is a voluntary practice for many plants and a regulatory requirement in some. (Regulations in the U.S. came in 1995 for fish and fisheries, in 1996 for meat and poultry, and in 2001 for juice.)

continued

Don't panic; the FSMA is 'just' HACCP on steroids!

Whether by regulation or voluntary compliance with industry best practices, HACCP has become widely adopted throughout the food industry because in addition to complying with the law, it's part of many major retail customers' requirements and can also help companies set food safety benchmarks for continuous improvement.

Many tools already exist for the above considerations and are in practice today, including the current Good Manufacturing Practices (cGMPs) and Sanitation Standard Operating Procedures (SSOPs) common for FDA-regulated products. These are important building blocks in support of an HACCP program, and they lay the foundation for safe food production.

• **cGMPs, or GMPs** (with the "c" for "current" assumed), have been fundamental to food safety assurance programs for manufacturing, packaging, and holding/storage for several decades. cGMPs provide the basic principles plants should follow in manufacturing safe food, providing clear procedures and documentation to ensure that the plant and the products and materials moving to and from it are being produced according to plan. This spans all aspects of the plant, from operator training to the operation of machinery to supply chain interactions. The FDA is updating GMPs as part of FSMA, and these regulations will continue to serve as a foundation for prerequisite conditions needed for safe food production.

• **SSOPs** are written procedures that plants create and implement as part of a preventive program. They include daily records that document procedures and corrective actions taken, and they are required by some plants, such as meat and poultry facilities, regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service. (Those plants must make SSOP

continued

Don't panic; the FSMA is 'just' HACCP on steroids!

records available to FSIS upon request, similar to the FDA's greater role under FSMA.) SSOPs can cover facilities (production and environmental monitoring); personal hygiene; equipment (processing, packaging, and storing); and operations (sanitation, processing, rework, and training).

Together, GMPs and SSOPs provide the foundation for other, more advanced programs for assuring product quality and safety. These include HACCP systems as components to international safety management standards from organizations such as ISO, the Safe Quality Foods Initiative, and the Global Food Safety Initiative.

It's no surprise that these tools, and the prevention-minded HACCP methodology as a whole, are at the core of FSMA. Like HACCP, the FSMA is based on the knowledge that end-product testing is insufficient for attacking the causes of hazards in the processing plant, on the packaging line, or in the supply chain—and that testing is not as effective as prevention.

Successful maintenance of an HACCP plan requires commitment from management, ongoing training and updating, and in general, ongoing vigilance to the plan's well-defined details.

As of this writing, the FDA has proposed several of the major rules and has opened them up to lengthy comment periods. The FDA will then take additional months to respond. Only then will final rules and guidance documents be published and the law implemented in the following months and years.

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continued

Don't panic; the FSMA is 'just' HACCP on steroids!

In the meantime, the best path for affected companies to take is: **Don't panic, be proactive, and be prepared.** If you aren't already operating in an HACCP environment, you should strongly consider doing so. If you are a food plant operator and have an HACCP program in your plant, now is the time to extend its reach to your processing and packaging lines. Because whatever changes may come with FSMA, its underlying principles and tools will ultimately be a market-driven requirement as well as a legal one. ◆

The 10 principles of sanitary machine design

Suppliers have played a role in the past, and can continue to assist food companies in evaluating compliance with various standards that are consistent with the Food Safety Modernization Act (FSMA), such as the 10 Principles of Sanitary Design developed in the early 2000s by the Equipment Design Task Force of the American Meat Institute. The task force included engineers, quality managers, and sanitarians from companies including ConAgra, Excel, Kraft, Hormel, Smithfield Meats, Sara Lee, Tyson, and others. The goal was to improve the sanitary design of equipment to reduce and eliminate potential harborage areas as well as help maintain and extend product shelf life and other product quality attributes.

These principles have been widely supported and expanded by groups including the Grocery Manufacturers Association, which has written checklists for Facilities Design and Equipment for Low Moisture Foods. (For links to these, see the Resources section of this Playbook.) These principles and associated checklists will prove useful as the FDA follows the lead of USDA-regulated meat and poultry plants to require a new level of sanitation.

The principles follow in their original form:

1. Cleanable to a microbiological level: Food equipment must be constructed to ensure effective and efficient cleaning over the life of the equipment. The equipment should

continued

The 10 principles of sanitary machine design

Multidisciplinary teams must consider all biological, chemical, and physical risks in food production and packaging equipment.

be designed as to prevent bacterial ingress, survival, growth, and reproduction on both product and non-product contact surfaces of the equipment.

2. Made of compatible materials: Construction materials used for equipment must be completely compatible with the product, environment, cleaning, and sanitizing chemicals, and the methods of cleaning and sanitation.

3. Accessible for inspection, maintenance, cleaning, and sanitation: All parts of the equipment should be readily accessible for inspection, maintenance, cleaning, and sanitation without the use of tools.

4. No product or liquid collection: Equipment should be self-draining to assure that liquid, which can harbor and promote the growth of bacteria, does not accumulate, pool, or condense on the equipment.

5. Hollow areas should be hermetically sealed: Hollow areas of equipment such as frames and rollers must be eliminated wherever possible or permanently sealed. Bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps, sleeves, and other such items must be continuously welded to the surface, not attached via drilled and tapped holes.

6. No niches: Equipment parts should be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets, and dead ends.

continued

The 10 principles of sanitary machine design

7. Sanitary operational performance: During normal operations, the equipment must perform so it does not contribute to unsanitary conditions or the harborage and growth of bacteria.

8. Hygienic design of maintenance enclosures: Maintenance enclosures and human machine interfaces such as push buttons, valve handles, switches, and touchscreens, must be designed to ensure food product, water, or product liquid does not penetrate or accumulate in and on the enclosure or interface. Also, physical design of the enclosures should be sloped or pitched to avoid use as a storage area.

9. Hygienic compatibility with other plant systems: Equipment design must ensure hygienic compatibility with other equipment and systems, such as electrical, hydraulics, steam, air, and water.

10. Validated cleaning and sanitizing protocols: Procedures for cleaning and sanitation must be clearly written, designed, and proven effective and efficient. Chemicals recommended for cleaning and sanitation must be compatible with the equipment and the manufacturing environment. ◆

HACCP for packaging: Addressing the critical knowledge gap

BY WYNN WIKSELL,
Lead Innovation Entrepreneur, General Mills

In his role at General Mills, the author fosters innovation and industry outreach, and has been auditing packaging specifications and supplier conformance for more than 12 years. He is also former Chairman of the Food Safety Alliance for Packaging (FSAP), a technical group of the Institute of Packaging Professionals (IoPP).

When Hazard Analysis & Critical Control Points (HACCP) methodology is applied to packaging, it can be a powerful tool, but because of application nuances, it has been more difficult to adopt. Packaging and HACCP go back years as either individual consumer packaged goods companies (CPGs) sought to make their processes safer for food applications and/or packaging suppliers took on the challenge themselves. This has been met with several frustrations and is only now being properly addressed through conversations between the food manufacturers and the packaging industry.

As we look to today, we find an interesting fact about packaging material and equipment suppliers: Even though they participate in the food supply chain, they also supply other industries as well. The packaging industry has one foot out of and one foot in the food business. This disparity has lead to a lack of focus and understanding. Couple that with the fact that CPGs have focused initially on their own processes and upstream ingredient suppliers, and we have an opportunity to achieve better coupling between food safety and packaging.

Packaging-specific HACCP considerations

When HACCP was originally applied to packaging, the packaging industry became confused. Sure, foreign material was an easy target. But for years prior, individual CPGs were telling the packaging industry to shore up their Good Manufacturing Practices (GMPs). So when the

continued

HACCP for packaging: Addressing the critical knowledge gap

CPGs were asking the packaging industry to incorporate HACCP-based programs, the packaging industry made assumptions about what constitutes a Critical Control Point (CCP), leading many to ask, "Why another level of quality? We have foreign material abatement programs in place, and they would not be a CCP anyway." Adding to the confusion was an overall CPG lack of understanding of the packaging manufacturing process, so they could not directly speak to the issues at hand. Adding to all of that was the fact that of the three types of hazards—micro, chemical, and physical—all of the regulation and training that the CPGs could offer related to microorganism controls, which the packaging industry thought they had very little impact on.

The packaging industry as a whole also sees itself as somewhat of an oxymoron with regards to the food industry's rules. Difficult questions and issues arise such as:

"What is your glass policy?" How does a manufacturer of glass respond to that? As much as the food producer gets rid of glass everywhere, this is 100% of the deliverable that the glass manufacturer is expected to deliver.

"How are you metal detecting and to what size?" Metal can producers are still wrestling with this question today.

"Create it please with die cuts, yet do not ship me any of the scrap." This issue speaks to the challenge of eliminating foreign material from the food packaging supply chain.

These examples highlight the areas where food manufacturers and packaging suppliers have not communicated well.

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HACCP for packaging: Addressing the critical knowledge gap

Historically, very little information was available to address these issues. But in recent years, training materials have been developed to specifically help address the area of food packaging and food safety. PAC- The Packaging Association has training and certification programs for packaging suppliers across North America wanting a certified HACCP packaging program. The Global Food Safety Initiative (GFSI) is also a resource for companies wanting to become HACCP-certified. Another resource, which is free, is the Institute of Packaging Professionals' (IoPP) Food Safety Alliance for Packaging (FSAP) models. Through the FSAP, hundreds of CPGs and supply chain partners in the packaging community have joined forces to discuss the issues that have been seen and to create HACCP plans and prerequisite programs for all to use. ◆

This article is adapted with permission from the book, HACCP: A Practical Approach, Third Edition, available from Amazon.com.

HACCP for packaging: Rules and realizations

BY WYNN WIKSELL

Whichever path a packaging supplier takes to get training, there are some rules, which Hazard Analysis Critical & Control Points (HACCP) methodology speaks to, that the supplier must keep in mind. What is critical for the supplier—and the supplier's customer—to understand is that to correctly implement HACCP for packaging, longstanding rules of HACCP must in some cases be broken. These rule breakers of HACCP speak to the uniqueness that the packaging industry must keep in mind when applying HACCP principles.

Rule Breaker #1: There *can* be more than one CCP for a particular hazard in a packaging plant. This goes against all training that exists in non-packaging applications, which states that there can only be one CCP for any given hazard in the food industry. For example, mixing labels that may entail allergens and/or chemicals with different handling requirements are a hazard with more than one CCP.

Rule Breaker #2: Glass is allowed. Of course, it must be controlled. For most food plants, it is most easily controlled by eliminating it. For the food glass manufacturer, it means understanding contamination zones upon breakage, 100% inspection, proper temperature, coating, and handling controls.

Rule Breaker #3: Allergens do not pertain to food. For the packaging converters, the issue is more accurately characterized as label control. While CPGs do not want

continued

HACCP for packaging: Rules and realizations

peanuts and other allergens in the packaging supplier's facility, when it comes to packaging a product on the production floor, CPGs need the packaging supplier to have programs in place that prevent copy mixing. This mostly occurs on lines that run side by side, or on an individual line that runs varied copy, one after another.

Rule Breaker #4: Pest control is about harborage. The food industry has an abundant amount of food and must be diligent to stay on top of its pest control programs. In the food industry, focus is on master sanitation schedules. The packaging industry creates nice homes for insects and rodents to hide in. Corrugated is the best example of this. Every flute offers the confined space in which insects will hide. The other area where we see some of the most frequent violations of basic GMPs is pallets that are stored outside. There is not adequate pest control outside, and everything from insects to small rodents have been found in these wooden or plastic homes. Once in a pallet, there is no good "kill step" to ensure that the pallets are fit for food manufacturing distribution.

By applying these rule breakers into the HACCP process, we can start to eliminate confusion, which is usually one of the barriers to adopting HACCP into a packaging facility.

A good way of looking at the packaging industry and its effects on the food manufacturer's supply chain is through the simple equation:

Risk = Hazard x Exposure

This is a great tool to use when evaluating all types of packaging industries. For example, look at corrugated. This packaging medium is usually a secondary or tertiary unit to the food item.

continued

HACCP for packaging: Rules and realizations

Fig. 1: A 'single' hazard such as mixing labels can have many CCPs, or Critical Control Points, as seen in this illustration, where mixing can occur on pouches (CCP 1), in cartons (CCP 2), on corrugated (CCP 3), and on pallets (CCP 4). For more detail on specific risks and controls, see the Resources & Downloads section of this Playbook.

If the hazard is a transient or there is resident infestation at the packaging supplier's plant, the recipient food plant is at greater risk. Why? Exposure. Due to the nature of exposure through volume, one food plant will receive multiple truckloads every day from the corrugated supplier. This constant movement links the corrugated supplier much more closely with the CPG supply chain, and therefore the movement of insects is more likely.

If we look at the flipside, one hazard could be a trial of a new glass item. While the hazard is great (foreign material, glass), one might view the overall risk differently for a one-time run on that trial than if one were setting up the item for longstanding production.

Five key realizations

Some suppliers have adopted HACCP and are much more aware of the supply chain risks that could have an impact. This new awareness has brought on the next level of learning. Better communication has brought about some realizations for new thinking on behalf of the CPGs and packaging suppliers.

Realization #1: If you test, do not ship. If the packaging supplier has as part of its process a Gas Chromatograph (GC) test for release, do not ship the packaging material to the CPG company while waiting for the results. Too many times the industry has seen where either the bad results were not communicated properly through the supply chain, or they were not communicated at all. Bringing material back, or worse yet, pulling product from the marketplace costs way too much compared to holding the packaging material at the supplier's location until the proper clearances have been given.

continued

HACCP for packaging: Rules and realizations

Realization #2: Test for one, impact another. A continuation from the last scenario, an additional issue arises when a test is implemented at the request of one CPG company (A), and the testing is applied to another CPG company's (B) products. If there is a bad result, then both companies could be implicated by the results. But, since company B did not request the testing for release program, they are not notified that 1.) the testing is going on at all, and 2.) that there is potential "bad" material out there.

Realization #3: Communicate results, not actions. Packaging suppliers have asked CPGs to recall their packaging material. A recall has certain implications and shall be issued by the CPG company through the appropriate channels. The packaging company shall communicate what the hazard (actual or potential) is and the quantity impacted. It should not state that the material needs to be recalled.

Realization #4: When quantifying impact, go big. We have seen this as probably the biggest mistake that the packaging industry makes. When a defect is found, old teachings say to go back to the last good check and hold. That adage does not work. Just because a defect was not found in the last round of inspection does not mean that it was not happening for a long time. Here is a time-based series of events:

10:00 Maintenance over-greases a gearbox above a production line.

10:05 Grease sporadically drips into empty cups below.

10:30 As part of a QC check, 10 cups are pulled for measurements and visuals. No issues reported.

continued

HACCP for packaging: Rules and realizations

11:00 QC check again on 10 new cups. No issues reported.

11:20 A packing operator notices a foreign material substance on the inside of the cup.

11:28 QC evaluates and issues a hold for material produced back to 11:00.

In this example, you can see that material from 10:05 on is suspect, and the supplier only captured material back through 11:00. Until the assessment could be made as to where the contamination came from and its root cause, a hold should be issued for the entire production time and maybe even further back, and then released for use after a positive root cause and time can be established. Going through records, hopefully there would be time and activity in the maintenance log stating the intervention, and the hold should be made for 10:00, as it would be difficult to pinpoint when the dripping actually occurred.

HACCP is a great tool for understanding and identifying risks from the packaging supplier to the food industry. With careful consideration of the controls, understanding of the rule breakers, and realizations of communication practices, a packaging manufacturer can protect itself and the CPG companies that it supplies. ◆

This article is adapted with permission from the book, HACCP: A Practical Approach, Third Edition, available from Amazon.com.

How plant automation impacts product, equipment, and packaging compliance

BY DAVID GREENFIELD
Director of Content/Editor-in-Chief,
Automation World

With FDA food safety requirements and inspections on the rise in response to the Food Safety Modernization Act (FSMA) deployment, the first question for most people involved in the food industry is: Who does this law affect? In reality, it affects everybody from one end of the supply chain to the other. Primarily it will affect food producers and processors, as they will be tasked with identifying where the risks are in their systems and controlling them.

That's where automation comes into the picture.

The following advice on how to leverage automation, for food manufacturers as well as food equipment manufacturers, summarizes remarks delivered to the industry by Dr. David Acheson, an expert on industry and regulatory matters who has contributed elsewhere in this Playbook.

Production tracking

The food industry has long struggled with product tracking, especially since the Bio-Terrorism Act enacted in 2005, which required product tracking one "step" up and one step back in the supply chain, a requirement that remains in the FSMA.

continued

How plant automation impacts product, equipment, and packaging compliance

To protect a brand, food processors and packagers need to truly understand the safety and security of the supply chain. For example, if you are relying on imported shrimp from China, what do you know about the shrimp farmer? What do you know about the drugs that he is putting in that pond to control bugs and keep the shrimp healthy?

If you don't know the answers to these questions, you are at risk. That's why product tracking in supply chain systems is critical. The new law is going to require you to know more about risks in your supply chain, and you will likely have to be able to show through some form of documentation process exactly what you are doing to control those risks.

Keeping records is also important within your own four walls. As an example, if your operation involves roasting nuts, you have raw nuts going in one end of your roasting process and roasted nuts coming out the other end. What matters are the temperature of the roaster, the speed of the belt through the roaster, and the depth of the nuts on that belt. If the belt's moving too fast, the nuts won't get cooked enough. If the depth of the nuts on the belt is too deep, then the ones underneath won't get enough heat.

With production tracking software, it's simple to monitor, react, and record all this information on a continuous basis. You simply have to monitor these three factors to know when something is going out of spec so that you can take corrective actions, and you'll have recorded verification that the corrective actions have worked.

continued

How plant automation impacts product, equipment, and packaging compliance

Packaging and equipment

The bottom line is that food companies are looking to minimize risk—not just compliance risk, but safety and quality first and foremost. And that means that to satisfy all three issues—compliance, safety, and quality—the legacy equipment in place throughout much of the industry will need to be upgraded or replaced.

Four areas to focus on with equipment include:

- Perform any equipment upgrades with validation in mind. The equipment will need to be able to validate that you exposed the product to enough heat to kill the agents of concern such as *Salmonella* and verify that it is working and capturing critical production/processing data elements.
- Validation capabilities also need to address equipment cleaning. With allergens, for example, a food company will typically run products containing allergens at the end of a day or at the end of a run; but then you need an effective and documented cleanup process before you run a product through the system with no allergens.
- Recognize that packaging equipment comes into contact with food. The notion that packaging is an inert item in your production process won't fly any more. Machinery comes into contact with food. As such, this is a relevant risk that the FDA now recognizes and around which documentation needs to occur.
- Labeling control (i.e., a product is not correctly labeled with regard to its contents) is another issue falling under tighter control with the FSMA. This is an especially critical matter on the subject of allergens. This is a simple issue to address with a product tracking system. ◆

Seven tips for FSMA compliance in plant automation

Automation can improve compliance with the Food Safety Modernization Act (FSMA). Here are some tips from food company managers that may help you improve your own technology choices:

1. Lock it down. Design and install food safety systems that are locked down to prevent human bypass and that navigate through garbage-in, garbage-out temptations while remaining extremely user friendly.

2. Give operators the right tools. Food safety often hinges on the proficiency of operators and other plant-floor personnel to work efficiently with equipment. Well-written procedural documentation is an invaluable teaching aid in compliance as well as productivity. Likewise, all automation should be user friendly, from controls to software and recordkeeping systems.

3. Involve QA/QC. Involve quality personnel (and others) in engineering reviews and meetings. They may catch something engineers, operations, and maintenance personnel on a project team might miss.

continued

Seven tips for FSMA compliance in plant automation

4. Verification is critical. The "CCP" in Hazard Analysis & Critical Control Points (HACCP) is critical. Establish standard operating procedures and at least a double control system that can verify any products before they leave the production line. You will need enough inventory to keep the products in a safe place and will need to wait for all testing to be confirmed before selling the product.

5. Track from origin through distribution. FSMA requires food companies to follow products from the origin of their raw materials through finished product distribution. In addition to using non-automated tactics, sensors can be a convenient way to track critical raw materials from point of origin through loading and transportation. Manufacturing processes require the most continuous analysis possible; technology now affords the same capability outside the plant.

6. Calibrate manually: Sensors should be calibrated with sufficient frequency, and if there is any doubt regarding their accuracy, they should be calibrated manually—not just with a field calibrator's "auto" mode. Trust in the reliability of sensor data led one survey respondent to engineer "bio-growth" tracking routines to ensure product was processed and packaged before it posed a risk and had to be scrapped. Another food company executive is seeking to expand the reach of sensor data upward from plant networks to "deliver data to the plant ERP system for trend analysis."

7. Real-time test results. To improve execution accuracy, implement real-time input for food safety test results and on-floor checklists, all of which should be stored in a central

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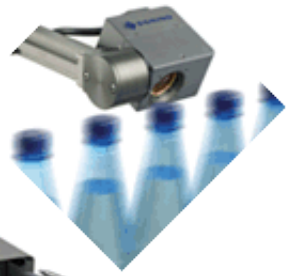

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continued

Seven tips for FSMA compliance in plant automation

database that is accessible to quality assurance, production management, and supervisory personnel.

8. Let your budget be your guide. There are limits to how cutting-edge a technology investment must be. As one food plant pro explains, "New innovations can be very difficult and expensive to properly retrofit to comply with rules." ◆

Find additional, related information in the Automation World Batch Process Playbook.

Five ways integrated software can ensure food safety

With nearly 60% of all food and beverage companies having been affected by a recall in the last five years, improving food safety is more imperative than ever for food and beverage manufacturers. In this era of heightened awareness of food safety issues and increasing regulations, the focus has shifted from reacting to recalls to preventing them.

It's critical to gain better visibility and deep insights across operations to improve food safety and quality. Leveraging the power of the Industrial Internet, manufacturers need to take a holistic approach by connecting their machines, data, insights, and people to deliver real-time operational intelligence. With the right information at hand, they can build a safer, more profitable food production environment.

Prevention begins with a comprehensive approach that targets risks and ensures food safety through five key software capabilities: real-time operational intelligence; trending capabilities; rich analytics; electronic standard work practices; and powerful traceability.

continued
Five ways integrated software can ensure food safety

1. Enable anywhere, anytime decision making

In today's mobile environment, it's imperative to deliver relevant information to operators and other key decision makers wherever they are. Whether they're on the plant floor or offsite, the ability to receive real-time information and notifications through a mobile device such as an iPad or smartphone enables them to respond immediately to critical events—increasing productivity and minimizing the risk of safety mishaps. Software can make sense of the complexity of data in today's plants and speed decision-making by putting the right, contextualized information in the right hands, based on role and location.

2. Eliminate the root cause of product risk

At the heart of preventing recalls is the ability to proactively recognize production trends as they happen and take immediate corrective action as needed. Instead of looking solely at historical data, plant managers today can view real-time production information to perform root-cause analysis and take corrective actions instantaneously. For example, temperature trending analysis led one food manufacturer to discover inconsistent oven temperatures. Operators were able to adjust the ovens "on the fly" to compensate for the temperature drifts, thereby ensuring food quality and safety.

Understanding patterns and relationships between various sets of data such as temperatures, speeds, pH levels, and humidity—rather than compartmentalizing potentially at-risk products using post-production testing—can help eliminate the true root cause of product risk.

continued
Five ways integrated software can ensure food safety

3. Prevent quality issues with predictive analytics

Real-time predictive analytics can provide critical decision support to foresee issues before an event occurs. Advanced software with predictive analytics may leverage robust modeling engines and multivariate analysis to preempt alarm and failure events based on historical models—enabling "active avoidance."

For example, if high pH levels can compromise product quality and safety, and the level starts deviating toward a critical condition, predictive analytics can, in real-time, prevent a critical condition from occurring. One U.S. dairy, for instance, used this technology to improve process control and reduce spoilage in dry baby formula through better real-time analysis of moisture content, drying time, and other parameters.

4. Minimize inconsistencies with standard work processes

Food safety Standard Operating Procedures (SOPs) are a key element to ensure that operators consistently adhere to recipes and comply with Hazard Analysis & Critical Control Points (HACCP) programs. The latest workflow software enables manufacturers to digitize manual and automated work processes instead of relying on static paper trails or a binder at an operator station.

Automating SOPs with step-by-step operator instructions provides greater precision and fewer errors. It also provides validated data entry; data capture for analysis and historical records; and automated HACCP management by integrating production work processes with real-time HACCP testing for faster response to compliance issues.

continued

Five ways integrated software can ensure food safety

5. Enable tighter controls across the supply chain with traceability

Rather than merely minimizing the impact of recalls after they occur, manufacturers today can use software traceability information to improve food safety and virtually prevent recalls. The latest software systems enable product tracing throughout every step of the manufacturing process to identify the product's exact materials and quality characteristics, control the flow of product between equipment, and manage in-process inventories in real time.

Such systems can be used to integrate all data and trace complex batches, continuous processes, sub-processes, components, or byproducts to determine the origin and destination of all incoming materials and outgoing finished goods. By tracing raw materials to finished product, you can establish tighter controls to safeguard the supply chain.

How automation capabilities minimize food safety risks:	• Put the right information in the right hands at the right time with real-time operational intelligence • Proactively recognize data trends and understand patterns and relationships • Leverage real-time notifications of process upsets for immediate corrective action • Identify process deviations and predict issues before they occur to enable "active avoidance"
…and how they can enhance process control and consistency:	• Digitize automated and manual work processes • Enable faster, more accurate responses to compliance issues • Control product flow with greater transparency and trace raw materials back to their origins

continued

Five ways integrated software can ensure food safety

Why integrate

With prevention as the core goal, each of the five critical software capabilities discussed plays a distinct role in minimizing food safety risk. Leveraging all five capabilities—as opposed to one or a select few—provides the greatest advantage, because the insight gained from each critical capability becomes exponentially more powerful as it builds on the intelligence provided by the others.

An integrated, plant-wide approach provides the deep facility-wide insight to help operators predict when issues are likely to occur, and take real-time corrective action when the process digresses from specifications. This ensures consistently high quality and food safety, which in turn, drives greater operational productivity. ◆

This article is excerpted and adapted from information supplied by GE Intelligent Platforms.

How integrated management software enhances audit readiness

So much of the food and beverage industry's safety and quality assurance operations are still manual, but many of the most efficient companies are turning to electronic systems to eliminate errors and increase efficiencies. But even electronic systems can be inefficient when different systems are used for different parts of the food safety plan—but not the whole plan. Other times, these systems don't "talk" to each other.

Preparing your plant for compliance with the Food Safety Modernization Act (FSMA) and an array of multiple regulations and standards can seem an insurmountable challenge in at least four ways:

The sheer volume of paper. Gathering and maintaining all of the documents and records that verify and validate the various components of food safety plans can be extremely time-consuming and costly, especially when it takes workers' time away from other duties. The more types of audits, the more complex it becomes to gather records completely, accurately, and in a timely manner.

Proof that plans are being carried out correctly. In addition to gathering records, there's also the challenge of making sure everything is in conformance with requirements. Preparing for an audit is not the time to find out that one facility is using old

continued
How integrated management software enhances audit readiness

forms, or a manager wasn't aware of a new or modified Critical Limit or Preventive Control for a given piece of your process.

Supplier/vendor management. Whether it's for FSMA's Foreign Supplier Verification Program (FSVP), GFSI's Approved Vendor Programs, customer requirements, or your own food safety plans, it's a huge challenge to track all of the necessary specifications, registrations, supplier audit documents, and proof of hazard analysis/Preventive Controls.

Response time. The time associated with meeting the above three challenges can be excessive—and that's for the audits you know about. When it comes to unannounced audits from customers, the FDA, SQF, or other standards bodies, the word "excessive" can be replaced with "disruptive" or worse.

For such reasons, demand has risen for dedicated management software systems that ensure that companies will comply with food quality and safety regulations.

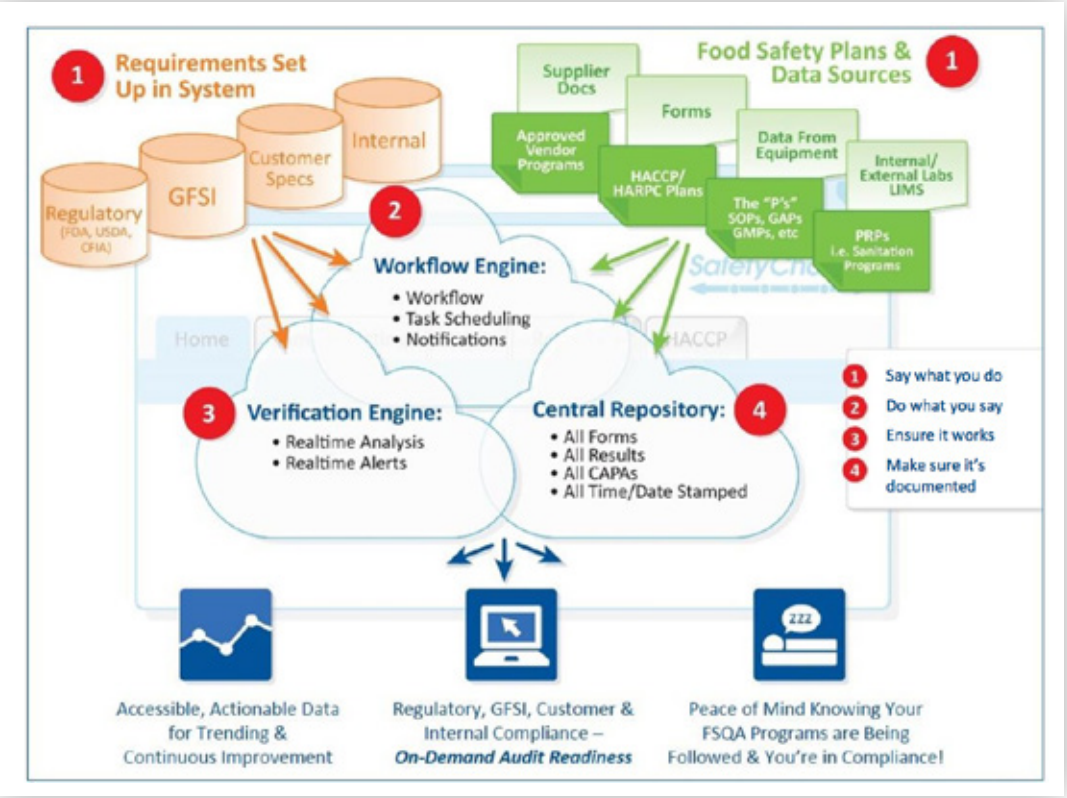
What is an automated food quality/safety system?

An automated food quality and safety management system integrates real-time data collection and analysis with specifications—along with automatic alerts when deviations are detected—to prevent non-compliant ingredients and raw materials from coming into a facility and non-conforming finished products from going out. It also helps ensure related workflow, processes, and documentation, and does so in a central repository of quality and safety data for trending, assessments, reporting, and of course, audit readiness.

continued

How integrated management software enhances audit readiness

Systems use various types of information technology infrastructure, but all provide an integrated repository for all data; requirements of various kinds of audits; food safety plans and data sources; and provisions for workflow, data storage, and verification. (See diagram on this page.)



Implementing a dedicated software system can allow companies to eliminate problems such as wasting time entering instead of analyzing data; searching hundreds of supplier documents to find the one or two that require action; incomplete revision logs; falling behind in facility inspection corrective actions; and discovering missing or mis-filed information only when found in an audit—which may be announced or unannounced.

Depending on your company's compliance requirements, you may need to manage programs that call for up to four types of audits, each with unique characteristics:

Regulatory audits. USDA requires proof of Hazard Analysis & Critical Control Points (HACCP) pre-shipment reviews before products are put into commerce, and can ask to look at documents for every single day of operation versus a time period. The FDA can arrive unannounced if they receive a complaint, and requires answers to most queries in two hours.

continued
How integrated management software enhances audit readiness

GFSI audits. GFSI audits require full documentation of compliance with approved vendor programs as well as documentation of PRPs, such as preventive maintenance and food defense. And, it was recently announced that, going forward, SQF will require one in every three audits to be unannounced.

Customer audits. In addition to safety documentation, customer audits also focus on compliance with your customers' specific quality specifications—weight, moisture, packaging, and the like.

Internal audits. These can be the most difficult, because they can encompass requirements from all of the other types of audits combined. They may also require operational documentation on Key Performance Indicators (KPIs). Additionally, FSMA's FSVP and proposed third-party auditor rules, which will require food safety violations to be reported directly to the FDA, could be a game changer when it comes to internal audits.

Common elements of all types of audits:

- **You must show that you say what you are going to do,** so your food safety plans, risk assessments, Preventive Controls-related SOPs, CCPs, PRPs, GMPs, etc., must be well defined, organized, and accessible.

- **You must show that you did what you said,** and therefore you must be able to verify scheduling and completion of tasks, and ensure that test results become part of your records.

continued

How integrated management software enhances audit readiness

- **You must prove through analysis and scientific validation that what you're doing is working.** Therefore you must validate that the frequency of your inspections is correct, and that your critical limits are working.

- **You have to show that you analyzed information for CAPAs.** The required corrective and preventive actions (CAPAs) must be completed, and management must get this information in a timely fashion.

- **You must show continuous improvement.** In meeting this need, you must consider questions such as: Is there new scientific information? New regulatory or GFSI requirements? Is your level of corporate food safety and quality assurance able to leverage best practices from the plant level?

- **You must have accurate, audit-ready documentation for all of the above considerations.** All responsible food safety and quality organizations are doing these things. But to an auditor, if an activity isn't properly documented, it's as if you never did it.

Benefits of automated 'readiness'

With the right integrated food quality and safety management software system, food safety plans, customer and internal quality specifications, and approved vendor programs are carried out on time, according to plan, and with the efficiency of a single, integrated system. Tasks happen when they are supposed to, and issues are dealt with in a timely, preventive manner. This is the first step in preparing for any audit.

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continued

How integrated management software enhances audit readiness

Because every task, document, record, test result, and action is time/date-stamped, the system provides unalterable records for greater audit efficacy. The robust nature of data recording also supports continuous improvement, something called for in almost all audit schemes and best practices.

Having a central repository helps organize and simplify reporting of all forms of audit documentation as well as reporting against internal KPIs. When the implementation uses current-generation technology, the value of this data is enhanced further through remote access to data using secure "cloud" or Internet-based sharing for greater transparency and visibility across plants, companies, and supply chain partners. ◆

This article adapted and edited based on information from SafetyChain Software.

Eight tips for selecting food safety compliance systems

Rising complexity, market realities, and regulations such as the Food Safety Modernization Act (FSMA) have given rise to numerous software systems for food quality and safety management. Such systems can manage everything from Hazard Analysis & Critical Control Points (HACCP) plans to compliance with the Global Food Safety Initiative (GFSI) and related standards (SQF, BRC, IFS, FSSC 22000, ISO 22000, etc.), and now, FSMA compliance.

Below are eight guidelines food and beverage manufacturers should consider when selecting a system:

1. Flexibility to suit your business processes: The system you choose must suit your existing business processes, or you'll have to adapt your processes to the system. It's a fundamental requirement to be able to match the system's capabilities and features to your needs.

2. Consider the Internet: Your system should be able to adapt to your level of on-site access requirements as well as intranet or remote extranet access requirements. Just as enterprise software vendors are building tools that move away from the old client/server models to a thin-client interface, food quality and safety software should allow for web-based and/or web-enabled functions. (There's a difference, and this should be researched.)

continued

Eight tips for selecting food safety compliance systems

3. Reporting and searching: Systems vary in their ability to help users make sense of the enormous amount of data created and stored in such systems. Look for robust features to streamline the time and effort it takes to find, filter, and report data—and perhaps export data and reports to external systems—as needed. Off-the-shelf levels of integration can vary, and systems use various levels of native features and third-party tools to accomplish this.

4. Enterprise scalability: Systems increasingly must serve multiple sites, whether through expansion, consolidation, or the increasing need for electronic communication with customers and suppliers. Compliance systems must therefore be able to scale accordingly. Scalable systems must handle both the load of additional users and additional system administrators.

5. Integration with other systems: Just as companies no longer operate in silos, compliance software must be able to communicate across production, financial, quality, and other areas to allow users to interact, collaborate, and coordinate across the business. This helps close gaps in processes and fosters visibility from one operational area to the next. The level of integration can vary from "lookups" that eliminate double-entry of data, through fuller efforts that share and "push and pull" data between systems, to true integration that will pull quality, non-conformance data, and other data between systems.

6. End-user acceptance: Cross-functional teams often include management-level participants from IT, quality, operations, purchasing, and other areas, but often overlook non-management end users. Once implemented, the success or failure of a system may hinge on whether the system has a friendly "look and feel" and a quick learning curve for these non-management personnel who, after all, are likely to be the highest-volume users.

continued

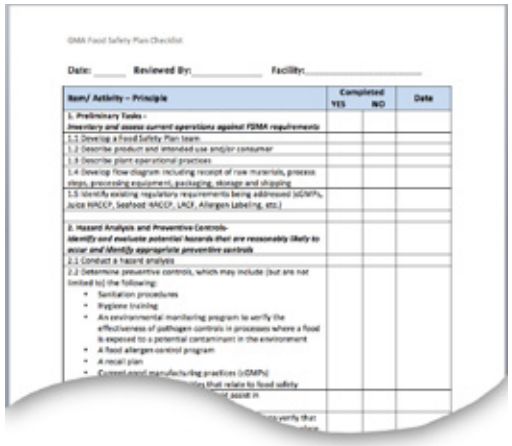
Eight tips for selecting food safety compliance systems

7. Implementation and deployment time: How long will it take for your company to realize the value of the system you choose? Many and perhaps most software implementations fail, miss implementation schedules, or are over budget. To minimize such problems, include all pertinent stakeholders early in the requirements phase; work closely with your vendor to clarify requirements; and avoid late or last-minute changes/additions of features and functions.

8. Look and feel: The ability to "make the system your own" can be an important consideration, from the look of the user interface (colors, logos, fonts, and layout used for navigation, forms, and reports) to the ease with which such customization can be made without extensive development. ◆

This article adapted and edited based on information from EtQ Inc.

GMA checklist offers seven steps to food safety compliance



Resources

Download as Word 'doc'

"Ensuring the safety of our products—and maintaining the confidence of consumers—is the single most important goal of our industry," said Dr. Leon Bruner, Chief Science Officer for the Grocery Manufacturers Association (GMA), in a March 29, 2011 public meeting held by the U.S. FDA shortly after the Food Safety Modernization Act (FSMA) was signed into law.

Five months later, the Washington, DC-based association submitted a document under the Federal Register's FSMA request for comment provision for FSMA. The document is titled: GMA Food Safety Plan Checklist. (See download link at left.) To quote a passage in the introduction:

"This checklist is provided as an aid to companies that are developing a new Food Safety Plan or revising their existing plan to be compliant with the requirements in FSMA and the regulations and guidance developed from that law. This document is not a comprehensive document on 'how to' develop a Food Safety Plan nor a summary of legal requirements, but rather is a tool to assist in the many activities associated with plan development."

The checklist is arranged in table form and organized under seven items or activity areas:

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continued

GMA checklist offers seven steps to food safety compliance

1. Preliminary Tasks: Inventory and assess current operations against FSMA requirements.

2. Hazard Analysis and Preventive Controls: Identify and evaluate potential hazards that are reasonably likely to occur and identify appropriate preventive controls.

3. Monitoring: Establish monitoring practices for each preventive control.

4. Corrective Actions: Establish procedures for corrective actions to be taken when preventive controls are not properly implemented or are found to be ineffective.

5. Verification and Validation: Establish procedures to verify that the preventive controls are effective and that the Food Safety Plan is working correctly.

6. Records: Establish effective recordkeeping procedures that document the Food Safety Plan.

continued

GMA checklist offers seven steps to food safety compliance

7. Training: Establish effective training programs for management and line workers.

If your company is required to have a food safety plan, the checklist is worth downloading for at least three reasons:

- First, the document is based on best practices already in place by leading food/CPG companies.
- Second, FSMA is based on the same best practices, making it very probable that if you follow it, your plant will likely be well on the road to FSMA compliance.
- Third, if you don't take a proactive role in following best practices such as those outlined in the checklist—and wait for the FDA to publish a guidance document—your company may not only lag behind more sophisticated competitors, your company will be at risk of operating with substandard food safety precautions.

Additional, related resources can be found on the association's website. Two FSMA-specific resources, in particular, can be found in the Food & Product Safety area of the site:

- FDA Food Safety Modernization Act Section-By-Section Analysis, and
- Effective Dates and FDA Requirements in the FDA Food Safety Modernization Act

Both of these are free PDF downloads, and both are authored by Hogan Lovells (whose Elizabeth Fawell contributed to this Playbook).

continued

GMA checklist offers seven steps to food safety compliance

Additional GMA resources:

• A Technical Guidance & Tools section of GMA's website offers a wealth of technical guidance on industry practices and regulatory compliance. Several links are provided and offered as free downloads. For example, a 34-page Food Supply Chain Handbook is offered in English as well as Spanish, French, Chinese, and Russian. Other links include guidance on equipment design, *Salmonella* control, and facility design.

• A fully automated, online HACCP training course (member login required) is touted for reducing the cost of trainers, travel, and related expenses through remote, 24/7 learning. GMA reports that this training courseware is "helping organizations of all sizes train employees at multiple locations, when needed, with fully centralized recordkeeping." ◆

Download these free food safety packaging resources

The critical role of Hazard Analysis & Critical Control Points (HACCP) in food safety and the emerging requirements of the Food Safety Modernization Act (FSMA) have led many professionals across the packaging supply chain to collaborate in an effort to "elevate food packaging safety awareness and provide resources for tools and training to the packaging supply chain." In fact, this is the stated vision of FSAP, the Food Safety Alliance for Packaging, a technical committee of the Institute of Packaging Professionals.

FSAP has brought together associates from food and CPG companies, service providers, trade associations, and suppliers of packaging materials and equipment to produce a wealth of resources for the industry. Among these are several free, downloadable HACCP and related models and forms. These include:

Prerequisite programs

FSAP's Prerequisite Programs document, in Microsoft Word document (*.doc) format, spells out purposes and expectations for programs in 17 areas relating to food safety management, quality systems, control of hazards, internal audit programs, and much more.

continued

Download these free food safety packaging resources

HACCP models

Examples of HACCP models for several categories of packaging materials provide guidance from which you can assess your own requirements and risks before implementing a HACCP program. Click to download the desired model(s) in PDF format:

- Folding Cartons
- Corrugated
- Cut and Stack Label Model
- Drawn & Ironed Steel Food Can
- Film: Extrusion Lamination Model
- Film: Print, Adhesive Lamination & Slit
- Film: Blown Model (Non-Printed)
- Multiwall Bags
- Rigid Plastics Model
- Spiral-Wound Cans

Forms

Several forms have also been created to help you plan your HACCP program. Click for the desired, free download(s) in Microsoft Word document (*.doc) format:

- FSAP HACCP Team Roster
- FSAP HACCP Charter
- FSAP Training Log

continued

Download these free food safety packaging resources

- FSAP Product Description
- FSAP Process Hazard Analysis Worksheet
- FSAP Raw Materials Hazard Analysis Worksheet
- FSAP Hazard Eval Summary
- FSAP HACCP Master Plan
- FSAP HACCP Plan Reassessment Checklist
- FSAP HACCP Plan Reassessment Change Form

Food safety examples: Potential food safety risks and possible controls for food packaging materials

FSAP has also compiled a Raw Materials Hazards and Best Practices guide with charts that break new ground in identifying risks and controls that are critical to FSMA compliance for packaging professionals.

This extensive guide has been adapted for use in this Playbook with permission, and appears in the following pages. ◆

Potential food safety risks and controls: Food packaging materials

FSAP offers this advice for those who use the following guide:
"The following list may be used as a guide for food packaging manufacturers and auditors of food packaging manufacturers for potential food safety risks that may be associated with the various types of packaging materials. This list is not all inclusive and does not eliminate the need for a thorough food safety risk assessment. Evaluation of potential food safety risk must be done for the entire process and performed from the perspective of the consumer. Also, some hazards may not be true food safety but in some cases could be perceived as food safety issues (e.g., chemical odor migration). Many of these hazards may be controlled by strong prerequisite programs but some may require being considered Critical Control Points (CCPs) in a HACCP plan or equivalent food safety focused control plan."

FSAP, the Food Safety Alliance for Packaging, has also compiled a Raw Materials Hazards and Best Practices guide that characterizes food safety and related risks and possible controls pertaining to packaging materials in the following categories:

- All packaging materials
- Cut-and-stack labels
- Pressure-sensitive labels
- Printed paperboard cartons
- Printed film
- Rigid plastic containers and lids
- Glass jars and containers

In each of these areas, examples of risks and controls are provided, but these are just a starting point. You can, however, use them as a springboard to better understand the requirements of your unique operation's packaging applications:

continued

Food safety risks and controls: Food packaging materials

All printed packaging materials	
The following issues and controls may be applicable to most printed materials such as labels, cartons, rigid plastic containers, lids, film, pouches, and sleeves.	
Potential Issue (*Food Safety Implications*)	**Possible Controls** (This list is not all-inclusive; alternate controls are possible.)
Printing error—allergen ingredient left off of ingredient line. *(Potential for unlabeled allergen after food is packaged.)*	• Controls at customer providing print proof copy to assure proof copy and file to make plates is accurate. • Controls at printing press to assure print from the line matches proof copy.
Wrong printing plates used. (P*otential for unlabeled allergen after food is packaged.)*	• *Controls to archive or destroy old plates and old print files.* • *Controls in place at press to verify that print matches proof copy that is scheduled.*
Rework process allowed for materials to be mixed. *(Potential for unlabeled allergen after food is packaged.)*	• Strict controls for rework procedures. (Only one material reworked at a time or no rework allowed.) • Controls to identify/label rework correctly. • Work procedures for in-process rework that assure that rework is used during the same production run if possible (vs. being set aside, which allows potential to rework into the next run by mistake).
Returned goods mixed with non-like materials. *(Potential for unlabeled allergen after food is packaged.)*	• Strict controls for identification and storage of returned goods. Strict rework controls utilized if material is to be reworked.
Incorrect label applied to identify finished goods (units, cases, rolls, and pallets). *(Potential for unlabeled allergen after food is packaged.)*	• Controls for preprinting case labels, core tags (rolls), and pallet labels. • Account for all labels printed; destroy or segregate any leftover printed unit labels. • Vision systems to verify that case label matches material within the case and matches the pallet label.
Mixed materials within a case or on a pallet due to inadequate/incomplete line clearance procedures (cases, rolls, etc.). (P*otential for unlabeled allergen after food is packaged.)*	• Strict line clearance/changeover procedures throughout the process, including all equipment areas, partial cases, partial pallets, cases on conveyors, quality check samples, rework, etc. • A detailed checklist must be used and a second verification utilized to assure that no materials from the previous run are inadvertently left on the line.
Mixed materials on a pallet—manual or automatic palletizing. *(Potential for unlabeled allergen after food is packaged.)*	• Barcode scanners and sorting devices to separate cases on a common conveyor to divert to the correct palletizing area. • Color-coded case labels to assist in correct palletizing for manual palletizing operations. • Full-pallet scanners to scan the exterior labels on a pallet to assure all are correct.

continued

Food safety risks and controls: Food packaging materials

All printed packaging materials (continued)	
Potential Issue (*Food Safety Implications*)	**Possible Controls** (This list is not all-inclusive; alternate controls are possible.)
HUMAN ERROR—Note that this is one of the main causes of many of the mixed material issues.	• Adequate training of employees, management commitment to food safety, and reinforcement are essential to prevent potential for food safety issues. • Documented work procedures, employee accountability. • Implementation of multiple systems may be required to adequately control the risk in some processes. (Vision systems are good if applicable to the process.) • Some packaging manufacturers have found that positive reinforcement for employees identifying potential issues or preventing or reducing issues at the customers' to be successful.
Inks not approved for specific use. *(Potential chemical or odor migration into food.)*	• Regulatory (FDA) approval letters for specific use (food contact, incidental contact, non-food contact).
Inks containing potentially allergenic materials (e.g., soy-based). *(Potential for allergen contact to food after packaging if material is printed on food-contact material.)*	• Inks containing potential allergenic materials must be coated with an appropriate coating to prevent exposure of the allergen (for product-contact surfaces).
Coating layer over printing not adequate or not suitable for use for food packaging. *(Potential chemical or odor migration into food—of particular concern if ink is touching product-contact surface of packaging, e.g., nested printed rigid plastic cups, rolls of film, stacks of flat cartons, etc.)*	• Controls in place to assure coating layer over print is adequate and correct coatings (GRAS or FDA-approved) are used for specific application.

continued

Food safety risks and controls: Food packaging materials

Cut-and-stack labels

Cut-and-stack labels are printed on large sheets and could be printed on sheet-fed or roll-fed printing presses. Printing more than one SKU on a sheet is discouraged (or may not be allowed by the customer), however, with some products, may not be avoidable. After the sheets are printed, the stacks of sheets are typically cut into rows, and then rows are die-cut into desired shape of labels. The stacks of labels may be shrink-wrapped and ultimately placed into cases and palletized.

Potential Issue *(Food Safety Implications)*	**Possible Controls** (This list is not all-inclusive; alternate controls are possible.)
Mixed labels within a stack or a mislabeled stack due to the top label being incorrect. *(Potential for unlabeled allergen after food is packaged.)*	• Prohibit combo printing (multiple SKUs on each sheet)—design layout with only one SKU printed on a sheet at a time. <u>If combo printing must be used:</u> • Design print layout so that print faces with like allergens or duplicate faces are side by side. • Design print layout so that print faces have different die-cut shapes that are side by side (so if they were mixed, it would be obvious that it was the wrong label when applied to the finished food package). • Print tick marks on labels to differentiate between SKUs. (Utilize different colors, location on labels, size, and appearance of mark, e.g., single vs. double line.) • Train operators to watch for and correct issues if sheets move after slitting and slide onto the adjacent row. • Train operators at die-cut operation to check dies between SKUs to make sure that labels are not stuck in die (and could cause next stack to have the wrong label on top).
Mixed stacks of labels within a case. *(Potential for unlabeled allergen after food is packaged.)*	• Train operators to be diligent when sorting and packing stacks into cases. • Utilize vision systems to sort stacks. • Utilize vision systems to read the top labels of stacks in a case and compare to case label to assure all stacks within a case are the same and match the case label. (Scanners cannot be utilized to check all labels <u>within</u> a stack, as labels are not handled individually.) • Assure reject or alarm mechanism for mixed cases is working properly and cannot be bypassed by human error (e.g., putting a case back on the line that was rejected without checking it). • Complete material inventory reconciliation. (If all materials are accounted for, inventory reconciliation could identify if labels were mixed due to one SKU being short and another with excess when comparing material printed and final quantities.)

continued

Food safety risks and controls: Food packaging materials

Cut-and-stack labels (continued)	
Potential Issue *(Food Safety Implications)*	**Possible Controls** (This list is not all-inclusive; alternate controls are possible.)
Mixed materials or mixed cases on a pallet. *(Potential for unlabeled allergen after food is packaged.)*	• Complete and thorough line clearance procedures to assure all material from the previous run is cleared from line—utilize a detailed checksheet and have a second person verify that line is cleared of all materials. (Second person visually check line; not just the paperwork.) • Removal of all partial cases and partial pallets. • Removal of any Quality Check samples remaining in the area. • Removal of rework from the area (identify and store properly or destroy per procedures). • Removal of all cases or bundles on conveyors.

Pressure-sensitive labels	
Pressure-sensitive labels are typically printed on rollstock through a printing press, and excess material is cut out and pulled off with labels remaining on rollstock. Rolls may go through rewinding/finishing process after printing process to verify print quality and make rolls with label quantities and sizes per customer specifications.	
Potential Issue *(Food Safety Implications)*	**Possible Controls** (This list is not all-inclusive; alternate controls are possible.)
Roll contains mixed labels due to splice. *(Potential for unlabeled allergen after food is packaged.)*	• Strict controls for splice procedures to prevent inadvertent splicing of unlike materials. • Utilize vision system (e.g., barcode reader) at rewinder to assure all labels are alike on a roll.
Roll contains mixed labels due to tail from previous run attached to new roll. (Typical process is to leave tail of material inside press rollers to prevent need to rethread rollers at changeover.) *(Potential for unlabeled allergen after food is packaged.)*	• Strict controls at printing press to assure tail of prior-run printed material is not allowed to be attached to new roll for next run: • Run tail from previous run out onto floor and cut off when new material comes through, then attach new material to roll and proceed. • Alternatively material left inside press rollers without printing on it: • Raise printing rollers at press but still leave material inside threaded through rollers at the end of a run. This will result in blank material that could be run directly onto the new roll and cut off at rewinding. (Easier to identify blank material vs. printed material.)

continued

Food safety risks and controls: Food packaging materials

Printed Paperboard Cartons (cut-and-stack—flat and glued)	
Note: Paperboard cartons are typically considered secondary packaging but could be considered primary due to forseeable use (e.g., cereal or crackers falling out of the inside liner and into carton itself). Also, some cartons are primary packaging and used without a liner (e.g., pasta, some cereals, rice). Blank paperboard is typically made at a separate facility from the carton manufacturing facility (or may be purchased externally). Paperboard is printed by sheet-fed or roll-fed printing presses depending on the operation. Printed paperboard is then die-cut to the desired carton shape per customer specs. Flat cartons are shipped in stacks and are folded and glued by the customer. Glued cartons require a separate operation after die-cutting and are fed through equipment where the cartons are folded and the side seams glued prior to stacking/casing/palletizing and shipment to the customer.	
Potential Issue (Food Safety Implications)	**Possible Controls (This list is not all-inclusive; alternate controls are possible.)**
Mixed cartons within a stack or a mislabeled stack due to the top carton being incorrect. *(Potential for unlabeled allergen after food is packaged.)*	• Prohibit combo printing (multiple SKUs on each sheet)—design layout with only one SKU printed on a sheet at a time. <u>If combo printing must be used:</u> • Design print layout so that print faces with like allergens or duplicate faces are side by side. • Design print layout so that print faces have different die-cut shapes that are side by side (so if they were mixed, it would be obvious that it was the wrong label when applied to the finished food package). • Print collation or tick marks on cartons (typically on flaps) to differentiate between SKUs. (Utilize different colors, location on flaps, size and appearance of mark (e.g., single vs. double line). • Train operators at die-cut operation to check dies between SKUs to make sure (e.g., single vs. double line). • Train operators at die-cut operation to check dies between SKUs to make sure that labels are not stuck in die (and could cause next stack to have the wrong label on top).
Mixed cartons due to handling errors at casing or palletizing operation. *(Potential for unlabeled allergen after food is packaged.)*	• Strict employee training and procedures to prevent mixing of cartons within a case or on a pallet. • Utilize vision systems (e.g., barcode reader or collation mark reader) after carton gluing operation to assure cartons are not mixed. (Can only be used for glued cartons; flat cartons are not handled individually.)

continued

Food safety risks and controls: Food packaging materials

Printed Paperboard Cartons (cut-and-stack—flat and glued) (continued)	
Potential Issue (Food Safety Implications)	**Possible Controls (This list is not all-inclusive; alternate controls are possible.)**
Ink used for interior carton printing. *(Potential chemical or odor migration into food.)*	• Ink used for interior carton printing (e.g., coupons or special offers) must be approved for food contact or incidental food contact.
Paperboard quality. *(Potential for micro, chemical, or extraneous contaminants.)*	• Recycle material utilized by specific type into appropriate board products. • Biocide added to pulp slurry to prevent micro growth during process. • Chemicals used in process are GRAS or approved for specific use. • Foreign material removal systems to eliminate foreign material in recycle pulp. • Metal detectors on finished board lines to detect metal.

Printed film	
Film may be made with various processes, and the finished printed film may be multiple layers of films extruded or laminated together to form a film with the desired properties for the customer. During this process, the film may be handled multiple times, including rewinding, printing, and various finishing processes to meet customer requirements and roll sizes.	
Potential Issue (Food Safety Implications)	**Possible Controls (This list is not all-inclusive; alternate controls are possible.)**
Roll contains mixed SKUs due to splicing unlike materials together at rewinding or finishing operation. *(Potential for unlabeled allergen after food is packaged.)*	• Strict controls for splice procedures to prevent inadvertent splicing of unlike materials. • Utilize vision system (e.g., barcode reader) at rewinder to assure all SKUs are alike on a roll.
Roll contains mixed SKUs due to tail from previous run attached to new roll. (Typical process is to leave tail of material inside press rollers to prevent need to rethread rollers at changeover.) *(Potential for unlabeled allergen after food is packaged.)*	• Strict controls at printing press to assure tail of prior-run printed material is not allowed to be attached to new roll for next run; run tail from previous run out onto floor and cut off when new material comes through, then attach new material to roll and proceed. (Potential for unlabeled allergen after food is packaged.) • Alternative material left inside press rollers without printing on it; raise printing rollers at press but still leave material inside threaded through rollers at the end of a run. This will result in blank material that could be run directly onto the new roll and cut off at rewinding (easier to identify blank material vs. printed material).

continued

Food safety risks and controls: Food packaging materials

Printed film (continued)	
Potential Issue (Food Safety Implications)	**Possible Controls (This list is not all-inclusive; alternate controls are possible.)**
Functional barrier or odor migration issues due to incorrect resin used. *(Barrier issues could lead to spoilage or micro issues; incorrect resin could cause odor or chemical issues.)*	• Controls in place to assure only correct resins are used. • Resins for film for food products must be approved by regulatory (FDA) for specific food use. • Controls in place to prevent non-food approved resins from mixing with resins to be used for food packaging film.
Film quality issues make functional barrier inadequate—package leakage. *(Barrier issues could lead to spoilage or micro issues dependent on type of food product.)*	• Process parameters monitored at a frequency to assure material is produced per specification. • Quality check procedures verify film is within specifications. • Material that is out-of-spec is identified and segregated for disposition or rework.
Potential for extraneous material, chemical, or microbiological contamination from raw materials, equipment, or environment.	• Controls in place during manufacturing and finishing processes to prevent contamination from equipment or the environment. (Examples: Film not allowed to touch floor between rollers or other processes; building and equipment maintained so as not to be a source of contamination [e.g., no roof leaks]; lubricants with potential for product contact; lights in process area shielded; etc.) • Rare earth magnets may be needed for bulk ingredients (unloading or later in process prior to melting resin pellets). • Metal detection is not typically used for film, but may be used in some applications.
Compressed air used on product-contact surfaces. *(Could pose potential for micro or chemical contamination.)*	• Air used on product-contact surfaces must be of acceptable micro quality (filtered) for the type of material being made (e.g., air used for film for dairy products needs filtration to prevent micro contamination). • Compressors for food-contact air must be oil-free or use food-approved oil, and must be filtered to remove oil prior to use.
Cooling water used in contact with film. *(Potential for micro or chemical contamination.)*	• Cooling water may be used for film in some specific applications—if recirculated, it must be treated to prevent microbiological growth and tested at a designated frequency to verify potability. Alternatively, single-pass potable water could be used.
Processing aids approved for specific use. *(Potential chemical contamination if not approved for specific use.)*	• Process aid materials must be approved for incidental food contact if appropriate.

continued

Food safety risks and controls: Food packaging materials

Rigid Plastic Containers and Lids

Rigid plastic containers and lids are typically produced from injection molding (hot, melted resin injected under pressure into a mold, then excess cut away) or from thermoforming (a sheet of plastic material is heated and pressed into the desired shape, cut out, etc.). Printing (decorating) typically occurs in a separate process following the molding/forming processes.

Potential Issue (Food Safety Implications)	Possible Controls (This list is not all-inclusive; alternate controls are possible.)
Potential for extraneous pieces of plastic inside containers. *(Potential for physical hazard.)*	• Vacuums, air blowers, or other removal/cleaning devices in place and functional in thermoform and molding processes to remove excess material after forming and cutting (as applicable for specific process).
Potential for metal contamination from materials, equipment, or process. *(Potential for physical hazard.)*	• Typically screens are in the process to prevent extraneous material from entering the equipment. Screens must be on a routine inspection schedule to prevent the screen from becoming a source of the contamination itself. • Metal detection or x-ray may be needed based on the type of material, the process, and history of issues • Incoming bulk materials may need rare earth magnets at the unloading area or in the process prior to melting the resin pellets.
Compressed air used on product-contact surfaces. *(Potential for micro or chemical contamination.)*	• Air used on product contact surfaces must be of acceptable micro quality (filtered) for the type of container being made (e.g., cups for cold-fill dairy products need filtration to prevent micro contamination). • Compressors for food-contact air must be oil-free or use food-approved oil, and must be filtered prior to use.
Processing aids approved for specific use. *(Potential chemical contamination if not approved for specific use.)*	• Mold release agents must be approved for incidental food contact if appropriate (e.g., cups will be nested after forming, and outside of cup will touch inside of the next cup).
Plastic quality issues make functional barrier inadequate; package leakage. *(Barrier issues could lead to spoilage or micro issues depending on type of food product.)*	• Process parameters monitored at a frequency to assure material is produced per specification. • Quality check procedures verify containers and/or lids are within specifications. • Material that is out-of-spec is identified and segregated for disposition or rework.
Functional barrier or odor migration issues due to incorrect resin used. *(Barrier issues could lead to spoilage or micro issues, incorrect resin could cause odor or chemical issues.)*	• Controls in place to assure only correct resins are used. • Resins for containers for food products must be approved by regulatory for specific food use. • Controls in place to prevent non-food approved resins from mixing with resins to be used for food packaging containers.

continued

Food safety risks and controls: Food packaging materials

Glass jars and containers	
Glass container production involves a continuous process where molten glass is formed, typically in two stages, then cooled, inspected electronically, cased or bulk-palletized, then shipped to the consumer. Defects that are culled out either by defective mold number or by inspection devices are reworked back into the process, as with recycle glass, and are received as a raw component of the glass manufacturing process.	
Potential Issue (Food Safety Implications)	**Possible Controls (This list is not all-inclusive; alternate controls are possible.)**
Potential for extraneous pieces of glass in jars or containers due to breakage in manufacturing process. *(Potential risk of injury to consumer.)*	Glass breakage prevention and controls: • Line layout to minimize potential for contamination when breakage occurs—lines covered past cleaning devices (if present). • Surface coatings adequately applied to minimize friction in container to container jars, seal defects, other. • Electronic vision systems in place to detect glass defects, extraneous glass in run. • Vision systems must be set up with actual glass defects from jars/bottles. • Reject devices must be set up to accurately reject the identified defective number. • Mold reader reject devices must be set up accurately to reject the specific mold. • Process parameters monitored to assure containers are made per specification. • Quality check programs in place and followed by operators.
Glass defects made during manufacturing process. *(Potential risk of extraneous glass or injury, leakage due to seal surface not sealable, and breakage at food manufacturer or consumer level.)*	Above controls applicable to this as well.
Damage to glass during post-manufacture handling procedures. • Bulk palletizing procedures (e.g., forklift squeezes jars and causes potential damage) • Casing procedures (e.g., internal case dividers not inserted properly allowing jar finishes to touch during shipping allowing cracking and breaking of jars.) *(Potential risk of extraneous glass or injury at food manufacturer or consumer level).*	• Procedures must be in place to prevent damage at the palletizing and casing processes. • Periodic inspections of post-manufacture cases or bulk-palletized glass to assure that damage has not occurred. • Employees must be aware of potential hazards and prevention measures for glass containers post-manufacture.

continued

Food safety risks and controls: Food packaging materials

Glass jars and containers (continued)	
Potential Issue (Food Safety Implications)	**Possible Controls (This list is not all-inclusive; alternate controls are possible.)**
Glass containers used for hot-fill products susceptible to breakage. *(Potential risk of extraneous glass or injury at food manufacturer or consumer level.)*	• Glass containers to be used for hot-fill products must be tested for thermo-shock during manufacturing process to assure containers will withstand the process at the food manufacturer and consumer level.
Coatings applied to glass prior to cooling and post-cooling are appropriate and approved for specific use. *(Potential for chemical contamination if coating not approved for food contact or if hot end does not eliminate the coating.)*	• Hot-end coatings are typically not an issue because they will be burned off in the Lehr—but need to be sure that the coating used is applicable. (GRAS for this use.) • Cold-end coatings must be approved for use for food-contact containers. (GRAS or other approval.)
Compressed air used on product-contact surfaces. *(Potential for micro or chemical contamination.)*	• Air used on product-contact surfaces must be of acceptable micro quality (filtered) for the type of container being made (e.g., jars for cold-fill products need filtration to prevent micro contamination). • Compressors for food-contact air must be oil-free or use food-approved oil, and must be filtered prior to use.
Source: FSAP	

Additional resources

In addition to the links and downloads provided throughout this Playbook—notably the FSAP and GMA—a wealth of resources is available to food and packaging industry professionals. One obvious but useful starting point for companies seeking greater food safety and FSMA compliance is your own backyard; consult your own supply chain partners, service providers, trade associations, and professional organizations. Below are additional resources, which in turn will lead you to more.

U.S. Food and Drug Administration - Food Safety: This section of the FDA's website features information and resources, including recall-tracking widgets and applications for your computer; HACCP and related food safety programs and resources; product category-specific information; details on foodborne illnesses and allergens; details on contaminants and adulteration; and more. Get all of this information at the above link; here are specific links to just a few:

- FSMA The New FDA Food Safety Modernization Act (FSMA): This section hosts exhaustive information on the law. An Implementation & Progress section includes a full set of links, including progress updates and a user-friendly implementation time line with month-by-month milestones that link to specific sections of the FSMA within an online version of the full text of the law. Resources in the FSMA section include:

- The full text of the FSMA is available at the FDA's site, which notes that the "official and authoritative" version is offered by the Government Printing Office (GPO) in PDF format.

continued

Additional resources

- A list of open and closed dockets that shows which pieces of the law are open for public comment.

- Food Safety Preventive Controls Alliance. An effort of the FDA in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, this effort by participants from academia, and industry trade and scientific associations that are developing training courses and materials to help industry—particularly small and medium-size companies—comply with the new preventive control rules.

- FAQ / Frequently Asked Questions: This link provides a comprehensive—exhaustive, even—document of questions, answers, and links. This can be viewed online or downloaded as a PDF. Main topics areas: General; Federal/State Integration; Fees; Food Defense; Imports; Inspections and Compliance; Prevention; Produce Safety Rule; and Product Tracing.

IFS PACsecure, from PAC- The Packaging Association and IFS Management, is an HACCP and food safety standard for packaging materials. GFSI (see below) has approved it for food and non-food primary and secondary packaging materials, and work continues.

The Global Food Safety Initiative (GFSI): Certifying to an accepted GFSI-approved food safety standard is key to facilitating an FDA-regulated food company to comply with FSMA requirements. Market-driven demands have driven the growth of industry-accepted food safety standards—as well as auditing and certification to them—since 2000. That's when

continued

Additional resources

leading retailers seeking consistent, global supplier standards, formed the GFSI. Today, it's a comprehensive umbrella resource for companies seeking compliance to global food safety programs (including SQF, IFS, BRC, Dutch HACCP) as well as most major audit/certification bodies. Visit the site for more information.

Packaging World offers a continuous flow of news, trends, and features that includes food safety developments. Additionally, the community features links to informational and educational resources that support best practices, including:

- Packaging Schools, from technical colleges to university programs.
- A list of packaging and industry associations that offer resources relating to your packaging machinery and materials as well as environmental and food associations.
- The Packaging Alliance, which provides several online courses from Packaging & Technology Integrated Solutions in partnership with *Packaging World*.
- Packager's Playbooks such as this one are free of charge for those who wish to register and download them. They reinforce industry best practices in planning, managing, and implementing packaging projects from primary packaging machinery and materials to end-of-line installations. ◆

Now that you've had a chance to review this, we'd love your feedback. Share your thoughts!

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