PACKAGING WORLD

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education for packaging professionals

2012 Edition

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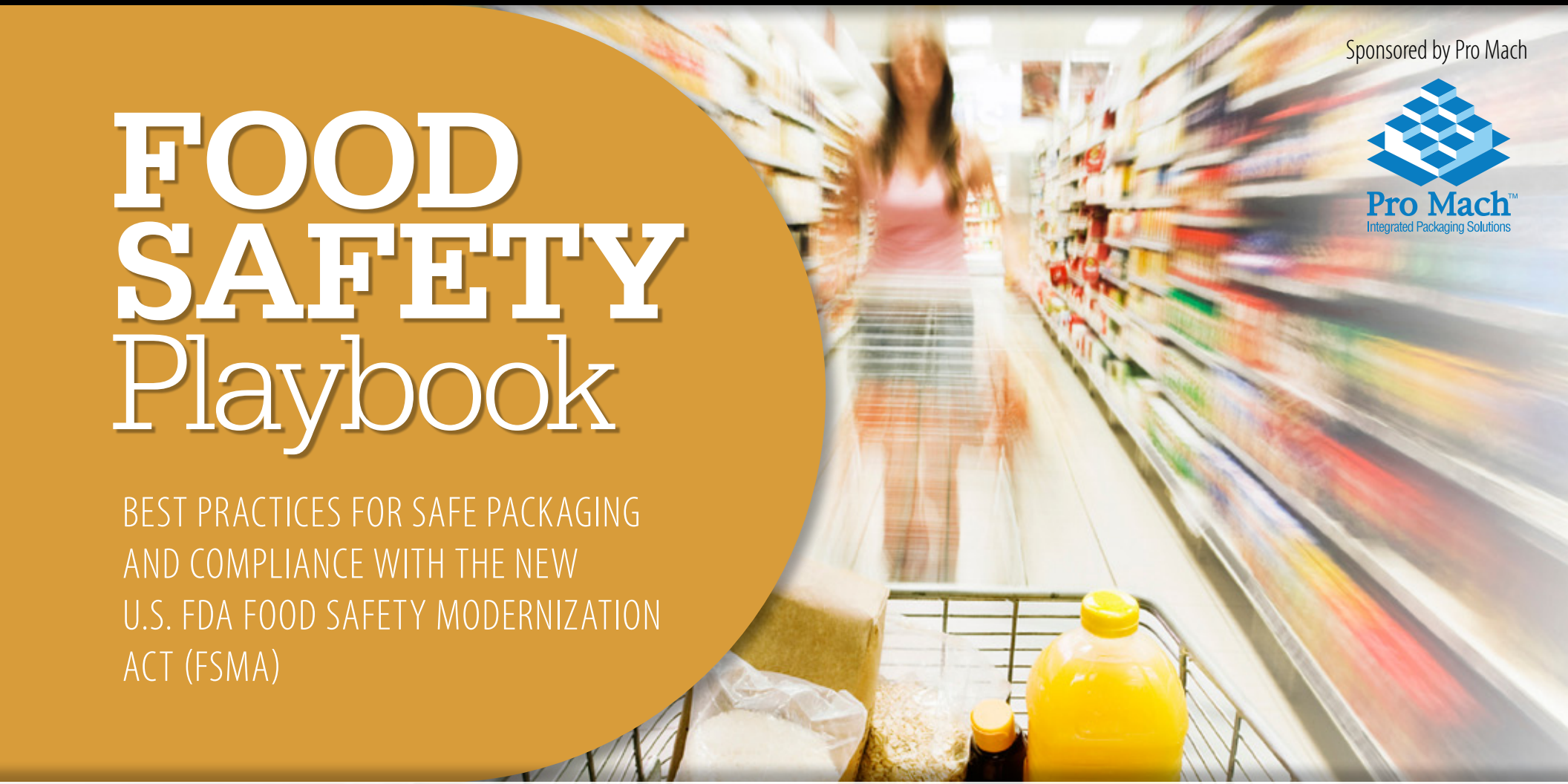
FOOD SAFETY Playbook

BEST PRACTICES FOR SAFE PACKAGING AND COMPLIANCE WITH THE NEW U.S. FDA FOOD SAFETY MODERNIZATION ACT (FSMA)



- How the FDA's new powers affect your supply chain
- When to tap packaging machinery partner expertise
- Where to find – and control – hidden packaging material risks
- Tables, downloads & management planning resources

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

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Special thanks to these industry organizations for their contributions:

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Everything you need to know about packaging in the new era of food safety

BY **BOB SPERBER,**
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In 2010 as the U.S. Congress was finalizing the details of what would become the U.S. Food Safety Modernization Act (FSMA), leaders in the food industry were especially anxious about how the pending U.S. Food and Drug Administration (FDA) would define the specifics of the law. In particular, one regulatory and food safety expert at a global brand told me: "We wanted to know how they would define best practices."

He and the industry at large wondered: Would the new law cause a major upheaval in the way food companies implement food safety programs?

When the FSMA was signed into law on January 4, 2011, the answer was a resounding: Nope. Or as our Big Brand friend said: "When the law finally came out, we liked it." Not because anyone likes new laws, but because the FSMA is largely based on the advice, standards and best practices already employed by those food industry leaders.

On one hand, the new law grants the FDA broad new oversight authorities. But much of the standards that will shift from voluntary to mandatory are prerequisites for doing business with large retailers. For example, leading brands are audited and certified to quality and

continued

Everything you need to know about packaging in the new era of food safety

safety programs based on Hazard Analysis Critical Control Points (HACCP), a cornerstone methodology for food safety management since the early 1960s, when NASA turned to Pillsbury to produce safe (if not exactly gourmet) meals for the first manned U.S. space flights.

As you will learn in this Playbook, the up-front cost of compliance can be significant, but can also return benefits. For example, solid tracking/tracing and supply chain recordkeeping can mean the difference between a massive business-ending recall and a temporary ding to a brand's image.

Packaging breaks the rules

There's much more to food safety, the law and packaging's part in it, and we're fortunate to have it explained by the leading experts in the field. Like Dr. David Acheson, who as Associate Commissioner of Foods at the FDA – a.k.a. Food Czar -- was responsible for the 2007 Food Protection Plan, which served as the basis for many of the authorities granted to FDA by the FSMA.

While so much of the new law is aimed at raising the bar so that all FDA-regulated food companies meet baseline standards, some unique risks and controls have been traditionally overlooked with regard to packaging machinery, materials and methods. In fact, to implement HACCP properly, packaging professionals have to break several rules, or conventions of HACCP plans.

Packaging, it turns out, has gotten relatively little attention, even in the technical committees of food industry trade groups developing plans for specific sectors of the industry, because they've tended to focus more on the processing side of the plant. Now, to ensure regulatory compliance, people are taking packaging risks more seriously.

continued

Everything you need to know about packaging in the new era of food safety

Among those people are the packaging, food safety and compliance managers from more than 60 leading food brands – and hundreds of their packaging supply chain partners – who formed the Food Safety Alliance for Packaging (FSAP). A technical group of the Institute of Packaging Professionals, the FSAP breaks new ground with an extensive collection of food safety forms, models and HACCP-planning resources. Founder and Chairman Wynn Wiksell not only shares his insights with you in this Playbook; he shares these significant resources with you in these pages.

You'll also learn packaging's role in food safety and the FSMA from Jeffrey T. Barach, Ph.D., who shares insights from his work with the Packaging Manufacturers Machinery Institute and before that, the Grocery Manufacturers Association. And Elizabeth Barr Fawell of the law firm of Hogan Lovells, who explains how packaging material suppliers will need to know how to help their food-industry customers. And attorney Eric F. Greenberg, author of the Guide to Packaging Law and a regular Packaging World contributor, explains how some preexisting FDA functions have already accomplished some of the FSMA's goals.

If your company can take away just one message from this playbook, it's that ensuring food safety – not regulatory compliance – is Job No. 1.

As you read, reference and share this playbook, realize that compliance with FSMA is not the point. Job No. 1 is and will always be food safety itself. Many specifics of the FSMA remain unknown, and FDA guidance is slow in coming. But if you continue to implement industry best practices, regulatory compliance will be a relatively automatic byproduct.

continued

Everything you need to know about packaging in the new era of food safety

QUESTIONS WE ADDRESS IN THIS PLAYBOOK:

This playbook is organized into three sections. Each addresses packaging's critical role in food safety compliance as follows:

- **Regulatory imperatives:** How does the new law affect packaging equipment and materials? What aspects of the law are driving modifications and upgrades to food packaging equipment and materials? How will the law affect documentation and reporting needs, and the systems used to manage those needs? How will the law affect packaging suppliers?

- **Packaging essentials:** How can food industry firms enlist the expertise of their packaging machinery suppliers? How can companies enhance sanitation and safety on their packaging lines? How much or how little will companies need to change if they already have a program in place based on current standards? If not, how can they implement such a program?

- **Resources & downloads:** What key resources can get food companies on the road to food safety compliance? How about packaging-specific resources? Are there any checklists that can serve as templates for that journey? Where else can a company turn for additional help?

Key food safety factors driving equipment upgrades

BY **DR. DAVID ACHESON**
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In addition to his role as Managing Director for the Food and Import Safety Practice of Leavitt Partners LLC, 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.

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
- 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

Key food safety factors driving equipment upgrades

Reliance on a global food supply chain:

In the United States alone there are more than 170,000 food manufacturers, processors and distributors; about two million farms and one 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 United States, 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 U.S. consumers eat. 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 it.

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 – has evolved to uncover sources of risk.

For example, 2007 marked the first salmonella outbreak linked to peanut butter in the United States, which 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

continued

Key food safety factors driving equipment upgrades

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
- Peanut butter
- Canned chili sauce
- Broccoli powder on snack food
- Pot pies
- Dog food
- Hot peppers
- White pepper
- Raw cookie dough

How has the science of food safety advanced? By "connecting the dots" from multiple reports and linking illnesses with 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 "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. Allergens are in the crosshairs, having risen from 31% to 43% of Class 1 recalls in the same period. (See chart.)

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.

continued

Key food safety factors driving equipment upgrades

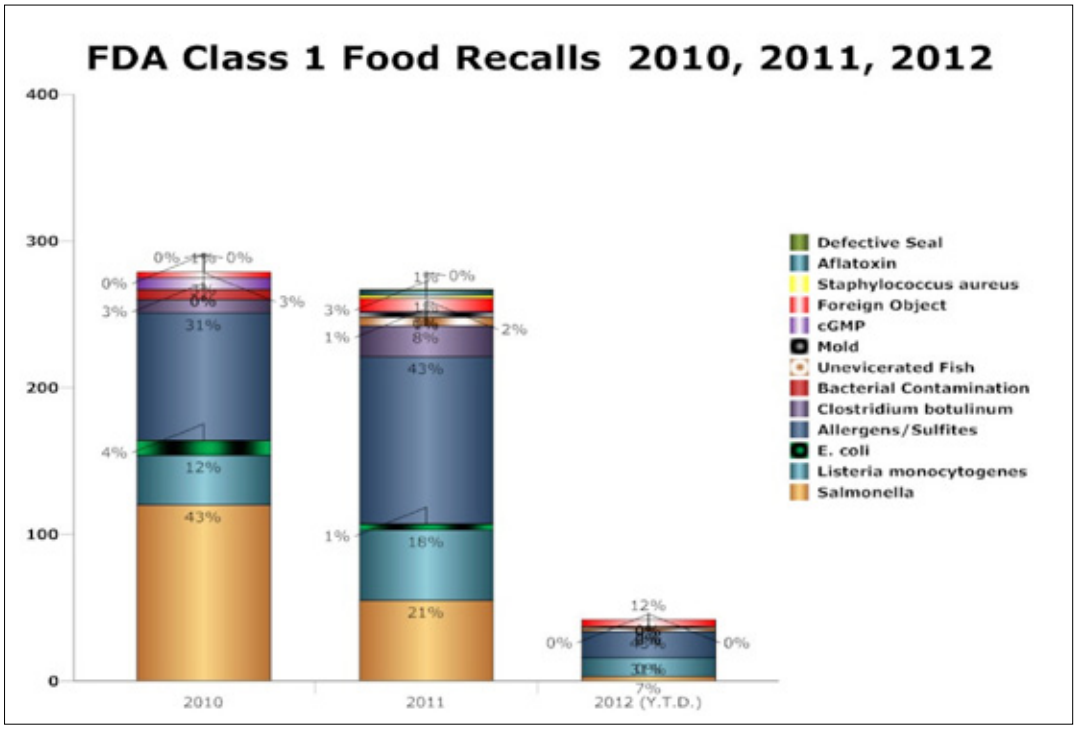

Chart shows the proportion of 13 causes of FDA Class 1 food recalls – the most serious kind. Such recalls for salmonella were reduced from 43% in 2010 to 21% in 2011; allergens are now in the crosshairs.

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 10s 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.

continued

Key food safety factors driving equipment upgrades

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 it. 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, and used for many years for products including hamburger patties. The product and process were safe – arguably safer than other meats for the heat process used – but the term went viral and consumer pressure effectively resulted in the 2012 shut-down 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.

continued

Key food safety factors driving equipment upgrades

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 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:

- 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

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 be doing 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 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 record keeping requirements.
- Systems that can be built into product tracking systems.

continued

The key role of equipment and packaging

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 market advantage in this growing area of complexity and the need to protect brands.

Recordkeeping key to the new era of prevention

BY **DR. DAVID ACHESON**

A primary goal of the 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.

While it is important to remember that we are still waiting for the proposed FSMA rules the new law strongly indicates that 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.

continued

Recordkeeping 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 included an FDA Food Defense Mitigation Strategies Database; authority to require import certificates; passing of an Interim Final Rule on Criteria for Administrative Detention; and a FDA/Department of Homeland Security Joint Anti-smuggling Strategy.

The 2012 agenda is ongoing, with product tracking pilot programs now completed and additional regulatory action in areas for preventive controls, import requirements and produce-specific controls.

continued

Recordkeeping key to the new era of prevention

The Foreign Supplier Verification Program, an all-new consideration in the area of preventive controls, is going to have a massive impact on food companies and their suppliers, who will have to keep records that demonstrate lot-level preventive controls 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.

The need for better documentation

The need for greater FDA access to records is illustrated by an outbreak of botulism several years ago: At one plant, 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. FDA had then 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 workweek.

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 the latter 2000s 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 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 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. [Note: Automation's role is discussed in this Playbook following this article.]

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.

continued

Recordkeeping key to the new era of prevention

The FSMA's plan calls for a program for imported FDA regulated foods that recognize accreditation bodies and third-party auditors to certify compliance, which will ease the burden on both companies and regulators. Audits that validate that a company's preventive controls are in place will reduce the likelihood of FDA intervention.

By keeping records, and knowing when a process deviates to threaten not just quality but safety, companies who 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 they will make it significantly easier for companies to reduce food safety incidents or at very least their impact and scope should one occur. This "carrot" is far preferable to facing the "sticks" of non-compliance.

How automation impacts product tracking, equipment selection and packaging compliance

BY **DAVID GREENFIELD**
Media and Events Director,
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 producers and food equipment manufacturers, was delivered in a keynote presentation at The Automation Conference 2012 by Dr. David Acheson, an expert contributor here and 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 automation impacts product tracking, equipment selection 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 automation impacts product tracking, equipment selection 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.

Food safety powers you might have forgotten about

BY **ERIC F. GREENBERG**
Attorney-at-Law

The author, Principal Attorney of Eric F. Greenberg P.C., has been practicing food and drug law, packaging law and commercial litigation for 29 years, is author of the pioneering Guide to Packaging Law and has contributed a monthly column for Packaging World Magazine since 1990.

Like a public relations rep for a forgotten celebrity, I sometimes find myself reminding people about the Reportable Food Registry. The Food Safety Modernization Act (FSMA) may be the latest shiny new toy in town, grabbing all the press, but the RFR continues chugging 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 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 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.

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

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.

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.

And in fact, FDA says, the total number of reports was down in year 2 over year 1, due in large part, to just three primary reports in year 1 that spawned over 1,200 subsequent reports: an instance of undeclared sulfites in prepared side dishes; Listeria monocytogenes in cheese spreads; and salmonella in a widely used hydrolyzed vegetable protein.

So although the year 2 total of submissions is 1,153, down dramatically from year one's 2,600, FDA attributes the big drop to those big three. The numbers of primary reports was about the same year to year, 229 in year 1 and 225 in year 2.

What hazards are inspiring the RFR reports? Over a third are salmonella (38.2%), another third are undeclared allergens on labels (33.3%), next biggest is listeria monocytogenes (17.8%). Other lesser causes included sulfites undeclared on labels, e. coli, foreign objects, and uneviscerated fish. The food products involved in the reports were quite varied, from produce, to animal foods, to 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

continued

Food safety powers you might have forgotten about

the marketplace" more quickly, says Michael R. Taylor, FDA Deputy Commissioner for Foods, in the new report. 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.

The FSMA actually tweaked the RFR, by requiring FDA to make rules for companies to communicate with consumers about reportable foods, and to prepare easily disseminated information for grocery stores to provide to consumers. FDA says it's working on those rules.

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 FDA' 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 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 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, D.C.. the author has significant experience with the development and implementation of the FDA Food Safety Modernization Act (FSMA).

On January 4, 2011, 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 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 importer/buyer?
- Third, who cares about your activities? Is it FDA or your customers (or both)?

continued

Key implications of FSMA for food packaging suppliers

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 and 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, FDA has exempted food packaging companies from the registration requirement (it defined "food" to exclude "food contact substances"). 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 package foods – are subject to it. And it is important to understand that one of the preventive controls that registered food facilities will need to have in place is a supplier verification program.

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.

Because food manufacturers will be required by FSMA (and FDA) to verify that their suppliers are making safe packaging materials, they may very likely require their packaging suppliers have preventive controls in place so they can meet their legal obligations.

Remember two of our key principles from above: Where are you in the supply chain? Who cares? In this case, if you are selling food packaging materials to food manufacturers, FDA will not require you to have preventive controls. Nonetheless, because food manufacturers (your customers) are accountable to FDA, you will be subject to your customers' oversight. And your customers may require you to comply with the Preventive Controls provision or otherwise assure them that your packaging materials are safe.

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 importers 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."
- Second, for purposes of this section, "food" includes food packaging materials.

continued

Key implications of FSMA for food packaging suppliers

Therefore, if you are an importer and you import food packaging materials, you will need to have a Foreign Supplier Verification Program. 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 Foreign Supplier Verification Program applies to all importers of food, whether they are registered or not. Under the FFDCA, the term "food" includes food packaging materials.

Although 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 FDA may grant an exemption from the FSVP for importers of food packaging materials in the regulations implementing the provision, as some members of the packaging industry have requested of the agency. As of this writing, FDA has written a proposed rule implementing the FSVP, but that proposed rule has not yet been published or made publicly available. Once FDA releases the proposed rule, the agency must provide time for public comment on its proposal. At that time, food packaging manufacturers can comment on the proposed rule to FDA expressing their support for an exemption. Even if FDA does not propose an exemption in the proposed rule, it is possible that FDA may grant an exemption in the final rule. So stay tuned.

Third Party Certification

Furthermore, there is a tool at your disposal that may help you comply with FDA's requirement that you have a Foreign Supplier Verification Program and/or your customer's

continued

Key implications of FSMA for food packaging suppliers

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 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 preparing for 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 FDA (FSVP), and what you need to do to satisfy your customers (preventive controls).

Work with others in your industry to see if FDA will grant an exemption from the FSVP for food packaging materials and think about whether third party certification makes sense to satisfy both FDA (if applicable) and customer requirements.

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Pro Mach provides a holistic approach to food safety and packaging

Companies working with Pro Mach benefit from the power of working with more than 15 brands unified in an approach to primary packaging solutions, end-of-line packaging machinery, and identification and tracking equipment.

Pro Mach powers what is possibly the most unique approach to food safety and packaging of any major packaging partner in the industry. Most suppliers offer point solutions for food safety in packaging. In other words, the supplier works on what it considers a best-in-class solution and offers that solution in isolation to upstream and downstream technology. Pro Mach takes a more holistic approach. Talking to one Pro Mach brand about the food safety aspects of packaging is in effect talking to more than 15 different companies with hundreds of solutions and underlying integration both upstream and downstream.

Pro Mach is a leading provider of integrated packaging products and solutions for food, beverage, household goods, and pharmaceutical companies. Through three business units and more than 15 related brands, Pro Mach provides product packaging equipment, PMMI certified training, installation, and parts for:

Pro Mach™
Integrated Packaging Solutions

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Pro Mach Provides a Holistic Approach to Food Safety and Packaging

- Primary packaging solutions
- End-of-line packaging machinery
- Identification and tracking equipment

Pro Mach's brands include Allpax, Axon, Federal, Fowler, Matrix, Ossid, and Roberts PolyPro in primary packaging; Brenton, Currie, Dekka, Edson, IPak, Orion, Rennco, Shuttleworth, and Wexxar/BEL in end-of-line packaging; and ID Technology and Labeling Systems (LSI) in identification and tracking.

To facilitate innovation within Pro Mach, each brand exercises significant amounts of autonomy, and general managers at each of the brands are selected based on entrepreneurial spirit, technical expertise, and business acumen. Through Pro Mach's unifying vision, the brands are powered through synergies in operational systems and a shared vision of inter-brand communications and commonality in customer service.

The Pro Mach ProCustomer® program is an excellent case example about shared processes. ProCustomer assures that all customer service, technical support, training, product upgrades, and parts programs provided by Pro Mach brands adhere to consistent standards of excellence. These standards are based on in-depth customer research and industry best practices. All Pro Mach brands deliver service and support that meets or exceeds 13 key attributes for reactive, interactive, and proactive care, with an emphasis on improving packaging line productivity.

Pro Mach™
Integrated Packaging Solutions

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Pro Mach Provides a Holistic Approach to Food Safety and Packaging

"Adhering to best practices ensures that customers have the support to maintain peak productivity," said Mark Anderson, president and CEO, Pro Mach, Inc. "Importantly, ProCustomer is designed to be flexible with individual goals suited to the needs of each customer. ProCustomer is one of a series of strategic initiatives, which include operations excellence, product excellence, customer service excellence, and distribution excellence."

A holistic approach to food safety

As stated earlier, engaging one brand is in effect opening the door to a network of more than 15. For example, discussing with Allpax FDA approved control solutions for ensuring consistent processing of shelf-stable food in a retort process may lead to discussions with Shuttleworth experts on clean conveyor strategies, or to the latest thinking on full-sleeve labeling/tamper banding with Axon, or to splash proof and wash down weigh price labeling equipment considerations with Ossid, or to world class track-and-trace solutions with LSI, or to the latest in the Produce Traceability Initiative (PTI) with ID Technology.

The subject matter experts at any Pro Mach brand will help coordinate, as appropriate, these discussions with other Pro Mach brands. Not only do the brands have an intimate awareness of broader Pro Mach solutions, but also the company powers the integration of multi-brand system solutions. For example, Fowler Products at its new customer center and factory acceptance testing facility assembles multi-machine rinsing, filling, closure sterilization, and capping systems for the factory acceptance test. These systems often include technology outside of Pro Mach. The result is faster and more trouble free installations. Brenton at its state-of-the-art facility performs similar final-system integration services with complex end-of-line systems. Importantly, planning for these systems may start out totally focused on food

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continued

Pro Mach Provides a Holistic Approach to Food Safety and Packaging

safety in packaging and end up with both the food safety and ancillary technology integrated into a complete – 360 degree – solution.

"We see the multi-brand holistic approach in action at trade shows where Pro Mach brands are exhibiting," said Anderson. "One of our representatives walks a customer from booth to booth and plans for a multi-technology solution take place on the spot. Customers come to one of our brands to talk about a machine, and they walk away with a systems solution and a partner with world-class capabilities on multiple fronts."

The phrase the company uses to describe this phenomenon is "Powered by Pro Mach." That states exactly what the company's holistic approach to food safety is all about – multi-brand solutions powered by best in class equipment, expertise, operational linkages, and communications. Pro Mach combines the best of entrepreneurial drive and organizational strength with a breadth and depth of packaging solutions that may be unequaled in the supplier community today.

Pro Mach Brands

ALLPAX powered by Pro Mach

Allpax, based in Covington, Louisiana, manufactures food processing and sterilization solutions for the food and pharmaceutical industries. Allpax provides fully automated retort rooms as well as individual retort room components like retorts, retort loaders and unloaders, shuttles, and other material handling equipment going into and out of the retort room. Allpax.com

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Pro Mach Provides a Holistic Approach to Food Safety and Packaging

Axon, based in Raleigh, North Carolina, manufactures shrink sleeving, tamper evident banding, and stretch sleeve applicators as well as heat shrink tunnels that are engineered for reliability, flexibility, and value. Utilizing continuous motion technology, Axon product labeling equipment applications include beverages, processed foods in tubs and jars, cultured dairy products, pharmaceuticals, health and beauty aids, novelties, and household products. AxonCorp.com

Brenton, based in Alexandria, Minnesota, engineers and manufactures case packaging equipment, shrink-wrapping machines, robotic packaging systems and material handling equipment for the food, personal care, and household products industries. Brenton offers innovative custom palletized packaging systems and is considered a leader in servo technology applications in the packaging industry. BrentonEngineering.com

Currie, based in Alexandria, Minnesota, manufactures conventional and robotic palletizers with proven, rugged designs for maximum reliability and value. Currie offers solutions to meet virtually every automatic palletizing challenge with low-level and high-level infeed palletizers, case elevators, pallet dispensers, slip sheet feeders, and complete palletizing systems. CurrieByBrenton.com

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DEKKA powered by Pro Mach

Dekka, based in Delta, British Columbia, Canada, is a leading manufacturer of high quality tape head systems that are easy to load, and feature Dekka's exclusive no break tape advance system. DekkaIndustries.com

EDSON powered by Pro Mach

Edson, based in Hamilton, Ontario, Canada, manufactures robust, high-performance case and tray packaging systems. Edson has long-standing customer relationships with food, pharmaceutical, consumer goods, and tissue converting companies that require innovative, high speed horizontal case packing, material handling, and top load robotic solutions. Edson.com

End of Line Packaging Solutions powered by Pro Mach

Pro Mach's End-of-Line Packaging Solutions group, based in Alexandria, Minnesota, offers customers a single source for all their end-of-line packaging needs, from stand-alone applications to complex packaging systems. EOLPackagingSolutions.com

FEDERAL powered by Pro Mach

Federal, based in Milwaukee, Wisconsin, manufactures durable, reliable, and hygienic liquid container filling and capping machinery. Federal serves a variety of markets, including dairy, juice, water, food, chemical, coatings, and pharmaceutical companies worldwide. Federal also provides custom tailored extended shelf life (ESL) solutions to meet the strict demands of today's marketplace. FederalMfg.com

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Pro Mach Provides a Holistic Approach to Food Safety and Packaging

FOWLER A-Z powered by Pro Mach

Fowler Products, based in Athens, Georgia, makes high-speed bottle capping machinery and bottle cap sorting and bottle cap feeding systems, high speed bottle rinsing and air cleaning machines, and cap/lid sterilization and decontamination equipment. Their quality equipment serves the beverage, food, pharmaceutical, chemical, personal care, household goods, and distilled spirits industries. FowlerProducts.com

ID TECHNOLOGY powered by Pro Mach

ID Technology, based in Fort Worth, Texas, is a manufacturer and integrator of labeling, coding, and marking equipment. The ID Technology product line includes label applicators, label printer applicators, RFID solutions, inkjet printers, laser coders, thermal transfer overprinters, labels, scanners, verifiers, software, and supplies. ID Technology also provides nationwide support through numerous facilities and satellite locations across the United States. IDTechnology.com

IPAK MACHINERY powered by Pro Mach

IPak, based in Delta, British Columbia, Canada, is a leading manufacturer of rugged tray formers, bliss formers, flange sealers, and tray stackers. IPak's heavy-duty construction delivers round the clock performance in even the most demanding environments. IPakMachinery.com

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Pro Mach Provides a Holistic Approach to Food Safety and Packaging

LSI powered by Pro Mach

Labeling Systems, based in Oakland, New Jersey, is a leading designer and manufacturer of pressure sensitive labeling equipment and systems for food, beverage, pharmaceutical, and consumer goods companies. LSI offers a range of products, including stand-alone labeling heads and turn-key systems as well as custom solutions all designed to operate in a 24/7 production environment. LabelingSystems.com

MATRIX powered by Pro Mach

Matrix, based in Saukville, Wisconsin, is an industry-leading manufacturer of vertical form-fill-seal (v/f/f/s) packaging equipment for all types of flexible packaging. Since 1988 Matrix has built a solid reputation for delivering rugged, well-engineered, cost competitive, easy-to-use packaging systems backed by outstanding customer support. MatrixPM.com

orion® powered by Pro Mach

Orion Packaging, based in Alexandria, Minnesota, is a manufacturer and worldwide distributor of automatic stretch wrapping machines and semiautomatic stretch wrapping equipment. Orion leads the industry with an extensive product line of more than 25 models, including rotary turntable, rotary tower, and horizontal wrapping systems. OrionPackaging.com

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Pro Mach Provides a Holistic Approach to Food Safety and Packaging

OSSID® powered by Pro Mach

Ossid, based in Rocky Mount, North Carolina, is a manufacturer of high-speed tray packaging, weigh/price labeling equipment and horizontal form-fill-seal packaging solutions. Ossid provides solutions across numerous markets, including fresh and processed meats, medical devices, convenience foods, and consumer goods. Ossid.com

Rennco™ World-Class Packaging Solutions powered by Pro Mach

Rennco, based in Homer, Michigan, is a respected manufacturer of semi-automatic vertical bagging machines, semi-automatic horizontal bagging machinery, and automated vertical bagging systems. Rennco equipment applications include consumer goods, consumer disposables, food, hardware, and medical goods. Rennco.com

Roberts PolyPro powered by Pro Mach

Roberts PolyPro, based in Charlotte, North Carolina, manufactures plastic packaging handles and components for the world's largest consumer products companies. Roberts designs and manufactures handles for bottles in both single and multipack configurations, as well as handles for cartons and boxes. Roberts PolyPro also produces the application machinery to apply these handles at a variety of speeds. RobertsPolyPro.com

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continued

Pro Mach Provides a Holistic Approach to Food Safety and Packaging

Shuttleworth, based in Huntington, Indiana, provides integrated product handling solutions using innovative technology and experienced problem-solving specialists to increase line efficiency, maximize profitability, and minimize risk. Shuttleworth serves a variety of markets, including automotive, consumer, electronics, food, health and beauty, industrial, medical, paper conversion, paper printing and binding, pharmaceutical, and solar energy. Shuttleworth.com

Wexxar/BEL, based in Delta, British Columbia, Canada, is a leading manufacturer of high quality integrated packaging solutions for case forming and case sealing machines. The Wexxar line of innovative case formers and case sealers has been installed in nearly 40 countries. The BEL line offers "end-of-line" corrugated box sealers, tapers, and packing systems. Wexxar.com

Pro Mach™ Integrated Packaging Solutions

How companies can tap their machinery suppliers for FSMA compliance

BY **JEFFREY T. BARACH,**
Ph.D., Principal,
Barach Enterprises LLC

Now with Barach Enterprises, the author is the FSMA expert for the Packaging Machinery Manufacturers Institute, participant in in the FDA-sponsored Food Safety Preventive Controls Alliance and former Vice President of Science Policy for the Grocery Manufacturers Association.

In general, food companies affected by the FSMA would be wise to call upon their equipment suppliers, who 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 for which 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, have 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 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 which 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 will help ensure that hazardous microorganisms are not transferred into the product stream by finding and eliminating real or potential pathogen harborage sites. The program should include a listing 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 is provided. The training content, comprehension and 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 helping deepen the effectiveness of customer-supplier relationships. Equipment suppliers have been known to work on their customers' behalf through stewardship programs. Such a collaboration with customers as well as the USDA and the independent, non-profit 3-A Sanitary Standards, Inc., led one prominent supplier to make design changes in its bagging machinery.

These included the elimination of "sandwiched" metals (caulked, welded or gasketed surfaces); the elimination of aluminum components (film cage, film rollers); 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 and Modernization Act (FSMA), there's bound to be a sense of information overload, perhaps accompanied by misinformation, panic and 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!

The best way to prevent a sense of panic is to realize one basic fact: FSMA is about 85% HACCP.

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 Food Safety Modernization Act, 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.

The 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 United States.

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, and can be likened to "HACCP on steroids."

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

A HACCP primer

For those not on the front-lines of HACCP, it can be broadly defined as a systematic approach to 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; 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 came in 1995 for fish and fisheries; 1996 for meat and poultry and 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 customer's 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 SSOPs common for FDA-regulated products. These are important building blocks in support of a HACCP program.

• **cGMPs, or GMPs** (with the "c" for "current" assumed) have been fundamental to food safety assurance programs manufacturing, packaging and holding/storage for more than a decade. cGMPs provide the basic principles plants should follow in manufacturing safe food, providing clear definitions 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 will be updating GMPs as part of FSMA, and these 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 records available to FSIS upon request, similar to the FDA's greater role under FSMA.) SSOPs can cover facilities (production, and environmental monitoring); personnel hygiene; equipment (processing, packaging & storing); and operations (sanitation, processing, rework & training).

continued

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

Together, Good Manufacturing Practices (GMP) and Standard Operating Procedures (SOP) provide the basis for other, more advanced programs for assuring product quality and safety. These include Hazard Analysis and Critical Control Point (HACCP) systems 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.

Successful maintenance of a 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 still needs to propose the first of 50 some rules, open them to a 60 or 90-day comment period and 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.

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

The 10 principles of sanitary machine design

BY **BOB SPERBER**

Suppliers have also played a role in the past, and can continue to assist food companies in evaluating compliance with various standards that are consistent with the 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 to 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, 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 shall 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 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,**
Chairman, FSAP/Food Safety Alliance for Packaging

In addition to his role as Chairman of FSAP/Food Safety Alliance for Packaging, a technical group of the Institute of Packaging Professionals (IoPP), the author has been auditing packaging specifications and supplier conformance for the last 12 years.

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 the 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 CPG companies were telling the packaging industry to shore-up their Good Manufacturing Practices (GMPs). So

continued

HACCP for packaging: Addressing the critical knowledge gap

when the 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 that food manufacturers and packaging suppliers have not communicated well.

continued

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. The Packaging Association (PAC) 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 create HACCP plans and pre-requisite programs for all to use.

This article is adapted with permission from the forthcoming book, HACCP: A Practical Approach, Third Edition, 2013. The book can be pre-ordered at 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 HACCP speaks to, that supplier must keep in mind. What is critical for the supplier – and 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 chemicals with different handling requirements is a resultant hazard with more than one CCP. (See Fig. 1 for an example.)

Rule Breaker #2: Glass is allowed. Of course, it must be controlled. For most food plants, it is easiest 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 CPGs, the issue is more accurately characterized as label control. While CPGs do not want peanuts and other allergens

continued

HACCP for packaging: Rules and realizations

in the packaging supplier's facility, when it comes to packaging a product on the production floor, CPG companies need the packaging supplier to have programs in place that prevent mixing. This can occur 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. 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 being 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 insure that the pallets are fit for food manufacturing distribution.

By applying these rule-breakers into the HACCP process, we can start to eliminate confusion, 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 manufacturers' 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

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 at 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.

item. If the hazard is a transient or 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 everyday 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 which they could have an impact. With this new awareness though has brought on the next level of learning. Better communication through has brought about some realization for new thinking on behalf of the CPG's and packaging suppliers around methodology:

Realization No.1: If you test, do not ship. If the packaging supplier has as a 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

continued

HACCP for packaging: Rules and realizations

the marketplace costs way too much compared to holding the packaging material at the supplier's location until the proper clearances have been given.

Realization #2: Test for one, impact another. A continuation from the last scenario, an additional issue arises when a test is implemented at a 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 one, the testing is going on at all, and two 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.

continued

HACCP for packaging: Rules and realizations

10:30 as part of a QC check 10 cups were pulled for measurements and visuals. No issues reported.

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 and understanding of the rule breakers and realizations of communication practices, a packaging manufacturer can protect itself and the CPG companies that it supplies. ■

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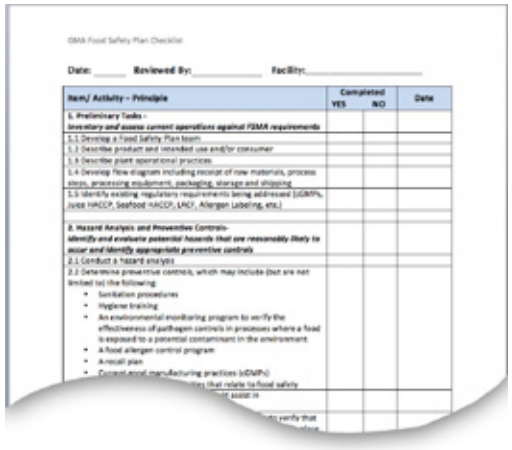
GMA checklist offers seven steps to food safety compliance

BY **BOB SPERBER**



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, D.C.-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:

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

continued

GMA checklist offers seven steps to food safety compliance

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, and

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 with FSMA compliance.
- Thirdly, if you don't take a proactive role in following best practices such as those outlined in the checklist – and wait for 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.

continued

GMA checklist offers seven steps to food safety compliance

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).

Additional GMA resources:

- A Technical Guidance and 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 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

BY **BOB SPERBER**

The critical role of HACCP in food safety and the emerging requirements of the 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 & 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:

- Carton Model
- Corrugated
- Cut and Stack Label Model
- Drawn & Ironed Steel Food Can
- Film: Extrusion Lamination Model
- Film: Adhesive Lamination Model
- 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 RM 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.

Pro Mach™
Integrated Packaging Solutions

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."

Potential food safety risks and controls: Food packaging materials

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 are just a starting point. You can, however, use them as a springboard to better understand the requirements of your unique operation 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 1 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 us 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 pre-printing case labels, core tags (rolls), and pallet labels. • Account for all labels printed, destroy or segregate any left-over 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.)*	• Bar code 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 1 SKU on a sheet is discouraged (or may not be allowed by the customer), however, with some products may not be able to be avoided. After printing the sheets, 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 1 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 by-passed 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. (2nd 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 roll-stock through a printing press and excess material is cut out and pulled off with labels remaining on roll-stock. Rolls may go through re-winding/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., bar code 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 re-thread 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 foreseeable 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 is made at a separate facility than 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 the 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 1 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., bar code 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 re-winding, 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., bar code 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 re-thread 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.) • 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 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 food grade, 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 post 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 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 blows, 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 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 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 dependent 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 2 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 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 being container. • Reject devices must be set-up to accurately reject the identified defective number identified as defective. • 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; potential for 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 cause 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; 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 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 & 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 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 timeline 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 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 listing 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, industry trade and scientific associations who 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

The Packaging Association (PAC) provides training and certification programs for packaging suppliers across North America wanting a certified HACCP packaging program. The organization began serving the Canadian packaging industry in 1950 and expanded to its present, continental focus in 2010.

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 include 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 listing 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.

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