



a framework called Hazard Analysis Risk-Based Preventive Controls (HARPC). Compared to HACCP, HARPC is more proactive, less reactive, and has a stronger focus on risk-based prevention. For food companies, one of the practical consequences of this shift is that steps and procedures that were part of HACCP’s Prerequisite Programs are mandatory in HARPC.

Although this is a significant change, according to Nancy Scharlach, president and chief technical director at FSMA International, many operators tend to

**“You may think you’re doing a mock recall, but all you’re really doing is a traceability exercise.”**

**—MATHEW SURI,**  
*president of Essential Food Safety Consulting*

think that preventive controls are just HACCP with a different name. “A lot of companies are too complacent, still in the mindset that they only have to make a few tweaks to their HACCP plan in order to be FSMA compliant,” she says. “In fact, we’ve grown beyond HACCP. The FDA felt that it didn’t cover all of the critical recall subject matters like allergens, environmental pathogens on ready-to-eat food, and food fraud from within the supply chain.”

The other risk of a complacent attitude is to have a false sense of security. “When companies use their HACCP plan as a reference to build their FSMA food safety plan, sometimes they don’t carry risks over,” says Mathew Suri, president of Essential Food Safety Consulting. “If they identified a hazard in their HACCP plan but never experienced a problem with that hazard, they just might not include it in their risk assessment, when in fact they still need to keep track of it as a potential hazard.”

Another common mistake is not being specific enough. “Many food safety plans that we review worldwide are too generic,” says Scharlach. “You’ll see a hazard analysis that simply says: ‘biological hazard,’ ‘pathogens,’ or ‘allergens.’ But you need

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# Prepare an FSMA-Compliant Food Safety Plan

Avoid these common mistakes and pitfalls

BY **ANDREA TOLU**

**S**ince the Food Safety and Modernization Act (FSMA) went into effect in 2011, U.S. companies have had to take their food safety practices to a new level. The law introduced substantial changes, such as a stronger focus on prevention, new hazards to consider (radiological, allergen control, and economically motivated adulteration), more transparency and accountability, and a closer inspection of the supply chain.

Adapting to these provisions means new challenges for food businesses, es-

pecially when it comes to preparing the food safety plan, the written document or set of documents in which companies must explain how they prevent food safety incidents from happening and how they’ll manage an emergency if one does happen.

## **Prevention’s Biggest Enemy: Complacency**

The authors of the FSMA greatly reduced the application of Hazard Analysis and Critical Control Points (HACCP) in favor of

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to know which allergens or pathogens are unique to your production line.”

For Brian Perry, senior vice president of food safety and quality at TreeHouse Foods, a manufacturer and distributor of private-label packaged foods and beverages, conducting a correct hazard analysis was one of the main challenges to making his company’s food safety plan FSMA compliant. “One of the things that we worked to improve upon across the board was making sure that we’re looking at all the inputs from the supply chain and at our risk assessment in a broad sense. We tend to focus very much on microbiological hazards because of the public health elements, but we can’t ignore radiological, chemical, and physical hazards.”

### Finding the Right Resources

What complicates things further for food companies is that they don’t always know where to find resources and guidance to put together a food safety plan, making the mistake of falling back into what they already know.

According to Perry, companies shouldn’t be insular in their risk assessment. They should actively seek expert opinions and use all the materials provided by FDA and other food safety institutions.

Kevin Byrne, senior consultant at Essential Food Safety Consulting, says most companies don’t do enough research. “Especially if you’re a smaller company with little time to look at what’s out there, you may not be aware that other hazards exist, so you can’t complete a thorough assessment of your ingredients, process steps or finished products. For example, something that a lot of people don’t even realize is that the FDA put out an appendix to the draft guidance on the food safety plan, which covers all of the biological and chemical hazards that you would expect to encounter with different ingredients based on their category. It’s a huge reference, but not a lot of people are aware that it even exists.” [The appendix is available at [fda.gov/media/99581/download](http://fda.gov/media/99581/download).]

### Make Your Food Safety Plan Crisis Ready

Managing a food safety emergency requires a lot of intense decision making,



“[The FSMA has] been like a tide that raises all boats. The focus on prevention brought a clear improvement and probably helped to weed out some bad actors.”

—BRIAN PERRY,  
senior VP of Food Safety and  
Quality at TreeHouse Foods

including knowing when to issue a recall or not. “There are a lot of layers involved, but if there’s even a chance that misbranding or adulteration occurred and you can’t prove that it didn’t, you still have to initiate a recall,” Scharlach says.

According to Byrne, the first step is obviously to assess the impact by identifying which customers the product was sold to and then to take care of the regulatory aspects by contacting the appropriate people.

The part of the food safety plan about crisis management should be a tool that helps quality and safety teams make the

right decisions quickly. Unpredictability is an objective limit here: When prevention fails, there are an infinite number of things that can go wrong, and it would be impossible to include all of them in the recall plan—in fact, this isn’t what FDA expects. “What the FDA wants to see in your recall plan isn’t necessarily the hundred different scenarios that could happen. What they want to see is that you have a list of key contacts, both internal and external, and a step-by-step protocol that the recall team will follow in order to decide on, initiate, and follow through with the recall process,” Scharlach says.

### Do Mock Recalls, but Do Them Right

A good way to bridge this gap as much as possible is by conducting mock recalls, but they need to be done the right way.

“A lot of businesses do mock recalls, but once they know which customers are being affected and they can account for everything, they stop the exercise,” Byrne says. He suggests companies add more specific steps to their mock recalls, such as root cause analysis and the drafting of a press release.

“You may think you’re doing a mock recall, but all you’re really doing is a traceability exercise,” adds Suri. “That’s only one aspect of a mock recall, though. There are several other things that have to be done, sometimes concurrently,” says Suri.

Mock recalls aren’t just for rehearsing for an emergency, but also to find out if there are any gaps in your recall plan. “[Businesses] put a plan together that looks like it should hold up procedurally, but practically they’ve missed steps because they’ve never really mocked the process the whole way through. So when an actual recall shows up, they’re lost,” Suri says. “You might not be able to role play every potential situation, but we encourage our clients to pick a different scenario each time and role play it out fully twice a year. That way, you wind up gaining experience with a wide gamut of issues.”

Byrne also warns food companies away from taking a superficial approach toward corrective action through a lack of monitoring. “We see a lot of companies identify the problem and what the

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# In The Lab

MOISTURE CONTROL



## Moisture Content Analysis

The pros and cons of current methods of moisture control

BY KAREN APPOLD

**M**oisture plays a critical role in many aspects of food production, from getting the right consistency to achieving proper shelf life. Too little moisture can lead to products that are crumbly, hard, or that have palatability issues, says Ian R. Olmsted, PhD, a product manager in the process control division at CEM Corporation in Matthews, N.C., while too much moisture can lead to spoilage.

A variety of moisture control methods are currently available, and each has its pros and cons. Here's a closer look.

### Loss on Drying

Loss-on-drying instruments, such as ovens, thermogravimetrics (TGA)/infrared, and microwaves, are a simple and robust way to measure moisture in foodstuff. The general principle is that a sample is weighed initially, then dried in an apparatus such as an air oven, under a heat lamp or via microwave energy, Dr. Olmsted says. Once a sample is completely dry, it is re-weighed and the amount of

loss on drying is calculated. Air ovens, a low-cost option, work well for many sample types but require up to eight hours to completely dry samples.

TGA is a very precise method of analysis, but to get reliable data a sample must be heated at a slow, controlled rate, Dr. Olmsted says. Therefore, TGA is not good for rapid process control.

Microwave moisture analyzers use microwave energy to dry samples; an integrated balance automatically measures sample weight during a test, Dr. Olmsted says. Microwave moisture analyzers are the fastest way to measure loss on drying, with typical testing times taking as little as two minutes.

Claas Boerger, head of the strategic product group at Mettler-Toledo GmbH in Greifensee, Switzerland, concurs, and says that microwaves are indeed fast. However, they can be used only for samples with high moisture contents approximately above 10 percent, limiting their applications. Typically, they cost more than an infrared moisture analyzer as well.

Infrared moisture balances provide a more rapid approach to drying samples. However, most instruments don't have active ventilation so high-moisture products can take as long as 20 minutes to dry, Dr. Olmsted says. Infrared moisture balances with active ventilation can reduce testing times to around five minutes.

Claas says that infrared moisture analyzers are fast and easy—providing results in minutes. “They are easy to use for untrained personnel (e.g., shift workers), and results match the official method of oven drying,” he says. Their versatility enables them to be used for all samples with moisture contents ranging from 0 percent to 100 percent. On the downside, method development needs to be performed in order to get the same results as a drying oven, which is why modern instruments support the user with integrated method development functionality.

### Karl Fischer Titration Method

To avoid the loss-on-drying method's main shortfall of not being specific to water, the titration method instead relies on a wet chemistry to detect the amount of water, says Brady Carter, PhD, senior application scientist at Novasina AG, based in Morgan, Utah. The concept involves creating a reaction chamber containing

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the sample plus a solvent that will help release the water from the sample, and creating the necessary conditions needed for the reaction to proceed.

Then, iodine is titrated into the reaction chamber and the amount is closely tracked. Iodine and water are both needed for the reaction to proceed. When all of the water is consumed by the reaction, the reaction stops, and iodine starts to accumulate in the reaction vessel, Dr. Carter says. This causes a change in the solution's electrical properties detected by an electrode inserted into the solution.

When the change is detected, the test is stopped, and the amount of iodine added is directly proportional to the amount of water present in the product. This amount of water is then divided by the wet weight to give a wet basis moisture content or divided by the dry weight to give a dry basis moisture content, Dr. Carter says.

The Karl Fischer titration method is specific to water, so it is a more pure determination of water content, says Dr. Carter in noting its positive attributes. It is not impacted by ambient conditions, making it more reproducible. However, this method does require using hazardous solvents that must be handled, stored, and properly disposed of. It's a complicated process, which requires training and understanding, Dr. Carter says. Furthermore, the equipment is typically more expensive than that for loss on drying. Because no independent standard is possible for moisture content, the measurement is completely empirical—making it impossible to determine accuracy or its true value.

### Near Infrared (NIR) Moisture Meter

NIR moisture meters use calibrations to convert an optical signal into the percent of moisture. They can be quite accurate if regularly calibrated, but users must be aware that as the optics of an instrument age, they change in a way that affects the signal. "NIR instruments are commonly used as inline detectors, but they need to be calibrated to a primary method to maintain accuracy," Dr. Olmsted says.

On the positive side, Claas says that these meters provide very fast measurements in 30 to 60 seconds, and multi-parameter options (e.g., fat, moisture, proteins). On the negative side, the meter



Some producers have eliminated moisture content testing completely and only measure water activity. By tracking water activity throughout the production process, these producers are able to catch changes in production that may lead to problems before they are widespread.

—BRADY CARTER,  
PhD, senior application scientist  
at Novasina AG

requires calibration; precision and accuracy depend on the quality of calibration. In addition, the meters are expensive.

### Preferred Methods

Since moisture content is subject to many sources of error and doesn't have an independent standard, it is impossible to know the true value, Dr. Carter says. Given this, he prefers the loss-on-drying method because it is the cheapest and easiest to perform. That said, he would not use moisture content to monitor moisture control, but instead would use water activity testing.

Dr. Olmsted prefers a method that is direct, easy, and rapid. For these requirements, a microwave moisture analyzer with secondary infrared heating is his instrument of choice.

Claas says his choice depends on the application and workplace. For food production in regular operation (e.g., goods-in, in-process control, final quality control) infrared moisture analysis is his choice because it's versatile and can be used for many different samples (e.g., liquids, creams, powders, granulates), it's

easy to use, results are provided quickly, and it offers great precision and accuracy.

### Innovations in Moisture Control

CEM Corp. combines numerous technologies to provide a loss-on-drying analyzer that is faster than any other primary method on the market—the SMART 6. "Not only does it combine microwave and infrared energy for faster heating, but it also uses active ventilation to both speed the process and to give SMART 6 the capability of operating safely outside a fume hood with no odors being released into the test area," Dr. Olmsted says. For customers using inline NIR sensors, the SMART 6 offers the ability to calibrate the NIR sensors in only a few minutes, instead of hours with an air oven.

Dr. Carter works with Novasina, a provider of water activity meters, and Neutec Group, Novasina's distributor for the U.S. market. "Although water activity meters are not new, many food manufacturers are now switching to releasing product solely on water activity values and relegating moisture content to only a measure of purity and standard of identity," he says. "Some producers have eliminated moisture content testing completely and only measure water activity. By tracking water activity throughout the production process, these producers are able to catch changes in production that may lead to problems before they are widespread."

In addition, by releasing on water activity, they are able to maximize moisture levels but assure product safety and stability using the water activity. "Since most products are sold on a weight basis, releasing based on water activity makes it possible to maximize profits, eliminate waste, save on energy costs, and release a safe product with optimal shelf life," Dr. Carter says.

### Educating Members

It's important for food industry organizations to keep their members educated on moisture control methods, and what innovations are happening.

The American Dairy Products Institute showcases equipment at its annual meeting and technical symposiums where instrument suppliers can present new or updated products. They can also network

with users to get answers to specific questions and training issues. Instrument manufacturers may have workshops for specific instruments as well as preventive maintenance training.

Software training for calibration adjustment or development is done via webinars or online training. “Most instruments have modem and interface capabilities, which allows the manufacturer or service technician access to an instrument in the event of a needed repair or updates,” says Dean Tjornehoj, a dairy industry quality and food safety consultant and Center of Excellence resource professional at the American Dairy Products Institute in Chicago. Control system manufacturers may exhibit control packages with integrated infrared or NIR instruments for moisture control. Webinars are used for company training sessions, with a manufacturer’s technical service joining in online to answer questions.

The majority of educational material that the American Association of Meat Processors (AAMP) provides and sponsors are

in the form of hands-on demonstrations or presentations for processor members on the preparation and techniques used to create safe and wholesome meat products, says Nelson J. Gaydos, outreach specialist for the AAMP, which is based in Elizabethtown, Pa. The organization presents several state and regional conventions throughout the year nationwide.

Tjornehoj says the American Dairy Products Institute may share particular issues with a type of instrument or test method with its members. “Generally, because accuracy and precision have a significant influence on production efficiencies and profitability, further detail is usually proprietary,” he says. “NIR in general works well for powder and condensed products with appropriate procedures. A discussion about methods is usually limited to those points, as well as the general reliability or ease of adjusting product calibrations.”

Service is critical for NIR or infrared systems, especially those instruments integrated into a control system that may

not be as flexible as a benchtop offline unit, Tjornehoj says. Less common are questions about networking instruments or networking software, which is important for companies that are large enough to purchase and take advantage of such software.

AAMP shares information in two major food areas: food safety and how preparation/cooking affects the final product. “Food safety, specifically prevention of pathogen growth and destruction, is of the utmost importance when it comes to any food product,” Gaydos says. “Cooking with humidity has been shown to be an extremely important factor when it comes to killing pathogens such as *Salmonella* and *E. coli*. Secondly, it’s also important to understand how processes like cooking and humidity (or lack of it) affects the final flavor, texture, and appearance of products so processors can make products consistently the same and to their desired preferences.” ■

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## Prepare an FSMA-Compliant ... (Continued from p. 38)

corrective action is or should be, and document that it’s being done. But then they don’t monitor it to make sure that the corrective action is continuing to prevent the problem from reoccurring. I think the main challenge is in making sure that corrective actions go far enough and that you’re not looking at them just as a Band Aid.”

### Company Culture Is Key

For Perry, the effort that FSMA has required from food manufacturers has definitely improved food safety standards. “It’s been like a tide that raises ... all boats. The focus on prevention brought a clear improvement and probably helped to weed out some bad actors,” he says.

This higher level of effort puts different challenges in front of both small and large enterprises, requiring them to allocate more time, knowledge and people to their food safety program. “Small companies may have a hard time getting people trained properly, creating bigger budgets around food safety, and understanding

how to comply with each element of the law,” Scharlach says.

Larger companies face different issues. “The challenge for us has been to manage a very complex portfolio and still make our food safety plan as simple as possible,” says Perry. “The main difference has been the level of validation, verification, and transparency that we have with our agency partners. As the FDA comes in and reviews our food safety plans, we know that our record keeping must prove that we did what we said we would do.”

Despite all difficulties and misconceptions, there’s no escaping this adaptation to FSMA requirements, no matter how large or small the business. “It’s a matter of sitting down, doing it correctly, rewriting everything properly, and retraining everybody,” Scharlach says. “That takes time, effort, energy, and culture change.”

The key to this culture change is a top-down approach to food safety culture,

where companies’ executives are directly involved in the implementation of the food safety plan. One example is TreeHouse’s steering committee, where, Perry explains, the C-suite and the presidents of the divisions meet monthly to review food safety objectives and challenges, and make sure they have visibility and alignment.

By contrast, when all responsibilities are left entirely to employees, the level of food safety culture is often poor. “If the project is dumped on the already overburdened food safety lead or QI-practitioner, then the workforce will resist change resulting in an ineffective plan,” says Jocelyn Lee, consultant at Superior Food Safety. “When food safety culture is embedded from the top down, the preparation of a food safety plan is likely to be smooth, comprehensive, effective, and implementable.” ■

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