2016
Food Safety and Manufacturing Forecast

What's In Store
For This Year

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Mixed Signals for Manufacturing 2016

Production and staffing are expected to increase, but food & beverage manufacturers are less optimistic about the new year than they were in 2015.

By Kevin T. Higgins, Managing Editor

On the surface, 2016 looks like a positive period for food & beverage production in North America, based on responses to Food Processing's 15th annual Manufacturing Outlook Survey.

Three-quarters of the 251 participating food professionals anticipate increased production at their facilities, marginally higher than last year's feedback, with the greatest increase occurring at plants with predicted throughput hikes of 20 percent or higher. Expansion of the workforce is expected at almost half of all plants, the highest ratio in recent years.

Nonetheless, an undercurrent of unease is evident, with two-thirds expressing optimism about the year ahead, down from three-quarters last year. And while the era of across-the-board pay cuts continues to recede, respondents are less likely to anticipate salary increases in 2016 than they were last year.

Americans may be tightening their belts and watching their waistlines, but food & beverage remains a manufacturing growth sector. That puts the industry in select company: Most manufacturing sectors are shrinking, according to the Institute of Supply Management, victims of a strong dollar and weak foreign demand. As long as locally produced has any meaning, food & beverage is insulated from those factors.

The pessimism needle barely budged for 2016, with one in 10 survey respondents indicating they are somewhat or very pessimistic heading into the New Year, the same ratio as last year. The biggest changes are slippage in those somewhat optimistic and an increase in those ambivalent about 2016's prospects. The latter group almost doubled to one in four.

Product safety is Job No. 1 in food and beverage manufacturing, as attested to by the one-fourth of production professionals who rank it as the top priority in 2016. January marks the fifth anniversary of passage of the Food Safety Modernization Act (FSMA), and with enforcement of FSMA regulations beginning to phase in later this year, manufacturers are paying closer attention to it.

Nonetheless, an undercurrent of unease is evident, with two-thirds expressing optimism about the year ahead, down from three-quarters last year.

FSMA references hazard analysis and risk-based preventive controls, FDA's version of the HACCP plans required by USDA for 20 years. Whether it's called HARPC or HACCP, almost half of survey participants indicate their firms are re-evaluating those practices as part of an effort to improve sanitation and food safety. An even higher proportion—two thirds—are focusing on more rigorous employee training in these areas. Two in five are arming sanitation workers with upgraded equipment.

The need for better food safety practices goes beyond regulatory requirements. As a processor of case-ready meat notes, "Regaining the trust of the consumers due to the increase in food recalls" is a top priority at his firm.

Microbial testing of products and the environment is standard procedure for meat, poultry and fresh produce, and the practice is spreading to other sectors. Only one in eight respondents are from

Whether it's called HARPC or HACCP, almost half of survey participants indicate their firms are re-evaluating those practices as part of an effort to improve sanitation and food safety.

the meat and poultry sector, yet 22 percent of respondents say rapid microbial detection systems are used in their plants.

Several professionals volunteer comments on the increased use of environmental monitoring at their facilities, and others say quality assurance programs are targets for capital spending this year. In-line monitoring via sensors and laboratory automation systems were singled out, although one respondent questions the ROI on food safety. "Value added to the product is not there," a produce professional lamented, "and the retail outlets are not willing to pay for the increased cost."

Third-party audits can be a burden, but a plurality of professionals welcome outside scrutiny and certification programs to help improve food safety. Many retailers, foodservice suppliers and food companies regard standards certified by the Global Food Safety Initiative (GFSI) as the gold standard, and almost half of respondents say their plant has been GFSI certified. Less than a third are not considering certification audits.

Half of the plants have been certified under SQF level 2 or 3, the same ratio as last year. BRC Global grew to one-third of certified facilities, followed by FSSC 22000 and IFS. Among those considering certification, SQF 2, BRC and IFS were the most frequently cited schemes.

Wanted: skilled workers

"Availability of qualified workers" and "Lack of key talent availability" are common refrains when professionals cite specific issues facing their organizations. Two in five indicate their companies

have expanded in-house technical training programs to address the skills gap.

Other popular strategies include stepped-up recruitment of maintenance workers and technicians (28 percent) and creation or expansion of in-house engineering competency (22 percent). Less common initiatives are increased outsourcing and working with schools to develop electromechanical curricula, each cited by one in 10 respondents.

Almost a third suggest their companies are doing nothing to address the issue. "Tearing out our hair" was one produce professional's explanation of his firm's approach. One in five are sidestepping the skills gap by throwing more labor into the production mix.

For some, more automation holds the solution. "Automation will play a role in addressing safety and shortage of workers," writes one. Presented with seven options of 2016 automation projects, only one in eight indicated nothing was in the works. Automation of some section of the production line is likely at more than two in five plants, closely followed by areas in the packaging department. Ambitions for complete line automation are contemplated by three

in five, and almost one-quarter seeks some degree of automation in warehousing and maintenance, repair and operations.

"Finding equipment to solve our automation needs" is a top priority for one small manufacturer. "Most likely it will have to be custom built (costly)," she wrote.

Re-staffing of engineering departments and other skill competencies suggests some organizations are reconsidering the focus on core competencies that began in the 1980s. On the other hand, others have concluded they may have reached the point of no return. About one-quarter of respondents say some or all engineering services are outsourced, and almost as many indicate the same for maintenance services and training.

Pest control was far and away the most common of seven competencies to be outsourced. Three in five turn pest control over to third parties. Microbiological testing is an outsourced service at almost half of respondents' facilities.

Next-gen staffing

Replacing older workers who will be retiring is shaping up as one of America's greatest manufacturing challenges. Presented with six possible steps their companies could take to address the issue, two out of five indicate partnerships with community colleges and trade schools are either being discussed or expanded. A majority of those individuals' firms also have campus recruitment programs and participate in job fairs, and a third of them have mentoring programs for high school and college students.

Overall, a third of respondents said job fairs and campus recruitment were part of their organization's new-blood strategy. One in seven say their firms have apprenticeship programs for skilled positions. "We are offering scholarships to college students," volunteered a manager at a grain-based business. "We also offer tuition for employees who want to pursue formal education that will be applied to our food processing demands."

Food companies are as likely to work with trade unions to hire skilled workers as they are to be involved in junior high school outreach programs that encourage education in science, technology, engineering and math (STEM). Less than 6 percent indicate either option was being pursued. Almost three in 10 say their companies

are doing little if anything to address skilled staffing needs. "Staffing, staffing, staffing," wrote one. "We can't get enough employees."

A majority indicates worker safety is a top priority of senior management and part of the company culture, and half say a continuous-improvement approach to machine guarding and other safety modifications is in place. Reportable injuries are declining at a third of the workplaces.

Less than one in 10 say there are no safety initiatives in place at their plant. Half have an active safety committee that recommends changes when problems are identified, and two in five record and review near-miss events for possible remediation. Almost as many have programs in which operators observe their peers and provide feedback when at-risk behavior is identified.

Reducing operating costs by increasing efficiency in energy use is an objective at two-thirds of respondents' plants. About a third are monitoring energy usage or upgrading lighting systems. "We switched to LED lighting in the plant in 2015," a further-processor wrote, and on-site generation of renewable energy is being considered. In fact, one in six of all participants say wind, solar, biodigesters and other renewable options are under review. A New Jersey professional says her firm is considering steps beyond solar panels, which already have been installed.

Those are worthwhile projects, as are worker skill development and injury reduction. The primary mission in food manufacturing, however, is not simply increasing throughput but rather the production of safe, nutritious products. The industry should do a better job of communicating its commitment to food safety, one manufacturer advised. A little chest-thumping could go a long way in elevating the industry's reputation. 🅵🅿

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Why Automatic Food & Beverage Sampling Is Essential

By AJ Naber of Sentry Equipment Corp.

As food processors, you know that nearly all foods undergo some form of processing. Whether it's oranges being squeezed and packaged as juice, fish being cleaned, frozen and packaged, or peanut butter being mixed and placed into containers, all food and beverage processing is required to follow good manufacturing practices (GMP) as well as additional local, national and international food safety regulations.

To ensure consumers are informed and can make educated choices, processed foods and beverages feature nutritional labels listing calorie and fat content, cholesterol, sodium, carbohydrates, fiber, sugars, protein, and vitamin and mineral content. Specific ingredients of the food, including allergen declarations, also are listed. To determine all of these, best practices and regulation of processed foods requires representative sampling and accurate analysis. Food is classified as "liquid", "solid", "wet" or "dry" depending on the amounts of water it contains. In the food and beverage manufacturing process, sampling and analysis can determine:

- Microbiologic pathogens such as e. coli, salmonella or listeria
- Moisture content
- Nutritional labeling content – described above
- Trace chemical contaminants such as pesticide residue, veterinary drugs or toxins
- Quality assurance: Appropriate mixture – such as for cereal or pet food that contains different types of flakes or other content – pH balance, acidity and more
- Ingredient authentication including the presence of various allergens
- DNA, genetically modified organisms (GMOs) or other biomatter

Nearly any food or beverage – including solid, powder, liquid and slurry foods, beverages and pet food – can be sampled. Required sample sizes are defined in part by the nature of the food, and to what extent the material to be analyzed is present. For example, some materials, such as veterinary drugs in animal foods, are present at only trace levels, but a sample must capture them. This means that a

General classification of food samples

Examples	Characteristics	Typical Analysis
Milk	Aqueous, protein, lipids	Veterinary drugs, toxic elements, pesticides, industrial contaminants
Eggs	High lipids, albumin content	Veterinary drugs, industrial contaminants, pesticides
Other samples of animal origin	Various fat, proteins, water	Drugs, industrial contaminants, pesticides
Plant material	Various water, plant pigments, lipids, proteins, essential oils, waxes	Pesticides, toxic elements, industrial contaminants
Meat, fish, milk, cereals, wine, juices, plant oils, sugar)	Various fat, oils, lipids, proteins, sugar, starch, water, or pigments	Pesticides, industrial contaminants, synthetic colorants, additives, synthetic sweeteners, antioxidants

Reference: Curren, M.S.S. and King, J.W. Sampling and sample preparation for food analysis.

sufficiently large amount of the product must be collected so minute quantities of the compound of interest can be analyzed. On the other hand, small samples may be collected for the macro analysis of larger food components such as crude fat, protein or fiber.

Sampling is required to ensure quality, safety, and specific attributes, and the data that sampling provides is essential to helping food and beverage plants control and optimize processes so they can run safely and efficiently. A few examples of the types of solid and powder foods that can be sampled are:

- cereals
- seeds
- grains or other raw ingredients
- coffee or loose teas
- sugars
- dry spices
- nutraceuticals
- pet food

Examples of liquids, beverages, pastes and slurries that can be sampled are:

- peanut butter
- gels
- juices, beer, wine, alcohol, soda, flavored water and all other beverages
- milk or cream products
- ice creams and other frozen desserts
- sauces and pastes
- soups
- canned goods
- food grade oils
- liquid and slurry raw ingredients
- … and even plant wastewater or effluent

Automatic sampling for efficiency

To obtain a truly representative sample, foods and beverages must be sampled automatically – continuously creating a composite sample representative of the entire batch or lot – while in their production environment. The chemical and physical properties of each food can vary, even between samples that originate from the same batch. However, representative sampling and analysis can identify this variability and allow for adjustments and corrections to the process.

Automated sampling – where a sampler is placed on or in a process pipeline, pneumatic convey line, gravity chute, hopper, bin, or a screw or belt conveyor – provides the inherent benefits of automation, with a composite sample easily and safely obtained with no need for direct human interface or interference. This ensures the integrity of the sample and increases efficiency over manual sampling. The product does not need to be sampled offline and production can continue.

Plus, for further automation efficiency, the sampler controller can be incorporated with existing equipment and systems so sampling can begin automatically without operator engagement. Overall, sample automation reduces risk and increases process efficiency.

Top four ways sampling improves efficiencies

Running an efficient operation requires controlled, real-time data obtained through representative sampling. The top four ways automated sampling solutions can help your plant include:

1. Improving yield

One specific way a plant can improve its yield is by keeping ingredient moisture content in the proper band. If it is too low, a plant may be giving away product, and if it is too high, the product will deteriorate more quickly. Improper moisture content also is key in product shrinkage or expansion, which directly affects the volume a product takes up in packaging. Plus, by sampling after a dryer, a plant can not only identify if a product is being over-dried or under-dried, but also monitor and control the drier power consumption.

In addition, sampling can help monitor product breakage to identify potential disruptions or issues within the process. Poor performance of the sizing equipment can result in a direct increase in product needing to be discarded in landfills or sold at lower price points for non-target users.

2. Ensuring quality

Sampling of foods and beverages is needed to ensure quality, safety and specific attributes. Sampling within a production environment easily can show product contamination and help identify the point at which it's happening. Sampling and analysis also shows specific attributes, such as e. coli, salmonella or listeria pathogens; specific food ingredients and content such as calories, fat and vitamins; trace chemical contaminants; DNA and appropriate mixture.

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Food Industry Regulatory Outlook for 2016

The new year brings a fuller implementation of FSMA, more debate over GMO labeling and more warnings about California laws.

By Eric Lindstrom of Keller and Heckman LLP

In the regulatory world, the big news for 2016 will be the implementation of the hazard analysis and risk-based preventive control (HARPC) provisions under Section 103 of the FDA Food Safety Modernization Act (FSMA). FSMA was signed into law in January 2011 and after almost five years the regulations implementing HARPC have finally been issued.

As background, FSMA represents a significant amendment to the longstanding Good Manufacturing Practices framework. With FSMA, FDA moves from a food safety approach that reacted to potential harm to a preventative framework that puts great responsibility on the food industry to identify potential risks to the safety of the food supply and to counter the risks before harm occurs.

The core obligations of HARPC require covered food facilities to conduct hazard analyses and, when necessary, implement risk-based preventive controls. This requires a covered facility to:

- Identify known or reasonably foreseeable hazards that may be present in the food handled at that facility (including biological, chemical, and physical hazards);
- Implement preventive controls for hazards that require such a control to significantly minimize or prevent them;
- Develop effective monitoring procedures for the controls;
- Establish written corrective action plans if preventive controls are found to be ineffective;
- Validate preventive controls, monitoring and corrective action plans;
- Re-analyze the food safety plan at least once every three years and sooner if made necessary by production changes.

Most companies, except for businesses defined in the HARPC rule as "small" or "very small," must comply with the final rule by Sept. 19. Given the complexities of the rule, companies should immediately begin work on their food safety plans in order to meet the compliance deadline.

Vermont's mandatory GMO labeling law also figures to impact food companies in 2016. As background, the Vermont law requires foods that are produced entirely or partially with genetic engineering to disclose that fact on the label or, in the case of unpackaged food, on a bin, shelf or container in which the food is displayed. The labeling requirement has numerous exceptions, including food for immediate consumption, food with "minimal" genetically engineered content, and processing aids, among others. The labeling requirement will go into effect on July 1, 2016.

The Vermont GMO labeling law faces several obstacles, however. The Grocery Manufacturers Assn. and other national food trade associations have challenged the law in court; the case is still pending. In addition, bills have been introduced in Congress that would preempt state GMO labeling laws, including Vermont's. But given the current political climate, it is unlikely those bills will be enacted into law. In the meantime, food manufacturers are faced with the prospect of labeling the GMO content of their foods that are to be sold in Vermont or implementing a potentially complicated distribution structure to avoid distribution of foods in the state.

The regulatory outlook does not always entail additional regulation of industry, and a case in point is California and its law regarding "Made in the U.S.A." claims. For decades, the California law prohibited such claims for products "if any article, unit, or part thereof, has been entirely or substantially made, manufactured, or produced outside of the United States." This in effect created a zero tolerance for foreign content in products, including foods, bearing a "Made in the U.S.A." claim or similar claims in California. The law was recently discovered by plaintiffs' attorneys and it had become a burgeoning and lucrative area of litigation for them. As an example, just last month, a well-known retailer settled a claim for $4 million regarding jeans with some foreign content labeled as "made in the U.S.A." and sold in California.

Just as plaintiffs' attorneys began to turn their full attention to this California law, the California Legislature – surprisingly – softened the impact of the law on businesses. Although the statutory language quoted above remains, the legislature added an exception for products with "articles, units, or parts from outside the United States" if (1) they do not constitute more than 5 percent of the final wholesale value of the product or (2) the manufacturer shows that it can neither produce or source the foreign content in the U.S. and that the foreign content is not more than 10 percent of the final wholesale value of the product. The amended law became effective Jan. 1. **FP**

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Companies Looking To Purchase Manufacturing Equipment Have Choices

By Federal Equipment

Buying through original equipment manufacturers (OEMs) often means long lead times and higher prices, which may not be necessary, nor acceptable for many manufacturing needs. Previously used or surplus pharmaceutical, nutraceutical, chemical, and plastics equipment used in production can also be found for sale, and in inventory, from qualified used equipment dealers. In fact, some of these pieces have never been used, or were installed, but never used in production.

A good used equipment dealer typically automatically gives a prospective buyer, who knows what they need, a competitive purchasing deal. Likewise, for those who need more guidance, an established dealer will be up to date on what's current, what's new, what you may need, or what controls and requirements are available for your specific manufacturing needs. Large companies often employ in-house scientists that develop products and teams to transfer that knowledge into production. Smaller or less established companies may not have those assets.

To that end, an established equipment dealer can work closely with small and medium-sized companies to find solutions uniquely suited to their needs. And some dealers already have established agreements with those larger companies to find a home for their surplus equipment. Equipment customers of every size are experiencing a shift in equipment needs with changes in technology and demand. New ingredients, formulations and batch sizes can significantly change what they need to create high-quality, effective products, thus freeing up machines.

Buying used equipment cuts down on the time it takes to get into production. For example, new machines can have long lead times, anywhere from eight to 16 weeks, depending on the make and model. Used equipment, already in a dealer's inventory, is often ready for delivery and can reduce the time an owner-operator might spend working out the kinks of new machines. Only in recent years have companies come to view pre-owned equipment as acceptable. Nowadays nearly every company either, at least considers or actually purchases used equipment. The quality of pre-owned equipment and the expertise of a qualified dealer in selecting the right machine for the right job have gone a long way in changing that.

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Enhancing Levels of Due Diligence

Exceeding standards in the food industry.

By Mettler Toledo

It is an ever increasing responsibility of food manufacturers to take every precaution to ensure that their products are safe, free from contamination and are unlikely to harm the end consumer in any way.

The Food Safety Modernization Act was signed in 2011 and tougher government and retailer food safety standards are here to stay. Demands on you to demonstrate your regulatory compliance and due diligence will continue to increase – just one failed performance verification audit or one product recall can significantly damage your business.

HACCP leads the way in providing a framework for food manufacturers to work within while the Global Food Safety Initiative (GFSI) manages and controls the bodies that can provide the certification and accreditation. The organizations and bodies that provide GFSI recognized schemes include the following:
- The British Retail Consortium - BRC
- The International Food Standard - IFS
- Food Safety System Certification 23000 - FSSC 22000
- Safe Quality Food - SQF

Other schemes exist but the ones mentioned above probably equate to over 90% of the adopted standards currently being worked to.

In these litigious times, lawyers and consumers alike will seize on any opportunity to take legal action against manufacturers in the event of finding something awry with the product they have purchased. Food manufacturers supplying retail organizations will fully understand the need to ensure their product quality is of the highest level.

It is therefore in the best interests of manufacturers to take steps to ensure systems and procedures are in place to minimize the risk of litigation and, in the event of such an instance, have the necessary documentary evidence to prove they have been duly diligent in the manufacturing process.

Are you confident that your systems and procedures will stand up to scrutiny?

Duty of Care

In law, we each have a Duty of Care which requires that we adhere to a standard of reasonable care while performing any acts that could foreseeably harm others. The Standard of Care is the degree of watchfulness, attentiveness, prudence and caution of an individual who is under a Duty of Care. In the food industry, the Standard of Care is determined by the standard that would be exercised by the reasonably prudent manufacturer of a product. Failure to meet the standard could be regarded as negligence, and any resulting damages may be claimed in a lawsuit by the injured party.

Due Diligence: what is it?

The Due Diligence defense is available to manufacturers accused of a breach of food safety regulations. Essentially, the defense is that the "accused" took all reasonable practicable steps to avoid the breach. It is a sufficient defense for the person charged to prove that:
- All reasonable precautions were taken
- They exercised all due diligence to avoid the occurrence, whether personally or through any person under their control.

"Taking all reasonable precautions" includes setting up systems of control which are appropriate to the risk. What is reasonable is determined by the size and resources of the business. "Exercising all due diligence" involves having procedures in place which review and audit the system to ensure it is operating effectively.

Whether or not a defense will be successful depends on the circumstances surrounding each case.

Hazards Analysis Critical Control Points

In food production, most manufacturers utilize a Hazards Analysis Critical Control Points (HACCP) based system as a framework to

identify where hazards might occur. The HACCP structure is then used to put into place procedures to mitigate the risk of the hazard from occurring in the first place. The HACCP process strictly monitors and controls each manufacturing step, to reduce the probability for hazards to occur.

HACCP is based on 7 core principles:
- Conduct a food safety hazard analysis
- Identify the Critical Control Points (CCPs) (point at which a hazard is optimally controlled)
- Establish critical limits for each CCP
- Establish CCP monitoring requirements
- Establish corrective actions when monitoring indicates that a particular CCP is not under control
- Establish record keeping procedures
- Establish procedures to verify system is working as intended

Instances of Metal Contamination

The manufacturing environment and general food processing can create the risk of metal contamination occurring. A metal detector often acts as a critical control point to mitigate this risk. This paper considers what additional elements should be included in the process in order to safeguard customer welfare and provide the basis for a robust due diligence defense.

Furthermore, a suitable metal detection system will allow manufacturers to fully maximize the opportunity to deliver the absolute best level of consumer and brand protection. All conveyor systems used to inspect products should be specifically designed to do just that and not just simply provide a "tick in a box" that says metal detection equipment is on the line and functioning.

A Metal Detection System: Concerns and Solutions

The opportunities for metal to find its way into a food product are numerous. The majority of equipment used in food processing plants is made of metal. For example, cutting blades, grinders, mixers, transport conveyors and packaging machinery are all predominantly metal based as are hand tools, machinery structures and support frameworks.

It is conceivable that some of these items could shed a small piece of metal into the manufacturing process during normal working

without the equipment failing. A metal detector downstream of all processes ensures that the resulting food product has been checked for the inclusion of metal.

Metal detectors are a common site in most modern food manufacturing plants and the technology employed is considered highly reliable. However, the incidence of metal reaching the end consumer remains high. More alarming is the fact that upon investigation, the metal being returned as a complaint is invariably detectable by the on-line equipment. This points the finger of suspicion at the operational procedures in place in the manufacturing or inspection process.

Simply installing a metal detection system will not eradicate the incidence of metal reaching the end user. A total approach to Quality Management must be employed and, as many metal detectors are defined as Critical Control Points (CCPs), it seems common sense that this CCP is managed accordingly.

A metal detection system fitted with a suitable reject mechanism and lockable reject bin will go a long way in providing a solution but, as highlighted earlier, system and procedural failure can have a serious impact on the overall effectiveness of the system employed.

In order to ensure all contaminated food packages are rejected efficiently from the process or packing line (and remain rejected) and to ensure the highest levels of compliance with the necessary standards are met, we should look at the table below which identifies concerns and solutions available to overcome the problem.

Components of a Failsafe Metal Detection System

1 Advanced Metal Detector Search Head

You will need a metal detector that is able to meet the required detection standard. This means it must be capable of being set-up to operate within the sensitivity guidelines detailed in either your own code of practice or, as is the case for many metal detector users, in line with the requirements of third party customers such as a retailer.

It is worth noting here that the general rule which governs metal detection performance is that the smaller the aperture, the better the performance.

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How ISO 9001:2015 Goes Beyond Food Safety

FSSC22000 and ISO 9001:2015 are a powerful combination for food safety and quality.

By Tassos Metaxas of ASQ

A wise man once said that nothing is permanent except change. Advances in technology and communication in recent years have increased the ability to detect and trace the source of product failure or recall resulting in greater accountability. This is reflected in the expectations of customers, regulatory, and other interested parties that prompt a need for change.

In the food industry, a series of food safety failures and low consumer confidence prompted the world's food retailers to form the Global Food Safety Initiative (GFSI), a non-profit foundation that established food safety criteria to benchmark and approve standards (schemes).

Following market lead, the U.S. in 2011 passed the Food Safety Modernization Act (FSMA) — the biggest change to food safety laws since 1906 — requiring hazard analyses and risk based controls to be applied across the entire food industry. Certification to GFSI benchmarked schemes provides the management system tools that meet FSMA regulations.

FSSC 22000 food safety system certification scheme is the only GFSI-approved scheme based on the ISO 22000 series of standards. Organizations certified to FSSC 22000 requested the ability to integrate ISO 9001 quality into their certification scope as ISO quality requirements add strength to food safety management systems. The latest revision of ISO 9001:2015 meets the FSSC 22000-Q requirements and adds new elements for improving performance.

Let's take a look at some of the changes:

- New requirements for defining the Context of the Organization and Needs Expectations of Interested Parties have been added to ensure the quality management system (QMS) is aligned with the company mission, purpose and strategic direction. Customer Focus and risk-based plans needed to enhance customer satisfaction are included. Also included are requirements for monitoring and review of these processes to ensure continual improvement.
- Integration of business processes – ISO 9001:2015 requires the organization to define the needed processes, including their sequence and interaction, risk-based controls and continual improvement. A major change requires involvement and commitment of Leadership to ensure that QMS processes are integrated into the organization's business processes that are core to its existence and for top management to take accountability for the effectiveness of the quality management system.
- A new element of Actions to Address Risks and Opportunities is added to the requirements as a strategic measure. Application is similar to that of the HACCP risk assessment process, but is less restrictive. It is important to note the risk is defined as the effect of uncertainty — positive or negative. This process can also be used as a tool to help leaders manage the positive aspects of the business culture.

For example, management of business objectives and new projects can be planned and evaluated not only for their potential negative impacts, but also for their actual financial benefits or their positive effect on business growth.

- Changes to Resources require consideration be given to staffing needs, allocation of responsibilities, and existing constraints for the provision of People needed for effective implementation. A new element of Environment for Operation Processes requires that the environment is suitable based on social, psychological and physical factors relating to personnel. This will require new approaches and possible involvement of HR.
- Operational Planning and Control processes help to ensure management of change. Requirements outline the steps needed to effectively design and develop products or services. The logical sequence of these process requirements includes key components (milestones) that an organization needs to effectively implement project management changes. While similar to HACCP, these processes are managed on a wider-reaching scale that, when integrated, will strengthen ISO 22000 food safety management and other business processes (e.g., environmental, safety, growth, profitability).
- Some Terms and Definitions have been changed in order to increase flexibility and facilitate integration of management systems into the organization's business processes. The term Leadership is used to increase involvement and accountability of people at different levels. External Providers is used as a specific term that includes requirements for providers of Services or materials. Documented Information is used instead of procedures and records.

The ISO 9001:2015 requirements, though more flexible, are sufficiently prescriptive and can be audited with confidence to ensure accountability at the point of use. Although procedures are not specifically required, however, the QMS processes needed shall be determined and maintained as documented information (clause 4.4).

ISO 9001:2015 goes beyond mere conformance and raises the bar to higher expectation of effectiveness (stated 23 times) and continual improvement (stated 20 times). Companies that effectively implement ISO 9001 will benefit from its strengths to improve food quality and business performance. **FP**

Tassos Metaxas is a senior trainer/consultant for AQS Management Systems Inc., for the last six years specializing in ISO 9001, ISO 14001 and FSSC/ISO 22000 management systems. He's also a member of ASQ, also known as the American Society for Quality, which has more information on ISO 9001:2015 at asq.org.

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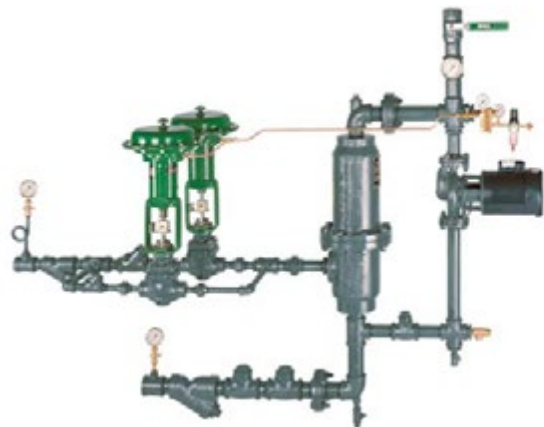
The Price of Safety in Plant Sanitation

By Pick Heaters

Pick Heaters has been providing liquid process heating solutions that use direct steam injection for more than 60 years. Direct steam injection offers unique benefits for heating water or water miscible liquids for numerous food plant applications. It is used wherever an immediate supply of precisely controlled hot water is required, such as sanitation, batch filling, blanchers, clean-in-place, and freezer defrost. Pick also has a sanitary design that can be used for in-line product cooking, the first direct steam injection sanitary heater to earn 3-A Sanitary Standards certification.

Our customers face challenges from many angles. There are ongoing food safety issues, as well as concerns over food borne illness. Energy savings and efficiencies directly affect profitability. Maintenance costs have always been important. Recently there has been a heightened concern for the safety of plant personnel. While the application of the Pick Heater can offer benefits in all of these areas, satisfying the concern for operator safety in plant sanitation is prominent.

The biggest concern in regards to plant sanitation is that customers need a reliable yet safe supply of hot water. They need water at a precise temperature to satisfy sanitation standards. At the same time, they cannot afford water temperature to exceed set point, resulting in a concern for their operator's safety. They want confidence that their hot water system will provide a safe, reliable source of precisely controlled hot water, regardless of demand.

Safety has become a problem, or risk, at the point of use. One of the more common methods for supplying hot water for sanitation has been the use of individual steam/water mixing stations, or tees, located at each hose station. While these units offer the responsiveness of steam injection heaters, they can pose a serious safety risk. Mixing tees require a minimum water supply pressure to operate properly. An internal valve serves to prevent live steam, or overheated water, to exit the hose station should there be a loss in water pressure. This mechanism often sticks due to hard water scaling, which creates a situation where operators have been scalded or injured. It's not a question of whether or not this happens, but when it happens.

In addition, water temperature is controlled individually at each hose station. This makes it susceptible to operators unnecessarily tampering with the temperature set point. There is a common misconception that the higher the temperature, the better — this isn't the case. Rather it is inefficient and a serious potential safety concern. Water that is too hot is a waste of energy, but water that is not hot enough won't get the job done or meet sanitation standards.

Pick Heaters developed the Variable Flow Heater with plant washdown in mind. It is designed to serve as a single, central water heating system that can be isolated from operators and use points. The heater can handle the wide range of water flow rates required throughout the facility. It features a low-head pump that maintains proper water velocity during low loads, while maintaining tight temperature control regardless of demand. It can respond to frequent start-stop applications and still deliver accurately controlled hot water, on demand. Temperature overrides can be put in place preventing any possibility of overheated water from reaching any of the points of use.

After a customer has experienced problems with point-of-use mixing tees, going with another steam injection heating method can be a hard sell. Both mixing tees and the Pick Variable Flow Heater are considered steam injection water heaters, but that is where the similarity ends. Once the customer understands that the Pick heater is being applied as a utility, they see the difference. The Pick heating system can be located well away from worker locations. They get all the benefits of steam injection heating but with operator safety foremost in mind.

Equipment cost for a Pick Variable Flow Heater is typically the same as the cost of replacing four mixing stations. However, it also eliminates the costs associated with running steam lines to all the plant drops. The steam line terminates at the Pick Heater, as a result eliminating live steam at the point of use. Beyond equipment costs, what value can you put on the price tag for personnel safety and reducing the potential liability?

The matter of safety isn't going away. The objective is to continue to identify potential safety problems for customers and to offer solutions. While direct steam injection water heating is the best method, its proper application is key to having a dependable and safe, plant wide hot water sanitation system. Once customers understand the hazards of point-of-use mixing tees, the upgrade to a Pick central hot water system is the obvious answer. 🄵🄿

Food Safety and the Importance of Environmental Monitoring

By Julian Hough, Marketing Specialist, Cooper-Atkins Corporation

Sickness. Death. Recall. Legal action. Financial loss. Brand destruction.

These words, for processing facilities managers involved in food safety, often produce a sweaty brow and elicit insomnia-inducing nightmares.

Nausea. Vomiting. Chills. Headaches. Fever. Death.

These words are symptoms of food poisoning; a malady far from the forefront of people's thinking when they eat out or prepare food, yet, according to the CDC, foodborne illnesses affect 48 million Americans annually, resulting in 128,000 hospitalizations and 3,000 deaths.

The importance of Food Safety

Food Safety is paramount to consumer confidence and business success. In the age of 24/7 news coverage, foodborne illness outbreaks fall quickly under the spotlight of public awareness.

In August 2015, at least 64 people who ate at 22 different Mexican quickserve restaurant locations contracted salmonella from tainted tomatoes. This chain is facing two lawsuits from customers affected by the outbreak.

A top-selling ice cream brand recalled all products last spring after 10 reported cases of listeria in four states were linked to frozen treats. Three of the people sickened in Kansas later died.

Managers and executives who must balance the burden of ensuring food safety while still maintaining a profitable business venture dread such outbreaks.

The newsworthy cases above are the tip of the iceberg; food safety has a much broader base of concern and relies on the implementation of safe handling and best practices in the supply chain that encompasses production, processing, distribution and preparation.

Before we look at the causes of foodborne illnesses and how factors such as temperature monitoring are essential, we need to identify what defines an outbreak, who responds to them and what forward-thinking solutions can be implemented to elevate risk prevention.

What is a Food Illness Outbreak?

If two or more people contract an illness from the same contaminated food or drink, the event is called a foodborne outbreak.

Who responds to Outbreak events?

When such events happen locally, Public Health officials are called in to investigate, but when the outbreak is more widespread, state agencies, the Centers for Diseases Control and prevention (CDC) and regulatory agencies, including the Food and Drug Administration (FDA), may be involved.

FSMA Regulations – a global solution

President Obama signed the FDA Food Safety Modernization Act (FSMA) into law in January 2011. The law followed a series of severe outbreaks of foodborne illness and was a response to the significant burden these outbreaks impose on the United States each year. The economic losses to the industry, including farmers, are enormous, estimated at over $75 billion per year.

What is the FSMA?

The FSMA reflects the need for a modern, global food safety system that prevents problems rather than primarily reacting to them after they have occurred.

Michael R. Taylor, FDA deputy commissioner for foods and veterinary medicine, following the multi-state 2015 outbreak of Listeria monocytogenes tied to a prominent ice cream brand said,

"Ultimately, the only way we will achieve the goals that we are focused on—the goals that consumers expect us to achieve and that industry wants us to reach—is if we have a system in which industry is systematically, every day, putting in place the measures that we know are effective in preventing contamination." (FDA Voice, May 2015)

FSMA 2016 - how will it affect you?

New laws were recently passed for 2016 to bolster the 2011 FSMA act. This will affect the industry with the first deadline for compliance for large companies (more than 500 employees) slated for 2016, and then 2017 for smaller companies (less than 500 employees)

The mandate is broad and far-reaching in its overhaul of food safety, and is beyond the scope of this article but, generally speaking, FDA-registered food facilities, manufacturing facilities and processors must:

- establish and maintain food safety systems that include a Haz ard Analysis and Risk-Based Preventive Controls (HARPC) plan.
- verify the controls are effective by monitoring, testing, taking corrective actions and document the outcomes.
- maintain risk-based supply chain programs for raw materials and ingredients and provide cGMP education and training to their relevant employees.

HACCP vs. HARPC

The Hazard Analysis and Critical Control Point (HACCP) is a systematic preventive approach to food safety from biological, chemical and physical hazards in production processes that can cause the finished product to be unsafe. It designs measurements to reduce these risks to a safe level and can be used at all stages of a food chain.

In tandem with the new FSMA 2016 amendments, is the recent FDA declaration that HACCP should now be referred to as the Hazard Analysis Risk-based Preventive Controls (HARPC). This is because prerequisite programs (PRPs) pose a significant level of concern and thus need to be factored into any risk assessments, e.g., while there may not be a system in place for hand washing, it poses a significant hazard and so should have controls and corrective actions associated with it.

An effective HACCP/HARPC plan should always be clearly documented and implemented.

The importance of Environmental Monitoring

There are many areas along the processing chain where food may be compromised. While there are many solutions available that help detect bacterial pathogens during processing, a HACCP/HARPC plan that integrates temperature monitoring is a must-have from the get-go.

Storing, receiving and holding food-related items at a temperature that prohibits bacterial growth are a necessity for facilities in their HACCP/HARPC plan.

Processing facilities that invest in a temperature monitoring system should benefit in the following ways:

- Eliminates manual labor
- Streamlines the collection of environmental data
- Provides custom reporting
- Complies with the new FSMA laws and FDA rulings

For more than 130 years, Cooper-Atkins has built a rock-solid reputation as a provider of environmental monitoring solutions and is a trusted resource in the industry. They are committed to providing customers with what they need in an ever-changing technological landscape.

As a leading manufacturer of wireless monitoring solutions, Cooper-Atkins offers TempTrak Enterprise® and NotifEye™ as state-of-the-art wireless technologies.

TempTrak Enterprise is a facility-wide solution that can monitor an unlimited number of points in unlimited locations – all from one software platform.

NotifEye is a more streamlined, self-installable system that is also a more affordable option. Both are exception-based systems and send out alerts only when preset limits are exceeded, saving time and labor and also protecting inventory and, more importantly, brand integrity.

If you look at the millions of dollars in recall costs associated with foodborne outbreaks, managers can't afford to be penny-wise and pound foolish. Purchasing a facility-wide environmental monitoring system would appear to be a cost-effective investment.

An ounce of prevention is better than a pound of cure to protect your brand in 2016 and alleviate those sweaty brows and sleepless nights. **FP**

Julian Hough is a marketing specialist with Cooper-Atkins Corporation, a company that has been manufacturing temperature monitoring equipment for 130 years.