FOOD SAFETY SERIES
The food processing industry continues to look at ways to improve and enhance food safety requirements and compliance. In this white paper, we look at proposed changes for the Food Safety Modernization Act (FSMA) and how Enterprise Resource Planning (ERP) systems can assist facilities in adherence to these new standards. We also explore trends in sanitary equipment design and important considerations when hiring an installation subcontractor.

THE FDA INVITES COMMENTS FROM FOOD PROCESSORS ON PROPOSED NEW FSMA RULES
The U.S. Food and Drug Administration (FDA) recently released a new strategy document that outlines the agency’s guiding principles for implementing the Food Safety Modernization Act (FSMA). This latest move by the FDA is designed to encourage dialogue and collaboration between the agency and the food industry as FSMA moves into its next phase – the effective and efficient implementation of the new standards.

According to the FDA’s Deputy Commissioner, “this is where the rubber meets the road.” The FDA is seeking comments from the food processing industry on the initiatives outlined in this strategy document before the final FSMA rules are released in late 2015 and early 2016.

The strategy document includes programs to provide greater support to food processors and help them achieve high rates of compliance with FSMA. It also includes a number of internal initiatives for the FDA to improve its outreach and response to food safety incidents. Highlights of the new strategy include:

• Advancing public health — Reducing the risk of foodborne illness through modern preventive practices and ensuring that food processing facilities are effectively implementing prevention controls is at the core of FSMA.

• Leveraging and collaborating — The FDA will leverage its relationships with outside partners in the food safety industry including international organizations, the food industry, growers, academic experts, and consumers. This component also includes data integration, analysis, and information sharing among partners.

• Strategic and risk-based industry oversight — Food processors will be equipped with a tool kit, developed by the FDA, that includes education to ensure expectations and requirements are understood, along with technical assistance to facilitate compliance. Additional tools include regulatory incentives for compliance such as less frequent inspections and reliable third-party audits to verify compliance.

• Planning — Internal performance metrics will be established for the FDA, which will be aligned with the FSMA’s mission of prevention, emphasizing the need for seamless data sharing and collaborative data analysis.

• Execution — The FDA plans to provide food processors with access to subject matter experts before, during and after inspections. These streamlined processes will enable more timely decisions and resolutions regarding corrective actions, enforcement, and other measures to achieve public health and consumer protection.

• Evaluation — The establishment of program-wide, public health-oriented outcome metrics with systematic collection will benefit the entire industry.

Food industry representatives are encouraged to review the strategy document and provide comment on these issues that will drive new rules. The FDA offers easy online access to provide comment on this strategy document via this link on their website.

FIVE WAYS AN ENTERPRISE RESOURCE PLANNING (ERP) SYSTEM CAN HELP YOU COMPLY WITH FSMA
The Food Safety Modernization Act (FSMA) is front and center for most food processors yet managing the regulatory and reporting requirements can be taxing and time consuming. Many food processors are investing in an Enterprise Resource Planning (ERP) system to more efficiently manage the process, allowing for better data collection, analysis, documentation, and reporting tools. Using an ERP program to manage your plant’s food safety program will improve your audit results, reduce food safety-related incidents and investigations, improve product quality and ultimately
increase operational efficiencies. Newer ERP platforms, those developed in the past ten years, offer numerous benefits over legacy systems including the ability to integrate with other components within your facility that impact food safety. Integration is a critical element as all aspects of a facility play a role in food safety.

- **Compliance** — Food industry-specific ERP systems provide the necessary platforms to integrate government regulations into your processes. As food safety requirements change, an ERP system will ensure that your processes maintain compliance standards.

- **Preventive measures** — An ERP system can provide electronic plans that help minimize risk and manage quality control, greatly improving compliance standards. For example, the proper ERP program can provide electronic plans for conducting systematic preventive measures including Hazard Analysis and Critical Control Points (HACCP) and Process Hazard Analysis (PHA).

- **Reactive measures** — Regulations require that processors have access to real-time data for product traceability. An ERP system manages and stores the appropriate information throughout the supply chain and production to provide immediate access to necessary information.

- **Recall management** — Food manufacturers must be able to recall products instantly when a breach has occurred. An ERP system provides a fully defined recall process in advance and provides guidelines for performing mock recalls ensuring the entire team is adequately trained.

- **Incident control** — FSMA requires that food processors take corrective actions in the event of a food safety incident and provide a method for prevention. An ERP system will provide a systematic approach that analyzes data, identifies the root cause, documents the corrective action taken, and continuously monitors the process to ensure regulatory compliance.

NEW TRENDS IN SANITARY EQUIPMENT DESIGN ARE IMPROVING FOOD SAFETY STANDARDS

As food safety regulatory requirements become more stringent, equipment manufacturers are stepping up to the plate and increasing the role they play in the industry. The American Meat Institute’s (AMI) 10 sanitary design principles offer baseline standards for equipment design, yet many suppliers are going above and beyond these standards by offering improved surfaces, cleaning chemicals, and construction processes.

In this day and age of heightened throughput and productivity, the sanitary design of equipment is driven primarily by food processors themselves, who are interested in increased efficiency, faster/effective cleaning procedures and reduced changeovers. The challenge is on equipment manufacturers to incorporate sanitary standards that meet and exceed these customer requirements and expectations.

Poor equipment design decisions, improper material selection, and inadequate finishes pose cleaning challenges that are often the root concern of many food safety related issues. We shared some best practices for sanitary equipment design in a previous blog post.

FOOD PROCESSING EQUIPMENT MANUFACTURERS ARE OFFERING MORE ADVANCED SANITARY SOLUTIONS INCLUDING SURFACES

- **Higher-grade stainless steel** — The industry is rethinking the grades of stainless steel used within food processing facilities in order to withstand the daily exposure to varying chemicals used in sanitation. Finish specifications and selections have been improved to decrease the likelihood of harboring dangerous microbes after sanitation. Higher-end finishes, while requiring greater upfront investment, often exceed
regulatory requirements and provide better bacterial resistance and improved cleaning capabilities. Type 304 and 316 are the most common stainless steel finishes in the food processing industry. Proper selection of these materials depends on the operating environment.

- **Anti-stick surfaces** — New FDA-approved coatings are now available that reduce the potential for raw materials to adhere to equipment surfaces which help improve pre and post operational performance by providing a better barrier against bacteria colonies and the formation of bio films that are often resistant to chemicals and inferior sanitation practices.

### CLEANING

- **Better chemical technology** — Chemicals used for clean-in-place (CIP) and clean-out-place stations (COP) are being developed with higher concentration levels that not only improve sanitation, but also reduce the amount of time required for cleaning. CIP and COP equipment manufacturers can help plants create the optimal mix of water, chemicals, temperature and flow requirements based on their unique product and equipment needs.
- **Tool-less equipment** — Equipment manufacturers are designing products that do not require additional tools for maintenance and cleaning. This eliminates the need for another product to come into contact with equipment when it has to be taken apart for cleaning or repair. An added benefit is that tool-less applications can typically reduce changeover times.

### SUPPLIER IMPROVEMENTS

- **On-site testing** — In the quest to gain competitive advantages, many equipment suppliers are conducting in-house tests on equipment to validate equipment’s sanitation integrity prior to delivery.
- **In-house food safety experts** — As food safety regulations become increasingly complex, manufacturers are more frequently forming in-house food safety teams to drive sanitary product design to meet the expectations of not only their customers, but also the industry.

### SANITARY PROCESS INSTALLATION: WHAT TO ASK WHEN SELECTING A SUBCONTRACTOR

Equipment manufacturers play a key role in the food safety program of a food processing plant, ensuring that equipment is designed and built to meet stringent sanitary requirements. Plant owners often spend significant time and money to acquire the right equipment with the proper sanitary construction. Yet once that equipment is designed and delivered, the next critical step is ensuring that it’s installed properly, within those same sanitary standards. If you do not carefully screen installation subcontractors, you could put your plant at risk of a food safety issue.

To minimize your risk, meet with potential installation subcontractors and conduct a thorough interview to assess their level of experience, knowledge and credentials as they relate to sanitary controls. Focus on the following key areas, using these questions while interviewing installation subcontractors. Be sure to document all your findings for future reference and comparison.

#### PAST EXPERIENCE

- Inquire about the subcontractor’s past projects. How do they compare to your current scope of work?
- Verify that the Subcontractor estimator fully understands your project scope of work, requirements and asks the appropriate questions. The more questions an estimator asks, the more accurate the estimate will be and the level of interest the subcontractor has in doing your project.

#### STAFFING

- How many people does the subcontractor actively employ? Is there enough manpower for crunch times? Avoid
subcontractors who hire temporary, sub-tier workers to ensure your installation is being handled by a reliable, cohesive team.

- How does field staff communicate on site? Do they have computers, Internet access, network access, and printers?
- If there is a rotating schedule of manpower? There should be a crew overlap of at least two days to allow for adequate transfer of duties to ensure that all tasks stay on track.
- Confirm that the onsite supervisor will focus on managing the crew and not doing the actual work. The supervisor should be monitoring crew members, looking at work in progress, and verifying installation for quality standards.
- Obtain supervisor and staff resumes for your files.

**INSTALLATION**

- Find out how subcontractor materials are shipped to your site, accounted for and stored. Is there a designated individual to receive materials and handle returns?
- How does the subcontractor ensure quality workmanship? Do they provide welder qualifications and training, as well as daily or weekly onsite welding coupons, or test welds?
- What is the subcontractor’s process for verifying the accuracy and quality of work completed?

**DOCUMENTATION**

- Understand the contractor’s change order (CO) process. Who is responsible for writing and submitting COs and are they submitted daily or weekly? How quickly are COs expected to be completed?
- Who is responsible for maintaining all bid, proposal and as-built drawings?

**KNOWLEDGE OF SANITARY PROCESS INSTALLATION**

- Make sure that your subcontractor understands the following standards of sanitary installation:
- The importance of the sanitary hanger system supporting the piping install
- Acceptable methods of constructing the piping system so it can be maintained and kept clean
- Proper method of hanging piping so fluids will run back to the low points and the system will drain
- Dead leg piping and how to avoid it
- Identification of an unsanitary piece of equipment verses a component or piece of equipment designed specifically as sanitary or hygienic
- Standards and specifications used in the practice of sanitary design as they relate to different industry sectors
- Process for wash downs and cleaning of equipment for sanitary facilities including cleaning clearances, construction materials and sealants, and installation requirements.
Contributions by:
Jim Oko, Director of Process Engineering
Joe Bove, Vice President Design Engineering
Luke Facemyer, Director of Refrigeration Engineering
Randy Peterson, Senior Project Manager

Published by Stellar 2014
2900 Hartley Road
Jacksonville, FL 32257