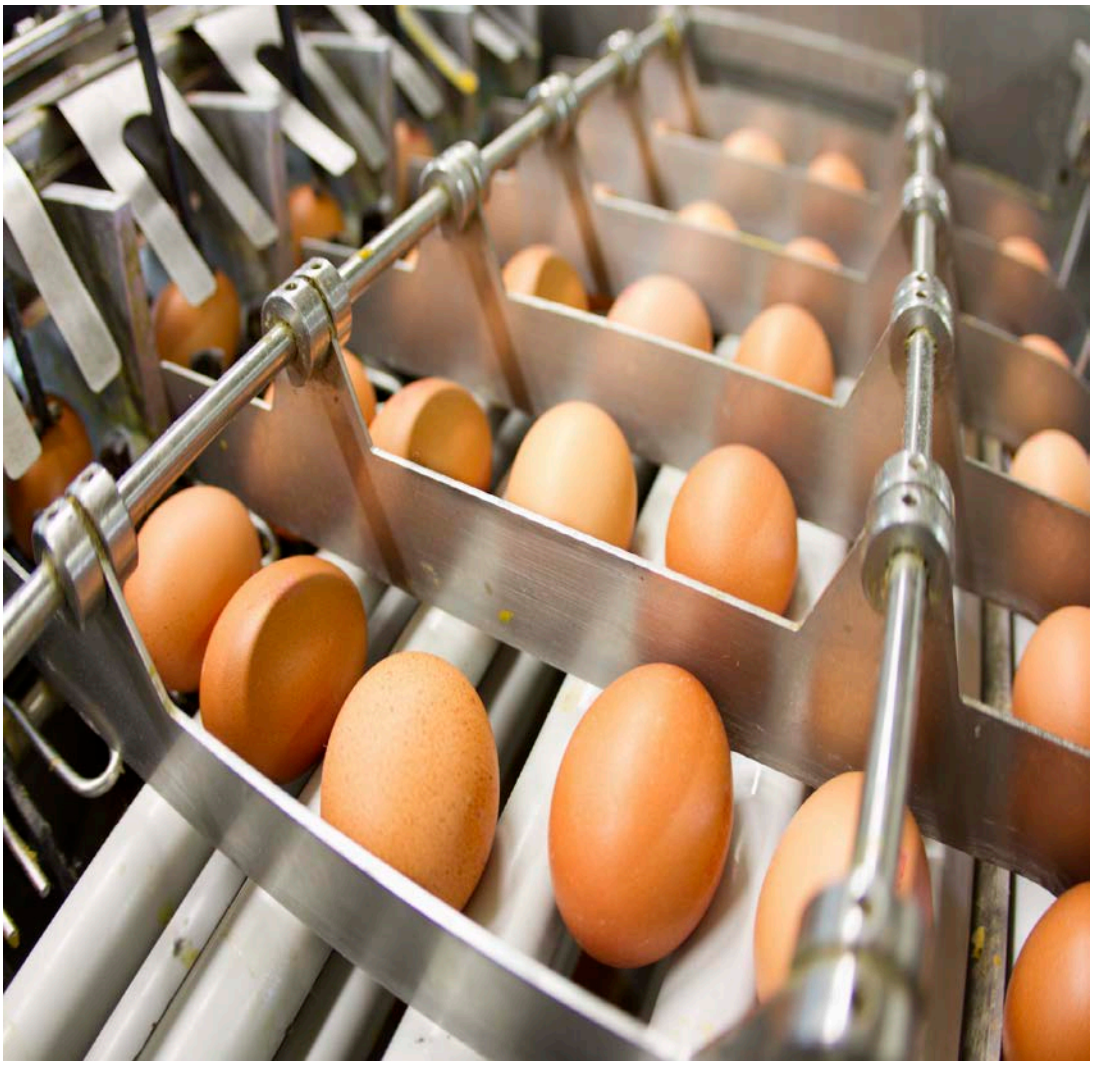

Food Safety Regulatory Requirements

Affecting hygienic equipment in food processing and packaging facilities

White Paper

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It all began with the public outcry resulting from the 1906 publication of *The Jungle* by Upton Sinclair. The revelation surrounding the filthy conditions at Chicago area slaughter houses prompted a federal investigation of the meat processing industry which in turn led to the U.S. Congress moving quickly to pass the Pure Food and Drug Act of 1906. This act was revised by the Federal Food, Drugs and Cosmetics (FD&C) Act of 1938 giving authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs and cosmetics.

The FD&C Act has been amended many times since then to enhance safety regulation and compliance. The Food Safety and Modernization Act (FSMA) is the first sweeping major amendment since the FD&C Act became law with added emphasis on preventive controls. Under FSMA, registered facilities will be required to establish and implement hazard analysis and preventive controls for human food.

Who Needs Hygienic Equipment?

Our modern food industry does. About forty-eight million, or one in six, Americans get sick and 3,000 die each year from foodborne diseases according to the Centers for Disease Control and Prevention (CDC)[1]. Of the total estimated 48 million illnesses annually, the CDC estimates that 9.4 million illnesses are due to 31 known foodborne pathogens. Additional findings for foodborne illnesses report that about 90% of estimated hospitalizations and deaths are caused by just seven pathogens *(see Infection Rates in Figures 1 to 3)*[2] with Salmonella being the leading cause of hospitalization and death, responsible for about 28% of deaths and 35% of hospitalizations. Of those infected, children younger than five years old have a higher incidence of infection and adults older than 60 are at greatest risk for hospitalization and death. "We need to intensify efforts to decrease the number of illnesses and deaths due to foodborne diseases," said Christopher Braden, M.D., director of CDC's Division of Foodborne, Waterborne, and Environmental Diseases. "We now know more than ever what pathogens are causing the most harm, and we will continue our work to help protect people from these illnesses."[1]

***Figure 1**: FoodNet 2011 Progress Report on Six Key Pathogens*

Keeping manufacturing equipment clean and sanitary is an integral part of any system bringing food from the farm to the table. If food is attractive for human consumption it is also attractive to microorganisms. Given the right nutrients and environmental conditions, bacteria can multiply quickly, doubling every 20 minutes. For example, a machinery surface with fresh produce, meat, dairy or other food product at 98°F (36.7°C) would enable a bacteria population generation time (doubling time) of every 20 minutes. These conditions would grow one bacterium to over 16 million bacteria by the end of an eight hour shift. Since pathogens can cause disease and spoilage and other microbes can cause odor and slime at varying levels of cell population, it is important to restrict all microbial growth as much as possible with clean and sanitary machinery and proper environmental controls.

[1] "New Estimates More Precise", Centers for Disease Control and Prevention press release, December 15, 2010.
[2] FoodNet, Centers for Disease Control and Prevention, Foodborne Diseases Active Surveillance Network, Tables and Figures 2011.

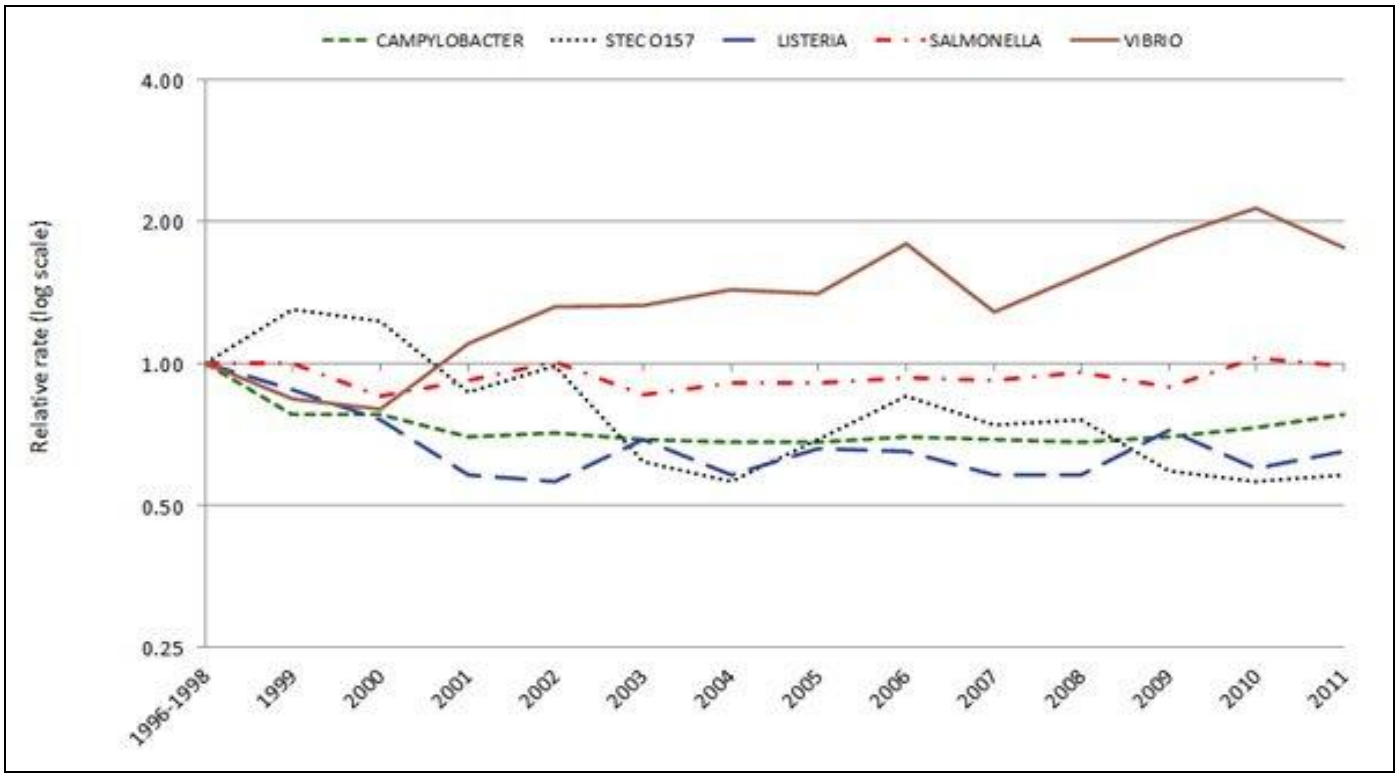

Figure 2: *Relative rates of laboratory-confirmed infections with Campylobacter, STEC* O157, Listeria, Salmonella, and Vibrio compared with 1996–1998 rates, by year, FoodNet 1996–2011.*

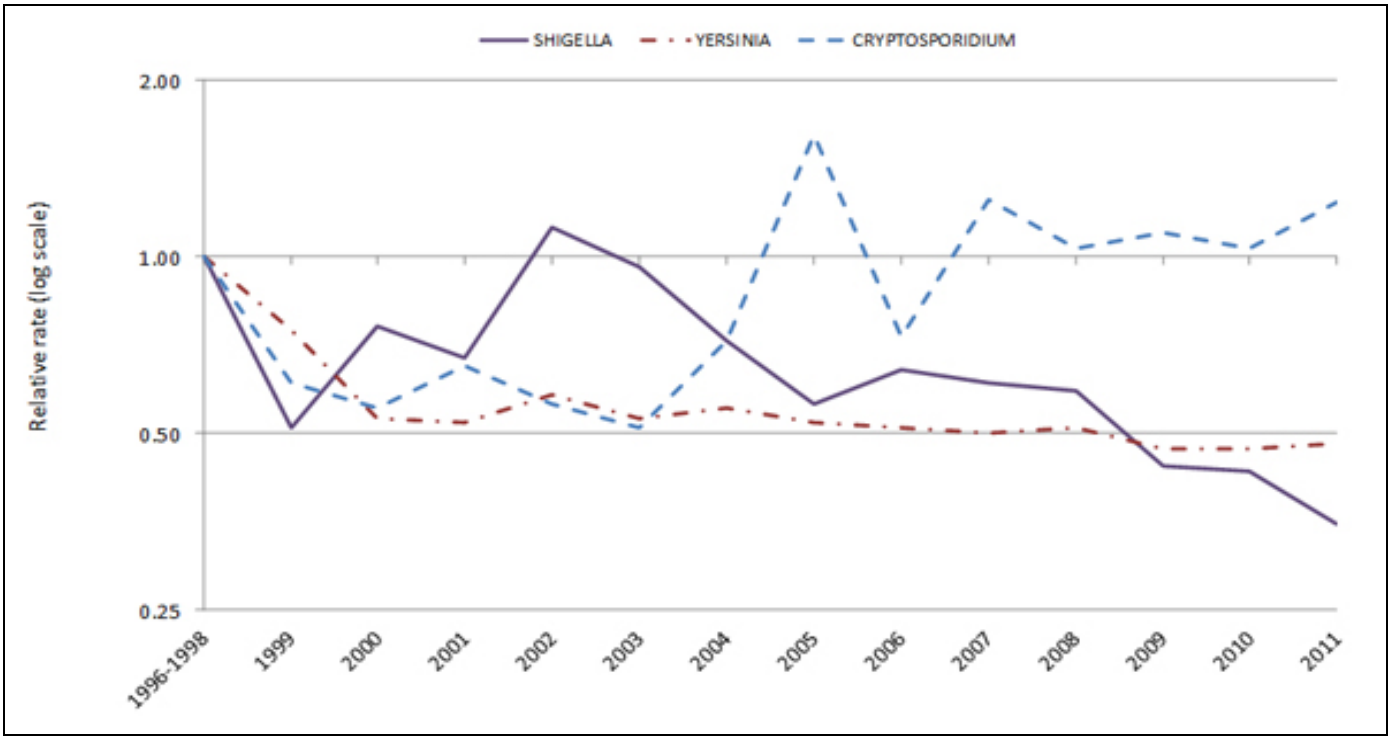

Figure 3: *Relative rates of laboratory-confirmed infections with Shigella, Yersinia, and Cryptosporidium compared with 1996–1998 rates, by year, FoodNet 1996–2011.*

How Do We Keep Food Safe Today?

In an effort to ensure safe food, the Hazard Analysis and Critical Control Points (HACCP) management system for food safety was established by the National Advisory Committee on Microbiological Criteria for Foods in 1992 and revised by a HACCP Working Group in 1995. The HACCP is a systematic approach accounting for every step in food processing to provide the consumer with a safe, edible product. It establishes control over the raw materials, processes, people and the environment. This system does the following:

- Provides for the safety of food products
- Reduces the risk of food borne illness and recall
- Improves regulatory compliance
- Identifies out of control areas for corrective action

An effective HACCP must consider physical, chemical and biological hazards. As part of those considerations, a food safety plan will establish Critical Control Points (CCPs) at which applying control is essential to eliminating food safety hazards or reducing them to an acceptable level—for every significant hazard, at least one CCP must be applied. Thus, these CCPs are to be monitored in such a way as to ensure a safe food supply. Each facility must determine what to control. In order to create an effective Food Safety Plan it is recommended that development begin with five preliminary tasks:

1. Assemble the HACCP Team
2. Describe the Food and its Distribution
3. Describe the Intended Use and Consumers of the Food
4. Develop a Flow Diagram which Describes the Process
5. Verify the Flow Diagram

Once these five preparatory steps are completed, the following seven HACCP steps are applied to the process:

1. Conduct a Hazard Analysis
2. Identify Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Verification Procedures
7. Establish Record-Keeping and Documentation Procedures

A prerequisite to the Hazard Analysis and CCPs being identified is a foundation of the current Good Manufacturing Practices (GMPs), established and developed by many federal, state and local agencies including the FDA. The GMPs give recommendations surrounding methods, equipment, facilities, operations and controls for processing food. As part of implementing effective methods, Sanitation Standard Operating Procedures (SSOP) are developed to maintain a clean and sanitary food facility environment which is free from food hazards. The SSOPs establish the processes of what, who, and how things are done daily and weekly to prevent the contamination or adulteration of food products. SSOPs also describe what levels of operations are in and out of control and how those are monitored for compliance (e.g. acceptable temperature ranges).

What is the Food Safety Modernization Act?

The key to effective preventive controls starts with a Food Safety Plan which identifies reasonably likely unintentional and intentional food safety hazards, develops and implements preventive controls, and assesses effectiveness. Preventive controls should be established and validated surrounding processes, environments and food allergens to ensure that the food will not be adulterated or misbranded under the FD&C Act.

The Food Safety Modernization Act (FSMA) "enables the FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides the FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur."[3] The new law specifies FDA mandates and authorities in five areas:

1. Prevention
2. Inspection and Compliance
3. Response
4. Imports
5. Partnerships

Prevention, Inspection and Compliance, and Response will have a direct affect upon the design and operation of US food producing facilities and associated equipment as FSMA is implemented in the coming years.

Prevention focuses on controls for food facilities, safety standards for producing and harvesting produce and avoiding intentional food adulteration. Food facilities are required to implement a preventive controls plan including: 1) evaluating the hazards that could affect food safety, 2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, 3) specifying how the facility will

[3] "Background on the FDA Food Safety Modernization Act (FSMA)", Food and Drug Administration, November 14, 2011.

monitor these controls to ensure they are working, 4) maintaining routine records of the monitoring, and 5) specifying what actions the facility will take to correct problems that arise.[3]

Inspection and Compliance focuses on inspection frequency, records and laboratory testing. The law directs the FDA to increase inspection to at least once every three years. Also the FDA shall have access to food safety plans and implementation records. FSMA directs certain food testing be done by accredited laboratories and the FDA to establish a laboratory accreditation program.

Response focuses on the tools that the FDA can use to effectively respond to problems when they occur. These tools include mandatory recalls, administrative product detention, facility registration suspension, product traceability, and records for high-risk foods. These tools give the FDA the new authority to take direct corrective action in the containment and removal of emerging food safety problems.

First FSMA Rules up for Public Comment

The U.S. Food and Drug Administration released the first two proposed FSMA rules on January 4, 2013 for 120 days of public comment. The FDA is aiming to improve its regulation for current Good Manufacturing Practice (GMPs) in Manufacturing, Packing, or Holding Human Food for facilities registered under the FD&C Act. The first two rules are Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food and Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. The Preventive Controls rule focuses on facilities that manufacture, process, pack or hold human food. The proposed Produce safety standards rule focuses on key areas of risk which include agricultural water, biological soil amendments, health and hygiene, domesticated and wild animals, and equipment, tools and buildings.[4]

More on the Preventive Controls Rule

The proposed Preventive Controls rule will affect the design and operation of food facilities. It focuses on new hazard analysis and risk-based preventive control requirements and revising the GMPs. Key aspects of hazard analysis and risk-based preventive controls (FSMA section 103) are to evaluate hazards, identify and implement preventive controls to address these hazards, verify that the preventive controls are adequate to control the hazards identified, take corrective action when needed, and maintain a written plan and documentation. Preventive controls are to be science-based and risk-based and are required only where necessary to prevent hazards to public health. The controls are to be developed so that they "significantly minimize or prevent all food safety hazards that are reasonably likely to occur."[4] The proposed rule states that a qualified individual is responsible for the written food safety plan. To be considered qualified, the individual must either successfully "complete training in accordance with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system."[4] A written Food Safety Plan includes the following elements:

1. A Hazard Analysis
2. Preventive Controls
3. Monitoring Procedures
4. Corrective Actions
5. Verification Activities
6. Recordkeeping

The Preventive Controls rule aligns with HACCP but differs in that preventive controls may be required in areas other than CCPs and would not be required to have control limits in all cases. Preventive controls surrounding process, environment and food allergens must be adequate to ensure that food will not be adulterated or misbranded under the FD&C Act.

Proposed revisions to the GMPs include preventing contamination through cross-contact of food by allergens, recordkeeping training and cleaning requirements for non-food contact surfaces. This Preventive Controls rule applies to those food facilities required to register with the FDA which include manufacturers, processors, warehouses, storage tanks and grain elevators. There are exemptions and modified requirements to the proposed rule which include low-risk foods, small operations and foods that are covered by other existing rules and regulations.

Food Safety Expectations

The U.S. Congress and the U.S. Food and Drug Administration (FDA) continue to work to improve food safety through existing regulations and the additional mandates and authorities written in the Food Safety Modernization Act (FSMA). The FDA looks to significantly lower infection rates due to foodborne pathogens by requiring food processors to improve the quality and safety of their products through a focus on preventive controls. The two new FSMA proposed rules, and the ones to follow, represent a major comprehensive reform in food safety regulations. Food processing and packaging companies will have to create food safety plans to encompass all likely hazards in products, equipment and environment.

[4] "Overview of the FSMA Proposed Rules on Produce Safety Standards and Preventive Controls for Human Food", Food and Drug Administration, January 2013.

What Does This Mean for Food Equipment?

Effective food hazard elimination and control starts with well-designed food processing and packaging equipment. Every food company relies on hygienic machinery as part of food safety plan. Look for machinery with the following characteristics:

- Cleanable and Accessible: Machines should be designed so that they can be entirely cleaned, sanitized and inspected in place. This means an open design for accessibility and all components capable of withstanding washdown processes (e.g. IP69K and Nema 4X enclosures).

- No Liquid or Soil Collection: Machines should be designed in such a way so that no pathogens are harbored. Eliminating places where water pools and soil collects prevents contamination.

- Compatible Materials: Equipment should be compatible with food products and processing materials as well as cleaning and sanitation chemicals so as not to react in an unwanted way to create a food hazard (316 series stainless steel is a good choice for most food applications).

- Hermetically Sealed Hollow Areas: Eliminate hollow areas from frames and rollers where possible, and seal where not. For example, IP69K stainless steel motors are sealed to withstand high-pressure washdowns.

The AKMH from Kollmorgen offers motor technology in a stainless steel housing with sealing that provides IP69K ingress protection for use in washdown environments.

- Sanitary Operation: While machines are running they must operate in such a way as to not create hazards during production (e.g. servomotors with food compatible greases and coatings).

These are some of the ways in which properly designed machines help ensure food safety.

These same design considerations are required when applying motion as part of a well-designed food processing or packaging machine. Motors and other system components should have features such as 316 stainless steel material to withstand the corrosive environment, no hardware to harbor pathogens, round housings and no flat surfaces to collect water, venting to maintain pressure equilibrium and sealing to an IP69K standard to withstand repeated exposure to water and high-pressure washdowns. Kollmorgen's new line of stainless steel servomotors offer these features and more to ensure that machinery is hazard-free every day.

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Conclusion

Failure to shift to a more heavily weighted preventive control approach increases the risk of U.S. Food and Drug Administration action to stop the distribution of adulterated or misbranded food. Suspended registration, production holds, held shipments and recalls all have the potential to damage brand images and reduce company profits. That is why it is important to eliminate or reduce risk throughout the food production system including the food processing and packaging equipment.

The latest generation of stainless steel motion products can reduce the risk of food contamination. These are designed and built by Kollmorgen to provide reliable, quickly cleaned and sanitized, hygienic, high-performance motion solutions. At Kollmorgen we know the challenges of processing and packaging safe food and have devoted our research and development efforts to create solutions for the food industry.

ABOUT KOLLMORGEN

Kollmorgen is a leading provider of motion systems and components for machine builders around the globe, with over 70 years of motion control design and application expertise.

Through world-class knowledge in motion, industry-leading quality and deep expertise in linking and integrating standard and custom products, Kollmorgen delivers breakthrough solutions unmatched in performance, reliability and ease-of-use, giving machine builders an irrefutable marketplace advantage.

For more information visit www.kollmorgen.com, email support@kollmorgen.com or call 1-540-633-3545.