Supporting Safe Food Production Through Leadership in Equipment and Packaging

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Many factors are driving change in the food industry, not the least of which is the new regulatory requirements that are part of the Food Safety Modernization Act (FSMA). Other factors (besides the FSMA) are also driving concern and leading to improvements in the food industry. As such, food manufacturers will increasingly be looking to their vendors—including those that manufacture equipment and packaging material, to help them meet, or more likely exceed, regulatory requirements and standard industry practices.

The pressure food processors and manufacturers face is greater than ever before, and is driven by:

- Reliance on a global supply chain
  - Materials, including food ingredients, packaging material, and equipment are sourced from all over the world, challenging consistency in quality
- Changing science
  - Allows for detection of lower concentrations of contaminants on the food and food processing equipment.
  - Gives us the ability to connect illness with foods more than ever before
- Consumers who expect great quality at a low price with zero risk
- The propensity for both mainstream and social media to weigh in on food issues
  - Issues expand beyond safety; ethical sourcing, environmental considerations and other practices may be called into question
- New regulatory requirements

The increasing number of recalls for allergens and the rising number of warning letters from the FDA are testimony to both recognition of new problems and ramped up enforcement actions. Some of the key areas that are creating concerns for the manufacturing and processing industry that can be addressed by equipment and packaging manufacturers include:

- Pathogen Control
  - Thorough risk assessment of equipment and packaging components
  - Assessment of chemical, physical, and biological hazards from their suppliers
  - Use of Sanitary design principles to make equipment more easily cleanable
  - Elimination of potential harborage sites
  - Effective implementation of process parameters and preventive controls
  - Should be easily calibratable
  - Process parameters should be able to be validated on the equipment
  - Allow for effective monitoring of process conditions

- Effective communicate with the facilities information system (wireless or wired)
- Prevent environmental contamination

- Allergens
  - Cleaning and sanitation issues
  - Prevent mislabeling through use of smart technologies

- Product tracking
  - Recall process data for tracking and trending purposes

These issues must be considered by the equipment manufacturer and the food processor that purchases them. Failure to account for these critical issues can and will result in significant negative brand impact which has to be protected by balancing safety, quality, and compliance.

The Key Role of Equipment and Packaging

While packaging material/equipment suppliers are not required to implement preventive controls, food companies need to evaluate packing materials for safety and can be expected to look to suppliers to help control risk. Food contact substances extend beyond direct product packaging and include polymers (plastic packaging materials), pigments and antioxidants used in polymers, can coatings, adhesives, materials used during the manufacture of paper and paperboard, slimicides and biocides (antimicrobial agents), and sealants for lids and caps. These, too, will be under increased scrutiny as safety is assessed by food manufacturers as well as the regulators.

As food companies are constantly looking for ways to control this risk, there is increasing recognition of the role all aspects of a facility contribute to the production of safe, quality products. Increasingly, food companies are looking to avoid problems before they enter the four walls of a facility. Here are some examples of ways equipment and packaging providers might feel the impact of these changes. Below are some examples of ways equipment and packaging providers might feel the impact of these changes.

Pathogen Control

Protecting public health is of paramount importance. The Preventive Controls Rule instituted by the FDA requires FDA registered facilities to evaluate and control food safety risks. Pathogens can contaminate a product at many points, some of which can be addressed through advances in equipment and packaging.

- Process controls and associated monitoring
  - Process controls, commonly referred to as “critical control points” in HACCP, are generally viewed as the measurable processes that can significantly minimize or eliminate pathogens.
  - FDA requires that process controls are fully validated (proof that they have the intended effect) and food companies often look to equipment manufacturers to provide or aid in that validation. “Process controls include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Examples of process controls include heating a food to adequately reduce pathogens and acidifying a food to prevent pathogen growth.”
  - Once validated, the process control must be verified (assurance that the process parameters are achieved).

        - Equipment manufacturers should consider how the key parameters (akin to critical limits) can be monitored
    - Additional considerations should be given to how effectively the equipment is calibrated as it will significantly impact the consistency, quality, and safety of the product.
- Cleaning and sanitation
    - FDA identifies two aspects of sanitation as possible preventive controls: sanitation of product contact surfaces, and prevention of cross contamination.
    - Equipment must be designed in a way that it can be cleaned and sanitized.
        - Equipment manufacturers should adhere to the recommendations around sanitary design of equipment.
- Environmental contamination
    - Related to cleaning and sanitation, food facilities, including the equipment used in them, must be designed to control environmental risk.
    - Equipment design should consider the potential for harborage sites where pathogens can take residence.

Allergen Control

The presence of an unintentional or undeclared allergen can be life threatening for a food- allergic individual. Allergens have long been recognized as potential hazards, but allergen issues continue to result in recalls. In addition to FDA requiring food facilities to consider the potential for allergens as reasonably likely to occur hazards, FDA has also updated current Good Manufacturing Practices regulations to emphasize the need to control allergen cross-contact.

- Examples of food allergen controls include procedures that:
    - Provide physical barriers;
    - Eliminate or minimize the formation of dust, aerosols, or splashes;
    - manufacturing/processing of foods in different parts of a facility;
    - Emphasize separation in time, such as by production sequencing or by cleaning equipment between production runs;
    - Emphasize storage and handling appropriate to reduce the potential for cross-contact; and
    - Control the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods that do not, or when the same production lines are used for foods that contain different allergens.
- Cleaning and sanitation
    - Pathogens are not the only hazard controlled by cleaning and sanitation. FDA is placing increased emphasis on allergen-related issues including cross contact.
    - Allergen controls are one type of preventive control, and food manufacturers may seek information on the ability to remove allergens from product contact surfaces.
    - Use of sanitary design principles must also be applied for control of allergnes.
- Labeling issues
    - Improper allergen declarations result in many recalls each year. Equipment and packaging design and systems must be in place to ensure fail-proof application of the correct label.
    - Use of technology to identify the proper label for each product is one way to reduce the risk of labelling issues.

Product Tracking

FDA has required additional recordkeeping requirements for qualified facilities aimed at improving traceability. Records are to be maintained to support the required documentation. The rule does not require that a qualified facility establish any new records, but merely retain those that the facility relied upon to support the required documentation. The rule also establishes that the records that a qualified facility must maintain are subject to the recordkeeping requirements of subpart F of part 117 which provides the general requirements that apply to all records required to be established and maintained, including provisions for retention of records (minimum 2-year retention, electronic records are acceptable), and for making records available for official review. The ability to store, trace, and trend electronic data on the equipment as well as ease of upload to the facility's main document depot will allow for better process control and records management. Together, § 117.201(a) and (b) makes the underlying records qualified facilities would rely on to support their self-certifications available to FDA upon request.

Summary

In short, recognizing the pressures faced by the food industry will allow suppliers of equipment and packaging to bring market leadership to food company customers. This includes providing information to food industry customers on safety evaluations, validation studies, and clean-ability. Because recordkeeping requirements are extensive, designing equipment with systems that can be readily monitored for the purposes of ensuring preventive controls are working, and that support or provide traceability, may also provide a market edge.

Packaging and equipment companies that are sensitive and knowledgeable about the current pressures on food companies and their brand risk will have market advantage in this growing area of complexity.