FDA Proposed Rules
Reset FSMA’s Preventive Controls

Although the final rules will not be issued for several months, the objectives for FSMA will remain, moving the industry from reaction to prevention.

by Len Steed
Food Safety

Public commentary and FDA responses to the supplemental rule changes issued September 19, 2014, are truly significant, and the dialogue for changes and clarifications will continue as FDA writes the final Food Safety Modernization Act (FSMA) rules. Although there are uncertainties in play, we know that the objectives for FSMA will not change. The primary goal is to move from reactive to preventive for any actual or potential food safety issue termed a Severe Adverse Health Consequence or Death in Humans or Animals (SACHODHA) event in the marketplace.

Identification and monitoring of preventive controls will be applied to food safety programs, supplier controls, process steps, and operational practices to prevent unsanitary conditions and cross-contact contamination. At minimum, this will require a risk-based analysis for hazards to be controlled by the good manufacturing practices (GMPs), HACCP plan, process controls, and a supplier verification program.

The regulatory focus will be food processors and distributors of products associated with Class 1 recalls (SAH-CODHA). This article focuses on FDA response to the public commentary and discusses a practical understanding of the proposed changes contained in Section IX: Overall Framework for Hazard Analysis and Risk-Based Preventive Controls (HARPC) for human food processors and the process for identifying preventive controls (PCs); Section XI: Potential Requirements for a Supplier Program which are the foundation for FSMA implementation; and other sections such as Section X: Proposed Requirements for Product Testing and Environmental Testing due to nature and importance if included in the final rules. (Author’s note: Quotations are taken directly from FDA documents, but are subject to further change when the final rules are issued.)

DEFINING HARPC. Regulated HACCP (Hazard Analysis and Critical Control Point) is considered to be a success story in the production of high-risk foods. FDA has applied these principles to “other than critical control points (CCPs)” in a company’s day-to-day operations. It is important to understand that HACCP is not the same as HARPC, but together they will enhance food safety through additional food safety programs and supplier controls that are monitored and verified similar to a CCP.

The regulatory focus for HARPC is to reduce the number of Class 1 recalls due to undeclared allergens and pathogenic bacteria such as Salmonella and Listeria. FDA defines a Class 1 recall as “a situation in which there is a reasonable probability
that the use of or exposure to a violative product will cause serious adverse health consequences or death” (SAHCODHA hazard).

The rationale for HARPC can be traced to regulated HACCP for seafood (21 CFR part 123) and juice (21 CFR part 120) (i.e., whether a “known or reasonably foreseeable hazard” was “reasonably likely to occur”). This phrase and definition has caused confusion as it is derived from HACCP hazard analysis terminology to identify potential CCPs and not preventive controls. In response, FDA has proposed the use of the term “significant hazard.” “Significant hazard would mean a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification and records) as appropriate to the food, the facility, and the nature of the control.” From this statement, FDA has clarified that the “known or reasonably foreseeable hazard” would apply to the facility conditions, type of food product, and raw materials. The minimal criteria to be applied to control significant hazards for a facility’s plant conditions and type of food product is listed in Table 1.

FDA has suggested that determining a significant hazard would be a two-step hazard analysis process:

1. List the known or reasonably foreseeable biological, chemical, and physical hazards associated with the facility and the food product. For HARPC, additional chemical hazards such as radiological, natural toxins, pesticides, drug residues, food additives/colors, and decomposition would need to be added to the raw material hazard analysis and include economically motivated adulteration (EMA).

2. Evaluate the importance of a preventive control (PC) to significantly minimize or prevent the hazard from occurring, and evaluate what level of monitoring and recordkeeping would be necessary to achieve effective control. The level of importance would be based on the severity of the illness or injury and the likelihood of occurrence if this hazard was not adequately monitored. In other words, not all PCs will have documented monitoring, only the most important programs for raw materials, plant conditions, and food safety programs that prevent “significant hazards” from occurring.

DOMESTIC SUPPLIER CONTROL.

The evaluation for having a supplier control program (i.e., supplier verification), would be based on the identification of a “significant hazard” during hazard analysis and then deciding what entity will be controlling the identified hazard. This could be the supplier to the supplier (sub-supplier), the receiving entity (processor or distribution), or the customer. It is expected that there will be additional changes in the Supplier Verification Program as the comment period for this and the Foreign Supplier Verification Program (FSVP) are finalized.

Currently, the options for controlling significant hazards associated with raw materials are:

- The supplier to the receiving facility (processor) controls the hazard.
- The supplier to the processor’s

<table>
<thead>
<tr>
<th>Table 1 – Preventive Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanitation procedures for food-contact surfaces in product handling systems and process equipment.</td>
</tr>
<tr>
<td>Procedures for cleaning utensils and equipment areas outside of the product zone.</td>
</tr>
<tr>
<td>Staff hygiene training for plant personnel.</td>
</tr>
<tr>
<td>As applicable, processors of ready-to-eat (RTE) product must assess plant conditions that could allow for pathogen cross-contact prior to packaging (e.g., application of environmental monitoring program).</td>
</tr>
<tr>
<td>As applicable, an allergen control program (ACP) prevents cross-contact through receiving, storage, processing, and packaging operations including proper labeling of all allergenic products and raw materials.</td>
</tr>
<tr>
<td>Recall plan and traceability of all raw materials, process aids, and packaging.</td>
</tr>
<tr>
<td>Existing and proposed GMPs applicable to preventive controls to prevent unsanitary conditions:</td>
</tr>
</tbody>
</table>
  - Building and equipment sanitary design. |
  - Sanitary operations and sanitary controls. |
  - Production and process controls. |
  - Warehouse and distribution. |
| Supplier controls as required by HARPC. |

<table>
<thead>
<tr>
<th>Table 2 – Supplier Verification Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entity Controlling the Hazard</td>
</tr>
<tr>
<td>Supplier</td>
</tr>
<tr>
<td>Sub-supplier</td>
</tr>
<tr>
<td>Receiving facility (Processor)</td>
</tr>
<tr>
<td>Customer</td>
</tr>
</tbody>
</table>
Food Safety

supplier controls the hazard (termed sub-supplier).
• The receiving facility controls the hazard.
• The customer of the receiving facility controls the hazard.
• A combination of these options controls the hazard through supplier verification or other verification activities.

Table 2 (page 7) provides a summary of when the receiving facility would need or not need to have a Supplier Verification Program to control the identified hazards.

If a company identifies significant hazards in its raw materials and ingredients controlled by the supplier or sub-supplier, the receiving facility will need to have a documented Supplier Verification Program (SVP). The current requirements for content are:

- Supplier Verification Requirements
  - Documented hazard analysis and records for identifying significant hazards in raw materials and ingredients.
  - Documented supplier verification procedures and records.
  - Annual on-site audit by a “qualified auditor” to review the supplier’s procedures, conclusions, and effectiveness of any necessary corrective action(s).
  - After the initial audit, the receiving facility (processor) can elect to require less than annual audits but must conduct other verification activities to ensure hazard control is adequate.
  - FDA would not have access to the full audit report, but could have access to audit conclusions and corrective actions.

The final FSMA regulations will be issued late 2015 and early 2016.

Do your food safety and food defense programs meet new FSMA requirements? Time is running out!

FSMA: The Pathway to Compliance

March 31 - April 1, 2015 • Chicago, IL

Prepare now before FDA begins enforcing these regulations.

Enroll Now!

http://tiny.cc/fsmapathway
Call: 800-633-5137
Email: info@aibonline.org