A Summary of the Proposed Rules for Food Safety Modernization Act Section 103

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Section 418 of the F.D.&C. Act)

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Introduction

The long awaited proposed rules for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, Section 103 of the Food Safety Modernization Act (FSMA) legislation, were released in January 2013, exactly two years after being signed into law by President Obama.

The proposed rule as currently written was published in the Federal Register on January 16, 2013 and then entered into a 120-day public comment period. Following the comment period, the U.S. Food and Drug Administration (FDA) reviewed all of the comments received. After the review was completed, the final rule was published and put into effect.

During the comment period, the FDA asked for comments on both deleting or modifying parts of the proposed rule, as well as implementing additional rules such as mandating environmental monitoring as a preventive control, complaints review, and submission of a given facility’s food safety plans to the FDA. The final rule could change based on public comments and the action that the FDA takes on them.

Actual compliance to the final rule will not be before the fall of 2014 for major facilities, fall of 2015 for small companies and the fall of 2016 for very small companies.

An extensive review of the 680 pages of this proposed Current Good Manufacturing and Hazard Analysis and Risk-Based Preventive Controls for Human Food clearly reveals that the FDA has put a lot of thought into what should be required for a facility to have an adequate food safety plan designed to prevent contaminated products, foodborne illness outbreaks and product recalls.

FDA has developed its proposed rule based partly on reviewing the Seafood HACCP regulations, the Meat and Poultry HACCP regulations, the Juice HACCP regulations and the Low Acid Canned Food regulations.
Having a firm grasp on the language and definitions used in the proposed rule is critical to understanding its overall impact on any given facility.

**Facilities Affected by the Rule**

While Section 103 will affect most facilities that process foods for human consumption, some facilities regulated by agencies other than FDA will not be mandated to comply. The following processing facilities are NOT required to become compliant with FSMA and therefore with Section 103, which requires a written food safety plan.

The following facilities are exempt:

- Facilities only required to be inspected by the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) and therefore not required to register with the FDA
- Seafood processors (covered by Seafood Hazard Analysis Critical Control Point (HACCP) regulations)
- Juice processors (covered by Juice HACCP regulations)
- Low acid canned processors (covered by Low Acid Canned Foods regulations)
- Dietary Supplement processors
- Alcohol processors
- Tester amendment exempts businesses with annual sales <$500,000 with >50% of these sales to consumers/retailers within 250 miles of their facility. FDA is proposing exemptions from written food safety plans for the following facilities.
- On-farm facilities performing low risk activities such as re-packing intact fruits, or grinding, milling, etc. of grains.
- Facilities solely engaged in the holding (previously called storage) of packaged foods that are not exposed and do not require refrigeration. These holding facilities will still need to comply with other applicable sections of FSMA.

FDA is proposing exemptions from written food safety plans for the following facilities.

- On-farm facilities performing low risk activities such as re-packing intact fruits, or grinding, milling, etc. of grains.
- Facilities solely engaged in the holding (previously called storage) of packaged foods that are not exposed and do not require refrigeration. These holding facilities will still need to comply with other applicable sections of FSMA.
Facilities that hold refrigerated foods would need to have temperature controls and monitor these for compliance. They will not be required to have a written food safety plan or do a hazard analysis. Rather, FDA will define what needs to be done, so no “qualified” individual would be required. This is an interesting portion of the rule as it differs from Seafood HACCP. FDA requires facilities receiving and holding Seafood to have a qualified HACCP individual on staff and to have a Seafood HACCP Plan. The proposed FSMA rule seems to segregate Seafood from other high risk refrigerated products.

Caution should be exercised by any facility granted an exemption by FDA from having to have a written food safety plan. The exemption is given with the understanding that if a facility is involved in a foodborne illness outbreak, FDA can rescind the exemption if the lack of a control at said facility was the cause of the foodborne illness outbreak.

Although the manufacture, packaging, holding and distribution of pet foods are covered by this same section of FSMA, FDA will issue different guidance for pet foods and animal feed at a later date.

**Preventive Controls**

FDA has avoided using the term HACCP to describe the Preventive Controls program because although it recognizes the principles and general success of the implementation of HACCP plans, HACCP has not prevented contaminated foods and foodborne illness outbreaks. Tendency to pay attention to Critical Control Points (CCPs), to the detriment of Control Points, has left some foods still unsafe.

FDA has also avoided the term CCPs and has defined them as Preventive Controls, stressing that if a hazard is likely to occur and a facility does not include it in their written food safety plan, then the facility needs to fully document the justification for that hazard's exclusion.

Critical limits for the control of hazards are now to be called parameters in a Preventive Controls program. FDA recognizes that not all of parameters may be quantifiable but facilities must be able to prove they effectively control the identified hazard.

If a facility indicates in its hazard analysis that a hazard known to occur is being controlled by one of its suppliers because its process will not control it, then the facility will need to verify that its supplier is achieving this control. That verification will be done by requiring knowledge of the Supplier’s Preventive Controls program that ensures the control is happening. A 2nd or 3rd party audit report will not suffice.

**How cGMP Could Affect the Rule**

The fundamental basis for a Preventive Controls program is to be combined with a still to be released, updated Current Good Manufacturing Practice 21CFR 217 which will replace the cGMP 21 CFR 110, which was last updated in 1986.

These revised cGMPs will place more emphasis on Sanitation, Allergen Controls, Supplier Approvals and Environmental Testing.

FDA has asked for comments on whether Sanitation programs, Supplier Approval programs and Environmental Monitoring programs need to be added as mandatory parts of this rule.

Allergens are included as hazards likely to occur and this proposed rule requires an Allergen Control program as a Preventive Control measure. There are numerous pages devoted to this in this proposed rule.
Preventive Controls Program Requirements

If a facility is required to register with FDA, then under FSMA, no matter what type of foods it manufactures, it must develop, document, implement, validate and have records showing verification of implementation of a Preventive Controls Program. The only exceptions to this rule are if a facility is exempt under the definitions and/or is currently governed by an existing FDA/FSIS HACCP Plan.

This differs from previous FDA legislation that only mandated HACCP plans for certain FDA-regulated products: Seafood, Juice, Low Acid Canned (and Acidified) Foods.

This requirement will be mandatory when finalized for all FDA registered facilities, unless exempted.

Qualified Individuals

The Preventive Controls program will need to be prepared by a “qualified individual” who does not need to be employed at your facility.

This qualified individual will need to have had specialized training, or have gained needed experience and knowledge through tenure in a specific industry and its processes, so they are able to validate the effectiveness of the implemented food safety controls, inspect the program’s records and perform a reevaluation of the hazard analysis every three years.

It appears that FDA may be moving towards standardized food safety training programs similar to its successful Seafood HACCP training curriculum that was introduced 15 years ago.

This could, in the final rule, require that a facility’s current HACCP-trained management employees attend new food safety training classes conducted by FDA-recognized training centers using an FDA approved curriculum.

Components of a Preventive Controls Program

A facility’s Preventive Controls program needs to have the following components. At first glance, these may appear to be the same as HACCP requirements, but are in some cases quite different:

- Hazard Analysis
- Preventive Controls
- Parameters
- Monitoring
- Corrective Actions
- Verification
- Record Keeping
- Recall Program

In this proposed rule, a documented Recall Program is required and is considered a Preventive Control even though it only would be used if a facility had a hazardous product out in the marketplace.
Hazard Analysis

The first requirement to facilitate the development of a Preventive Controls program is that each facility has to perform a brainstorming session to determine all possible hazards that could likely occur based on known hazards from raw materials, ingredients, packaging materials, employees, equipment, facility environment, etc.

The proposed rule has added radiological hazards to the commonly considered biological, chemical and physical hazards even though FDA identifies the source of these hazards as private well water and/or nuclear power station accidents. This hazard category may be removed before the publishing of the final rule if public comments are successful.

FDA also asks facilities to consider deliberate contamination of food products by “terroristic” individuals or employees as potential hazards but asks facilities to place the preventive controls for these possibilities in the facility’s Food Defense program and not in its Preventive Controls program.

For each of these potential hazards a facility is then asked to perform a risk assessment based on the probability of its occurrence and the severity of its effect on the consumer if it did occur and was present in the finished food product.

Records of the justification to either include or not to include these potential hazards in a Preventive Controls program must be maintained by the facility.

For each hazard deemed to be likely to occur in the finished product where the risk assessment identifies a health or injury concern to the consumer there will need to be a preventive control.

Preventive Controls

Preventive Controls by definition are controls designed to prevent, eliminate or reduce the known hazard to an acceptable level for safe consumption of the food. A facility will need to provide documented proof of the validation basis for its Preventive Controls being able to achieve this control.

This rule places these controls into three groups: process controls, environmental controls and allergen controls. Clearly, this establishes the direction in which FDA wants facilities to go. It places more emphasis than has been there in the past on the facility’s plant environment as a source of product crosscontamination and on allergens that affect 2-3% of consumers and are found in foods that are either mislabeled or contaminated by cross-contact.

FDA recognizes that not all Preventive Controls are process controls, defined as Critical Control Points (CCPs) in HACCP plans, as some of these preventive measures can be controlled by pre-requisite programs like sanitation, supplier approval programs or foreign material control programs. These preventive non-process controls have been previously designated as Control Points (CPs) with no requirement to keep documented records of controlling the hazards at these points in a process.
If a facility has previously relied on a supplier to control a hazard because its process will not control the named hazard, then that facility will be expected to identify how it verifies that its supplier is effectively doing so. This can be done by assessing the supplier’s Preventive Controls program or by testing its incoming raw material for the potential hazard. Acceptance of a Certificate of Analysis (COA) may not be considered sufficient, nor will simple acceptance of a copy of a 2nd or 3rd party audit be robust enough.

The facility will need to develop parameters for each of these preventive controls that will ensure the food products are safe for consumption.

**Parameters**

Similar to Critical Limits in a HACCP plan, parameters are criteria used to control hazards. If the parameters are measurable, they need limits. If not measurable, then how they will be assessed need to be defined.

As parameters need to be assigned to each Preventive Control, this will include any program that is defined as a Preventive Control, as well as steps that are process points, so they can all be shown to be effective.

The proposed rule mentions sanitation assessments after clean up as an example and uses visually clean as the parameter for judgment of clean for removal of food residues, allergens and microorganisms. It does not require ATP swabbing or allergen swabbing. Facilities may want to continue to swabbing as a validation step but it is not required for verification.

The proposed rule is full of guidance from the FDA on how to develop the support material to set parameters or to know where to place your Preventive Controls. For example, it stresses the importance of properly applying accurate labels to the correct products as an important step in an Allergen Control program.

**Monitoring**

It is essential for a facility to have set Preventive Controls in place and monitor compliance with those controls and the assigned parameters. FDA has stressed the importance of doing this and doing it frequently.

FDA has allowed facilities to determine their own frequency based on the risk of losing control and the costs incurred in handling out of compliance products.

The benefits of monitoring are that it gives a facility assurance of food safety compliance; it catches noncompliances quickly enough to allow corrective actions; it immediately alerts of noncompliance and ultimately averts the possible distribution of a potentially hazardous product; and it verifies that a facility’s Preventive Controls program is working.

Frequency of monitoring is based on the determination by a facility of the acceptable level of out of compliance product that can be produced before a noncompliance is identified. Continuous monitoring is recommended whenever possible.
Corrective Actions

Each Preventive Controls program must have written Corrective Actions to address every foreseeable noncompliance.

These Corrective Actions must be documented and need to correct the problem, address the disposition of affected product, have a root cause analysis of why the process went out of compliance and, if any unforeseen event occurs, there needs to be the ability to make safe decisions using a qualified person’s input. In addition, these unforeseen occurrences now need to be added to your plan as they are now foreseeable.

FDA has decided that, under the rule, any products that are not within your food safety parameters are unsafe products and cannot be shipped until reconditioned and then further evaluated to prove they are safe to be consumed.

Facilities must remember to keep documented records of all Corrective Actions, any root cause analysis and any preventive actions taken to correct any deviations.

Verification

The proposed rule requires that every Preventive Controls plan be validated by a “qualified individual” either before its implementation or within the first 6 weeks of production against known scientific studies or by a facility conducting its own scientific study.

The controls put in place for assessing Sanitation, Allergen Control and Recall programs are currently exempt from these validation studies.

In addition to validating the plan, the qualified individual must be able to verify that the controls have been implemented and are being monitored consistently according to the frequency specified in the plan. Lack of monitoring results will result in FDA considering the food unsafe as it may be adulterated or misbranded. Monitoring records are expected to be reviewed at least weekly by the facility’s qualified individual to ensure compliance with the preventive control.

Equipment calibration records are expected to be reviewed within a timely manner after the calibration activity.

Each written food safety plan and Preventive Control need to be re-analyzed a minimum of every three years and this review needs to be documented even if the review resulted in no changes.

If changes are made in your food safety plan at any time, then what was changed, why it was changed and how it was validated that the change produced a safe product must all be documented.

Recordkeeping

Records of monitoring the Preventive Controls have to be made at the time of the observation in accordance with the frequency as defined in the food safety plan.

These records need to be initialed or signed by a trained person and include the date and time of observation, the product information and contain corrective actions if a deviation is observed.
Records need to be kept on-site at the facility for two years and made available to an FDA inspector upon request. Other records that apply to non-preventive controls in your food safety plan can be moved off-site after six months as long as they are also retained for two years. If requested by FDA, these non-preventive control records must be produced within 24 hours.

Preventative Controls Expected In Your Food Safety Plan

Recall Program

In the proposed rule, FDA has listed an effective Recall program as a Preventive Control that can prevent further foodborne illnesses by rapidly removing the product from the marketplace.

FDA is currently asking for comments on whether Recall program testing and results of testing need to be a part of the records associated with your food safety plan. Currently, it is not a requirement in the proposed rule, although FDA encourages facilities to regularly test their Recall programs.

Environmental Pathogens

In the proposed rule, FDA has determined that ready-to-eat facilities need to include Preventive Controls for environmental pathogens that may be present in a facility in areas where the product is exposed (i.e., packaging room).

However, the current requirement does not require environmental monitoring but has asked for public comment on whether this should be included.

For products vulnerable to environmental contamination – raw or ready-to-eat – that the consumer will eat without further processing, it is a risk that each facility has to determine if they want to accept without monitoring their plant environment in those stages of production where the product is exposed to possible airborne contamination containing pathogens.

Sanitation

The proposed rule has many pages of discussion on the importance of sanitation in a food processing facility and how the lack of sanitation can cause foods to become contaminated from environmental pathogens (Listeria monocytogenes and Salmonella), airborne allergens causing cross-contact, cross-contamination from unclean equipment, or cross-contact concerns.
FDA has added Sanitation as a preventive control – not as a pre-requisite program as has been the case in most HACCP plans. Therefore, each food safety plan must have fully documented procedures on how to clean, how often to clean, the concentrations of chemicals used to clean and sanitize, how these are applied, and the contact time. It also stresses the importance of training of the sanitation crew.

Where it currently stops short is that it does not require validation by swabbing to show the removal of microorganisms and allergens from the food contact surfaces. It requires only visual verification that these surfaces are clean.

FDA has asked for public comment on whether some form of validation should be required and hence added to the final rule.

**Allergens**

As expected, the proposed rule addresses the risks associated with the presence of allergens in foods that are not labeled correctly or are contaminated by cross-contact. It requires facilities to address allergen controls as a Preventive Control by having documented allergen control programs that include procedures for sanitation of environment and equipment, policies to change personnel clothing since garments are a potential vehicle of cross-contact, programs for the storage of allergens, for labeling controls, etc.

The rule cautions facilities to examine incoming ingredients, spice mixes, flavors, colors, etc. for the presence of allergens and again reminds facilities of the importance of training of employees in allergens.

As mentioned under Sanitation above, currently the rule does not require the testing of equipment surfaces or finished products for allergen presence. However, FDA has asked for public comment on possibly adding testing of equipment and surfaces for allergens to the final rule.

The new and updated cGMPs 21 CFR Part 117 will contain a section on allergens when it is released in the near future.

**Equipment Calibration**

The proposed rule recognizes that the measurement of parameters is only as good as the accuracy and reliability of the equipment used to perform the measurements. Therefore, it requires as a part of a facility’s food safety plan that a procedure be in place for checking the calibration of these testing instruments that states how this is done, the validity of the calibration method and the frequency of performing the calibrations. It also requires the plan to identify the disposition of products found to have been assessed with instruments that were later shown to be out of calibration.

FDA requires that a facility’s instruments be reliable and able to repeatedly give the same measurement on the same parameter when used. This is different than calibrated.
FDA has asked for public comment on whether the following components should be added as required Preventive Controls in a facility’s food safety plan. These are finished product testing, environmental monitoring and supplier approval programs. OMB has asked that all of these requirements not be required.

**Supplier Approval and Verification**

The proposed rule discusses the fact that many recent problems with contaminated foods have been the result of facilities receiving contaminated ingredients or raw materials from their suppliers. It encourages facilities to have a Supplier Approval program and to purchase from approved suppliers. It also recommends that facilities verify that their suppliers have written food safety plans that address hazards particularly those hazards that cannot be removed at their own facilities.

It is currently not a requirement in the proposed rule but could be added after the public comment period.

SAI Global recommends that facilities add a Supplier Approval and Verification program to their food safety plans. We also caution against relying solely on 2nd and 3rd party audit reports for verification, although FDA does acknowledge the Global Food Safety Initiative (GFSI) including Safe Quality Food (SQF). Facilities should ask their suppliers for details of their food safety plans, specifically how they address environmental pathogens, allergens, foreign material contamination, and food safety hazards known to be associated with the type of ingredients being purchased.

We also would caution against accepting COAs without ever verifying the validity of the claim that is being made, especially if a facility's process will not remove the pathogen whose absence is cited in the COA.

**Finished Product Testing**

The proposed rule does not require finished product testing as a Preventive Control designed to stop the distribution of possibly unsafe products; however, the FDA does recognize the benefits of finished product testing.

FDA is currently seeking comments on whether finished testing should be added into the required Preventive Controls in the final rule.

**Environmental Testing**

Although FDA has recognized sanitation as a Preventive Control in a food safety plan, it currently does not require environmental monitoring to be performed. No monitoring does not necessarily mean testing as it can be visual.

SAI Global recommends environmental testing if your product is a ready-to-eat product and could become contaminated in the final steps of processing and packaging. It is a risk that needs to be addressed.

FDA has asked for public comment on whether this should be a mandatory Preventive Control for certain facilities.
Submission of the Food Safety Plan to FDA

There is no requirement in the proposed rule that a facility submit its food safety plans to the FDA for it to have on-file. Currently all that is required is that a facility have a plan, that it is in effect, and that it is available to be reviewed by the FDA upon facility inspection or request.

Public comment could change this and have it added to the final rule.

Conclusion

It is obvious from the tone and extensive content of the proposed rule for FSMA Section 103: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, that compliance to the final rule will be mandatory and enforced. Facilities will be expected to have robust Preventive Controls that have been well thought out, validated and implemented.

Although enforcement of the final rule will not begin until at least 2014 for most facilities, it will take time to develop, implement, validate and collect records to verify all parameters of the new rule are in place and effective. To ensure compliance when the final rule is adopted, the best time to begin development or revision of current preventive controls programs is now.

For more details and to access the entire proposed rule, visit: http://www.fda.gov/Food/Foodsafety/FSMA/default.htm
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