I. Introduction

On January 4, 2013, the U.S. Food and Drug Administration proposed its rule to implement the hazard analysis and risk-based preventive control (HARPC) provisions of the Food Safety Modernization Act (FSMA). This proposed rule requires the owner, operator, or agent in charge (shortened to “operator” throughout this summary) of a food facility to:

- Evaluate the hazards that could affect food in that facility;
- Identify and implement preventive controls;
- Monitor the performance of those controls; and
- Maintain records

If you are required to register a food facility with FDA under its existing rules, then you likely will be required by the agency to have a food safety plan, once these rules are final and effective. Note that this proposal is not limited to produce facilities, it applies to food facilities in general.

FDA will accept comments on this proposal until November 16, 2013. It will then review all of the comments and develop a final rule, which FDA proposes would be effective 60 days after publication in the Federal Register. One year later, facilities would have to comply with the final rule, except small businesses (two years) and very small businesses (three years).

II. Application of the Rule

Facilities that manufacture, process, pack, or hold food must be registered with the FDA. Unless it qualifies for an exemption, under the proposal such a facility must have a hazard analysis and preventive controls plan. Because farms are not required to register, they would not be required to comply with this rule’s requirements to have a food safety plan. Farms growing raw produce will be regulated under the produce rule, a draft of which FDA released at the same time as this rule. (For more information on the produce rule, please see PMA’s summary of that proposal.) FDA attempts to clarify the distinction between farm activities and on-farm processing and manufacturing that would trigger the application of HARPC to the farm under this proposal.
**Mixed Use Facilities:** To help clarify on-farm activities, FDA proposes a new definition for “mixed-type facility.” This would be a facility that conducts some activities that are exempt from food facility registration AND other activities that would trigger the registration and written food safety plan requirements. An example of such a “farm mixed-type facility” is one that conducts activities that go beyond the farming activities to include processing, such as chopping vegetables. Those activities that fall outside the farm definition trigger the need to register as a food facility and would subject the facility to the requirements in this proposed rule – but only for those manufacturing or processing activities.

To further clarify what activities on a farm mixed-type facility would trigger the registration and food safety plan requirements, FDA describes the difference between raw agricultural commodities (RACs) and processed foods. The agency presents organizing principles to articulate the differences between certain activities when they are conducted on a farm.

One of those proposed principles is: “Activities farms may perform on others’ RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed in commerce.”

FDA revises the definitions of harvesting, holding, manufacturing/processing, and packing, to clarify which on-farm activities would trigger the food facility registration and HARPC requirements. FDA also is reinterpreting its classification of pesticide treatments, waxing/coating, or drying of a farm’s own food to fall within the farm definition so those activities do not trigger a registration requirement or the need to have a food safety plan, unless the waxing/coating or drying activities results in a distinct commodity (e.g., drying grapes to raisins).
This summary table compares RACs and processed foods under the proposal.

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<tr>
<th>The Effects on Activities on RACs that are Foods</th>
<th>Activities That Do Not Change the Status of a RAC</th>
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<tr>
<td>Activities That Change a RAC to a Processed Food</td>
<td>Canning Application of a pesticide (including by washing, waxing, fumigation, or packing)</td>
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<td>Chopping Coloring</td>
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<td>Cooking Drying for the purpose of storage or transportation</td>
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<td>Cutting Hydro-cooling</td>
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<td>Drying that creates a distinct commodity Otherwise treating fruits in their unpeeled natural form</td>
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<td>Freezing Packing</td>
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<td>Homogenization Removal of leaves, stems, husks</td>
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<td>Irradiation Shelling of nuts</td>
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<td>Milling Washing</td>
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<td>Pasteurization Waxing</td>
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<td>Peeling Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant</td>
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<td>Slicing</td>
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<td>Activities that alter the general state of the commodity</td>
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**Low-Risk Activities and Food Types Exempt from HARPC:** Certain facilities that would be required to register with FDA as a food facility are exempt from HARPC or face modified requirements. These include:

- Activities subject to the proposed rule on produce safety standards;
- Low-risk, on-farm activities performed by very small or small businesses;
- Activities that are covered by FDA’s seafood, juice, and low-acid canned food HACCP requirements (though low-acid canned food facilities are exempt only from the microbiological hazards of this proposed rule);
- Facilities that only store RACs, other than fruits or vegetables, intended for further processing or distribution;
- Facilities that store packaged food that is not exposed to the environment (modified requirements would apply to refrigerated packaged food storage);
• Alcoholic beverages at a facility that must obtain a permit from, register with, or obtain approval from the U.S. Secretary of the Treasury as a condition of doing business; and

• Dietary supplements

The proposed rule provides that facilities that store packaged food that is not exposed to the environment would have modified HARPC requirements. These would include time and temperature control for safety. For unexposed packaged food that is not subject to time and temperature control for safety, the HARPC requirements do not apply and FDA does not prescribe any specific safety requirements.

In the proposal, FDA specifies the hazard and appropriate preventive control to address the hazard reasonably likely to occur in a refrigerated packaged food that requires time and temperature controls. Hence, facilities engaged solely in the storage of unexposed packaged foods do not need to conduct their own hazard analysis or reach their own conclusions about the hazard and the appropriateness of temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. Rather, such facilities would only need to meet requirements related to temperature controls and monitoring, verification activities, corrective actions with regard to potential temperature issues, and recordkeeping.

Such facilities would not be required to develop or update a food safety plan, and because only a single preventive control is prescribed, no validation or reanalysis would be required. A qualified individual would not need to perform or oversee calibration records or monitoring records review and actions taken to correct a problem with temperature control.

Qualified Facilities and Their Modified Requirements: In addition, the proposed rule would establish modified HARPC requirements for “qualified facilities,” which is defined either by business size or a combination of facility size and its customer base (this is, in part, the so-called Tester Amendment to FSMA). A facility may be a “qualified facility” in one of two ways:

• A very small business. FDA has proposed three definitions and seeks comments on which option to adopt in the final rule: (1) average annual sales of less than $250,000; (2) average annual sales of less than $500,000; or (3) average annual sales of less than $1,000,000, adjusted for inflation.

• A small and direct or local business. The facility must have average annual sales of less than $500,000 and at least half its sales must be directly to consumers or to retailers or restaurants that are within the same state or within 275 miles of the facility.

The proposed rule would provide qualified facilities with two options for satisfying the documentation requirement related to food safety practices at the facility:
- Qualified facilities may submit documentation that the operator has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective to satisfy the requirement.

- Qualified facilities may submit documentation that the facility complies with state, local, county, or other applicable non-federal food safety law, including relevant laws and regulations of non-U.S. countries.

The proposed rule would permit the operator of a qualified facility to submit, within 90 days of the compliance date of the rules, a statement certifying that the facility has exercised one of the two options above. The rules do not require the qualified facility to submit to FDA the hazard identification, preventive controls, monitoring, or other documents. The facility would maintain records and need to resubmit the information every two years or whenever there is a material change to the information.

If the qualified facility does not submit documentation to FDA that it has identified hazards and implemented controls, it must provide consumers the name and complete business address of the facility where the food was manufactured or processed. If a food packaging label is required, this information must appear prominently and conspicuously on the label. If no label is required, the information must appear prominently and conspicuously at the point of purchase.

Under the proposal, FDA may withdraw the exemption of a qualified facility:

- In the event of an active investigation of a foodborne illness outbreak that is linked directly to the facility; or

- If FDA determines that it is necessary to protect public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a facility that are material to the safety of the food manufactured, processed, packed, or held there.

III. Requirement for a Food Safety Plan

The proposed rule would require the operator of a food facility to prepare and implement a written food safety plan. Although a third party may prepare the plan on behalf of the facility, the operator is responsible for its implementation.

A food safety plan must be prepared by a “qualified individual,” who has completed training in the development and application of risk-based preventive controls that is at least equivalent to a standardized curriculum recognized as adequate by FDA. Instead of training, the individual may be qualified through job experience to develop and apply a food safety system. Facilities may rely on a team of individuals to develop different components of the plan, but the ultimate responsibility for ensuring the adequacy of the combined plan falls on the qualified individual.
Finally, the proposed rule would require the food safety plan to be facility-specific, rather than, for example, an overarching plan intended to apply to numerous facilities under the same corporate ownership. The food safety plan must include:

- A hazard analysis;
- Preventive controls;
- Monitoring procedures;
- Corrective action procedures;
- Verification procedures; and
- A recall plan

FDA has proposed that the facility operator must sign and date the food safety plan when it is first completed and whenever it is modified.

IV. Hazard Analysis

The proposed rule would require the operator of a food facility to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. A facility may need to conduct multiple hazard analyses depending on the number of food types involved. For example, beverages packaged in both glass and plastic bottles at the same facility present different hazard profiles because they are different processes with different handling. A facility could potentially conclude from its hazard analysis that one or more (or even all) known or reasonably foreseeable hazards are not likely to occur for a certain food type, and therefore there is no need to identify and implement preventive controls for those hazards.

**Hazard Analysis Must Be Written:** The proposed rule would require a food facility to prepare a written hazard analysis that will be available for auditors and inspectors. The analysis must justify whatever conclusions are reached, including any conclusion that no hazards are reasonably likely to occur.

**Hazard Identification Requires Consideration of Different Hazard Types:** The hazard analysis must consider hazards that may occur naturally or that may be unintentionally introduced, including:

- Biological hazards (e.g., microbiological hazards such as parasites, environmental pathogens, other microorganisms of public health significance);

- Chemical hazards (e.g., pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens);
Physical hazards (e.g., contamination by stone, glass, or metal fragments); and

Radiological hazards (e.g., radionuclides present in water used in manufacturing)

**Hazard Evaluation Must Take into Account Probability of Occurrence and Consequences of Exposure:** The proposed rule would require evaluation of whether a hazard is reasonably likely to occur, including an assessment of the severity of the illness/injury if it were to occur.

**Environmental Pathogens Must Be Considered for Ready-to-Eat Foods:** The proposed rule would require the hazard analysis to include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging.

**Specific Factors Relevant to the Hazard Must Be Considered:** The proposed rule would require a facility to consider the effect of several specific factors on the safety of the finished food for the intended consumer, namely:

- The formulation of the food and the interaction of individual ingredients;
- The condition, function, and design of the facility and equipment;
- Raw materials and ingredients;
- Transportation practices;
- Manufacturing/processing procedures;
- Packaging and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use of the product;
- Sanitation, including employee hygiene; and
- Any other relevant factors that might affect the safety of the finished food for the intended consumer

**V. Preventive Controls**

The proposed rule would require the operator to identify and implement preventive controls, including at critical control points, if any exist. This is to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and that the food manufactured, processed, packed, or held there will not be adulterated. Preventive controls may be required at points other than critical control points, and critical limits may not be required for all
preventive controls. In this way, the HARPC requirement goes beyond the HACCP approach used for other foods.

Preventive controls required under the HARPC rule would be subject to monitoring, corrective actions, and verification.

**Preventive Controls Must Be Written**: The proposed rule would require that the required preventive controls be written.

**Parameters Associated with the Control of Identified Hazards Must Be Included Where Appropriate**: Preventive controls for those identified must include the maximum or minimum values (or combination) to which any biological, chemical, radiological, or physical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. This would apply, for example, to parameters associated with heat processing, acidifying, irradiating, dehydrating, and refrigerating food.

**Process Controls Must Be Included**: The proposed rule would require that those preventive 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.

**Food Allergen Controls Must Include Processes to Prevent Cross-Contamination**: The proposed rule would require that food allergen controls include those procedures, processes, and practices employed to ensure protection of food from cross-contact, including during storage and use. Examples of such controls include procedures for separating allergen-containing ingredients from non-allergen-containing ingredients. These might include the use of physical barriers, controlling the movement of tools and personnel that might carry allergens from one production line to another, or ensuring that correct food labels are applied to food.

**Specific Sanitation Controls Are Required Where Necessary**: Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur, the proposed rule would require that sanitation controls include procedures for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. And it would also include procedures for the prevention of cross-contact and cross-contamination from insanitary objects; from personnel to food, food packaging material, and other food-contact surfaces; and from raw material to processed product.

**Preventive Controls Include the Recall Plan and Other Necessary Controls**: The proposed rule would require that preventive controls include a recall plan, which is also a component of the facility’s food safety plan. There is also a catch-all provision that requires facilities to incorporate additional preventive controls when necessary to significantly minimize or prevent hazards.

VI. Recall Plan
The operator of a facility must establish a written recall plan for food in which there is a hazard that is reasonably likely to occur. The recall plan must describe the steps to be taken, and assign responsibility for taking those steps, including:

- Directly notifying the direct consignees of the product being recalled and how to return or dispose of the affected food;

- Notifying the public about any hazard presented by the food when appropriate to protect public health;

- Conducting effectiveness checks to verify that the recall is carried out; and

- Disposing of the recalled food appropriately

VII. Monitoring

**Monitoring Procedures Must Be Written:** The operator of a facility must establish and implement written procedures, including how often they are to be performed, for monitoring the preventive controls.

**Frequency of Monitoring Procedures Must Ensure Consistent Performance:** Preventive controls must be monitored with sufficient frequency to assure they are consistently performed. The proposed rule does not specify a single monitoring frequency applicable to all facilities and processes.

**Monitoring Must Be Documented in Records:** The proposed rule would require such monitoring to be documented in records subject to verification and records review.

VIII. Corrective Actions

**Corrective Action Procedures Must Be Written:** The operator must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. Corrective action procedures must describe steps to be taken to ensure that:

- Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;

- All affected food is evaluated for safety; and

- All affected food is prevented from entering into commerce if the operator of such facility cannot ensure that the affected food is not adulterated or misbranded.

**Corrective Action Must Be Taken in the Event of an Unanticipated Problem:** If a preventive control is not properly implemented and a specific corrective action has not been established (or a preventive control has been found to be ineffective), the operator must take corrective action to identify and correct the problem. The operator must also evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure that is part
of the facility’s written food safety plan. This provision is intended to cover situations where a facility has not anticipated all problems that may occur in its written food safety plan.

Corrective Actions Must Be Documented in Records: All corrective actions taken must be documented in records that are subject to verification and records review.

IX. Verification/Validation of Preventive Controls

The proposed rule would require the operator of a facility to validate the adequacy of the preventive controls implemented to control the identified hazards. A qualified person must perform or oversee validation of the preventive controls. This must take place before implementing the food safety plan or, when necessary, during the first six weeks of production. Validation must be based on the collection and evaluation of scientific and technical information about the preventive controls. If such information is unavailable or insufficient, a facility must conduct controlled scientific studies to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur.

Validation does not need to address: food allergen controls, sanitation controls, or recall plan, as FDA does not view scientific or technical information as necessary to validate these three preventive controls.

Monitoring and Corrective Actions Must Be Verified: The operator is responsible for verifying monitoring and corrective actions. For instance, a facility supervisor could observe employees engaged in monitoring activities and making decisions about corrective actions to verify that such actions are being taken appropriately.

Instrument Calibration is Necessary: The proposed rule would require calibration of process monitoring instruments and verification instruments. In many instances, monitoring and verification activities may rely on instruments (e.g., pH meters or thermometers) that must be calibrated to assure accurate measurements. Instrument calibration must be performed regularly or periodically depending on the type of instrument being used and its sensitivity to factors such as the operating environment and the wear and tear of ongoing use.

Records Review within Specified Time Frames Applies to Monitoring, Corrective Actions, and Certain Verification Activities: The proposed rule would require a qualified individual to review specific records related to monitoring corrective actions, and certain verification activities within specified time frames. This is to ensure that records are complete, activities reflected in the records occurred according to the food safety plan, preventive controls are effective, and appropriate decisions were made about corrective actions. Review of monitoring/corrective action records must occur within a week after the records are made. Review of records relating to calibration must occur within a reasonable time after the records are made.
X. **Reanalysis of the Food Safety Plan Is Required**

The rule would require the operator of a facility to reanalyze the food safety plan:

- At least once every three years;
- Whenever a significant change is made in the activities conducted at the facility, if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;
- Whenever the operator becomes aware of new information about potential hazards associated with the food;
- Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and
- Whenever a preventive control is found to be ineffective

FDA may also require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

The operator of a facility must either revise the written food safety plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. A qualified individual must perform or oversee the reanalysis of the food safety plan and all verification activities taken in accordance with the reanalysis requirement must be documented in records.

XI. **Requirements Applicable to a Qualified Individual**

The proposed rule would require that one or more qualified individuals:

- Prepare the food safety plan;
- Validate the preventive controls;
- Review records for implementation and effectiveness of preventive controls; and
- Perform reanalysis of the food safety plan

The rule would establish the qualification requirements. The individual must have completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum FDA recognizes as adequate. Or the individual must be qualified through job experience. Training used to establish the qualification must be documented in the records, including the date of the training, the type of training, and the name of the person trained.

XII. **New Recordkeeping Requirements and Access to Those Records**

As discussed above, the operator of a facility must establish and maintain the following types of records:
The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;

- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification, including, as applicable, those related to validation, monitoring, corrective actions, calibration of process monitoring and verification instruments, records review, and reanalysis; and
- Records that document applicable training for the qualified individual;

The rule would require that records are kept as original records, true copies, or electronic copies, such that it would be possible to detect whether the original record was changed or corrected. The records should be accurate, indelible, and legible, and they should be created concurrent to the activity being recorded. FDA has proposed that records must contain actual values observed during monitoring. For example, it would not be sufficient to state that measured temperatures were “satisfactory” or “unsatisfactory.” Rather, the actual times and temperatures should be recorded in an effort to monitor trends in a non-subjective manner.

All records must be maintained for two years after the date they were prepared. With the exception of the food safety plan, records may be stored offsite six months after the date the record was made, provided the record can be retrieved within 24 hours.

Under the proposed rule, a facility must promptly make available all records required to an authorized representative of the U.S. Secretary of Health and Human Services for review and copying. FDA is seeking comments as to whether a facility should be required to send records to FDA, rather than just making the records available at its place of business. In particular, FDA has requested comments about the need for submission of the food safety plan.

Under the proposed rule, all records required by the rule would be subject to public disclosure requirements. FDA notes that the proposed disclosure provisions are similar to those for shell egg production. FDA’s general policies on the protection of confidential information would be applicable under the proposed rule.

XIII. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed

In the preamble to the proposed rule as well as the appendix, FDA discusses certain preventive controls and verification measures that the agency thinks are an important part of a modern food safety system, even though FDA does not include these provisions in the proposed rule. The agency specifically seeks comments on whether it should include such measures in the final rule.
Product Testing: Although finished product testing is rarely considered a preventive control, FDA asserts that it can play a very important role as a verification measure to ensure food safety. For instance, FDA suggests that finished product testing may be useful as a verification method where:

- A biological hazard is reasonably likely to occur in an ingredient and the preventive controls developed do not include a process control that will significantly minimize the hazard;

- A biological hazard is reasonably likely to occur in an ingredient added during manufacturing after the stage that applies a process control to significantly minimize biological hazards; or

- A biological hazard is reasonably likely to occur as a result of product handling or exposure to the environment after a process control that significantly minimizes a hazard such that a hazard could be introduced or re-introduced into the product

If finished product testing is to be used, a scientific basis should be used to determine the frequency of testing and the number of samples to be tested, taking into account a variety of hazard/commodity/facility considerations.

Environmental Monitoring: FDA believes that environmental monitoring – for an appropriate microorganism of public health significance or for an appropriate indicator organism – is useful as a verification measure for preventive controls when contamination of food with an environmental pathogen is a hazard reasonably likely to occur. The agency envisions the facilities that could adopt environmental monitoring to be those that produce ready-to-eat products exposed to the environment whereby they may become contaminated and for which such testing would be particularly useful as a verification method for sanitation controls. FDA describes Salmonella spp. and Listeria spp. (as an indicator for L. monocytogenes) as good candidates for environmental monitoring.

Supplier Approval and Verification Program: FDA states that the development of a supplier approval and verification program can be part of a preventive approach. Particularly because many facilities acting as suppliers get their raw materials and ingredients from other suppliers, there often is a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. FDA asserts that a supplier verification approach can help ensure that the supplier has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility itself will control the identified hazard.

Metrics for Microbiological Risk Assessment: The proposed rule does not establish criteria or metrics for verifying that preventive controls achieve a specified level of public health control, although FDA will consider appropriate microbiological risk management metrics in the future.
XIV. FDA Requests Comment on Review of Complaints and Submission of Facility Profiles

Although the new food safety law does not explicitly address the review of complaints or the submission to FDA of information on the facility, and FDA does not include these components in its proposed rule, the agency seeks comments on whether provisions addressing these issues should be included in the rule.

Complaints: With respect to complaints, FDA asks whether review of consumer complaints may help a facility evaluate the effectiveness of its food safety plan. The agency requests comments on whether a requirement that facility personnel review consumer, customer, or other complaints should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards.

Submission of Facility Profiles: Although the proposed rule would require the operator of a facility to prepare (or have prepared) a written food safety plan, such plan would not be reviewed by FDA investigators until they are physically present at the facility and have begun an inspection. FDA suggests that it would be beneficial if the agency had access to a facility’s food safety plan in advance of an inspection. FDA seeks comment on whether to require submission of a subset of the information that would appear in a food safety plan. This information, which FDA refers to as a “facility profile,” would include some or all of the following:

- Contact information;
- Facility type;
- Products;
- Hazards identified for each product;
- Preventive controls established for each of the identified hazards;
- Third-party audit information;
- Preventive control employee training conducted;
- Facility size;
- Full time operation or seasons; and
- Operations schedule
FDA proposes that such information could be submitted at the same time as the facility registration and updated biennially along with the biennial update of the registration. FDA requests comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile.

XV. Proposed Revisions to Current Good Manufacturing Practices

The current good manufacturing practices regulations for food set out detailed requirements for food industry, personnel, plants and grounds, sanitary facilities, controls and operations, equipment and utensils, processes and controls, warehousing and distribution, and natural or avoidable defect levels. In addition to proposing hazard analysis and preventive controls, the FDA proposes to amend the good manufacturing practices regulations. This would include designating and reorganizing some of these regulations, along with changes to make them consistent with the proposed rules.

Personnel: Under the proposed rule, all persons working in contact with food, food-contact surfaces, and food-packaging materials would be required to adhere to hygienic practices to protect against cross-contact with allergens and contamination of food. This new provision would remove the current requirement that gloves worn by personnel be of an impermeable material, because this may not be necessary in the case of certain foods, such as those that will be heat-treated. FDA is seeking comments on the training that personnel receive on food handling and food protection principles to address deficiencies in such training in light of evidence that a lack of training is the root of a large portion of recalls related to good manufacturing practices.

Plants and grounds: The proposed rule would revise current law to clarify that plants are subject to certain design requirements to prevent cross-contact with allergens and contamination of food. Such factors affecting cross-contact include location, time, partition, air flow, and enclosed systems. This section would be broadened to require food safety precautions for all outdoor bulk vessels, not just fermentation vessels as currently required.

FDA is proposing that a plant be constructed such that:

- Floors, walls, and ceilings may be adequately cleaned;
- Drip or condensate from fixtures do not contaminate food, food-contact surfaces, and food-packaging materials; and
- Aisles and working spaces are provided between equipment to permit employees to perform their duties and protect against contamination of food, food-contact surfaces, and food-packaging materials.

Sanitary operations: The proposed rule would require that cleaning and sanitizing agents are safe and effective and do not contain any undesirable microorganisms. FDA is proposing to remove the recommendation that a facility follow all relevant regulations promulgated by other entities for the use and holding of toxic cleaning/sanitizing compounds, as this is considered to fall outside the scope of the good manufacturing practice regulations.
Several revisions are proposed on the sanitation of food-contact surfaces. The proposed rules are more explicit that food-contact surfaces used to manufacture/process/hold low-moisture food must be clean at the time of use. Likewise, single-service articles (such as paper towels) must be stored in a manner to prevent cross-contact and contamination.

**Sanitary facilities and controls:** The proposed rule would require that any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of an adequate sanitary quality. It also contains new performance standards for toilet facilities that are intended to prevent contamination of food and food-contact substances. These performance standards are considered to provide greater flexibility to industry than requirements for specific bathroom features; toilet facilities must be readily accessible and kept clean and similar provisions apply to hand-washing facilities.

**Equipment and utensils:** Changes to the existing regulations on equipment and utensils focus on clarification that steps should be taken to prevent cross-contact with allergens, as well as contamination.

**Processes and controls:** The proposed rule clarifies that raw material and ingredient practices should be implemented to prevent cross-contact and contamination. FDA has proposed to revise the current standard, which prohibits that raw materials and other ingredients from containing levels of microorganisms that “may produce food poisoning or other disease in human,” by replacing the “may produce food poisoning or other disease in human” standard with that of “may render the food injurious to the health of humans.”

**Warehousing and distribution:** The provisions of current law require that storage and transportation of “finished food” be under conditions that protect against contamination and deterioration of the food. FDA is proposing to remove the term “finished,” such that the warehousing and distribution standards apply regardless of whether it is a raw material or ingredient or whether it is a finished food. The proposed rules also would add radiological hazards as a new category of contaminants that may be encountered during warehousing and distribution.

**Defect Action Levels:** The proposed rule would revise current law regarding natural or unavoidable defects in food for human use that present no health hazard. Specifically, it clarifies that food containing defects above an established defect action level is not automatically adulterated. Defect action levels are nonbinding and whether defects adulterate food is a case-by-case determination.