I. Introduction

On September 29, 2014, the U.S. Food and Drug Administration (FDA) published a supplemental proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods, commonly referred to as the “preventive controls rule” to implement the FDA Food Safety Modernization Act (FSMA). These supplemental rules may be found on the PMA FSMA page. The FDA issued this supplemental proposal which proposes making changes to a number of key preventive controls rule provisions based on feedback received from stakeholders meetings and comments submitted to the agency. PMA is pleased that FDA has responded to comments from stakeholders and is providing a supplement to the original proposals for review and comment regarding specific proposed provisions of this important FSMA rule. This will help insure that when these regulations are finalized and implemented, they will best serve public health and industry food safety needs. FDA requests comments on these specific provisions by December 15, 2014.

The proposed preventive controls rule applies to all manufactured or processed foods and modernizes Current Good Manufacturing Practices (CGMPs). The proposed rule also establishes requirements for hazard assessment, the development of practices to manage potential contamination hazards (preventive controls), outlines potential verification activities and defines those that are subject to these regulations and those that might be exempt. The text of the original FDA proposal on preventive controls may be found here and PMA’s comments to that original proposal can be viewed here.

The preventive controls supplemental proposal does not address all comments and concerns that were submitted to the FDA in response the original proposals but only addresses a limited number of significant rule provisions for which FDA’s current thinking has changed significantly or where additional comments are requested by the FDA.- Importantly, all proposed preventive controls rule provisions are still subject to change in the final rule, even those that have not been specified in the supplemental proposals.

Among other issues, the supplemental proposal for preventive controls addresses the following key provisions:
A. Revised definitions for “farm”, “harvesting”, “packing” and “holding” and the changes this brings about in terms of the need for farms to register with FDA
B. Framework for hazard analysis and risk-based preventive controls
C. Proposed requirements for product and environmental monitoring
D. Proposed requirements for a supplier program
E. Proposed requirements for a hazard analysis to address economically motivated adulteration
F. Definition of business size and provisions for withdrawal of an exemption for a qualified facility and reinstatement of a “qualified exemption”

II. Specifics of Supplemental Proposal Provisions

A. The definition of “farm” and other activities; “harvesting”, “packing” and “holding”

FDA has attempted to address a major point of confusion from their original proposals in the produce and preventive controls rules; i.e. the definition of farm and the activities that may change the status of a farm operation to a manufacturer or processor (e.g. “harvesting”, “packing” and “holding” produce). The newly proposed definitions are listed in PMA’s summary of the produce rule here. FDA is proposing to revise these definitions to provide more clarity around whether an establishment is within the “farm” definition and thus exempt from FDA registration and other requirements conditional on facility registration (e.g., preventive controls, mandatory recall, the reportable food registry, and traceability recordkeeping). The proposed change in the definition of “farm” and revised definitions for “farm” activities are important to the produce industry for the following reasons:

- In general, on-farm packing and holding of produce would be subject to the proposed produce safety rule and not the preventive controls for human foods rule, unless additional activities that meet the FDA definition of “processing” or “manufacturing” occur on the farm. This should provide farming operations with a more streamlined view to applicable regulatory requirements to permit greater focus and more efficient use of food safety resources.
- Farms that pack or hold produce from other farms would not be subject to the preventive controls for human foods rule. This is a key change in FDA’s thinking and better reflects the realities of fruit and vegetable production.
- A farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under a different ownership. Again, this alteration in FDA’s thinking is a truer reflection of current practices in the produce industry and still helps insure the safety of the food as the farm that packs or holds product must still operate under the produce rule.
- Importantly, this definition still means that if an entity such as an off-farm packinghouse does not meet the definition of “farm” they would still be subject to preventive controls for human food rule.
FDA provides a number of examples that arose from stakeholder comments to their initial proposals to help clarify their current thinking. For example, a “farm” could dry or dehydrate a raw agricultural commodity (RAC) like a grape to create raisins and package, label and hold them for distribution and, as long as there were no additional processing steps like slicing or application of preservatives prior to the dehydration, this activity would not be considered processing. Even though drying grapes to create raisins creates a distinctly different commodity and the packaging, packing and holding would be subject to good manufacturing practices (GMPs), FDA is proposing that compliance with the provisions for packing, packaging and holding in the produce rule would meet these requirements and the farm conducting these activities would be exempt from facility registration and the proposed preventive controls rule and regulated under the produce rule. Other examples included a definitive statement that “field coring” of a RAC is an example of a harvesting activity that FDA would consider an on farm activity and not a processing or manufacturing activity.

B. Framework for hazard analysis and risk-based preventive controls

FDA has proposed eliminating the term “reasonably likely to occur” throughout the regulations and to use the new term “significant hazard” instead. A “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 to manage those controls as appropriate to the food, the facility, and the nature of the control.” Examples of managing controls might be monitoring the process, performing corrective actions, recording keeping, preventive maintenance and sanitation, etc.

Following a hazard analysis performed by the operator (or a designate), the FDA is proposing that the operator determine the probability of the hazard occurring and the severity relating to public health, if it did. FDA is expecting a facility operator to first narrow “hazards” to those hazards that are known or reasonably foreseeable. Then the facility would narrow the known or reasonably foreseeable hazards to those “significant hazards” by assessing “the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.” The supplemental proposal provides processors greater flexibility in determining the nature and oversight for controls. The FDA is recognizing that not all hazards require the same level of management rigor. Essentially it will be up to each operation to specify in its food safety plan the level of oversight needed for the preventive controls being utilized. In addition, the regulations would explicitly acknowledge that:

- Preventive controls may include controls other than those applied at critical control points (CCPs). Examples of these preventive controls might be maintenance, training practices, sanitation practices, product tracking, etc.
- For some processes or practices that there may not be any controls at CCPs.
- Recordkeeping requirements do not require duplication of existing records if those records contain all required information and satisfy the recordkeeping requirements. Additionally, required information does not need to be kept in one set of records.
• FDA recognizes that allergen controls and supplier controls are not “process controls”.
• Not all monitoring activities generate records; not all corrections require records; not all preventive controls require validation (such as segregation of allergens, training, preventive maintenance, and refrigeration).
• Not all corrective actions require verification.

C. Potential requirements for product testing and environmental monitoring

• **Product Testing:** In FDA’s original proposal on preventive controls, they asked for industry thoughts on product testing requirements without really sharing their thinking on the subject or making specific proposals to industry. PMA and many others called upon FDA to propose specific language for product testing in response to the initial preventive controls proposal. In the supplemental proposal, FDA provides proposed regulatory language for product testing requirements. FDA has proposed that all verification activities, including product testing, be conducted “as appropriate to the facility, the food and the nature of the preventive control.” In the provision on corrective actions, the agency does suggest that ready-to-eat foods (RTE) would be appropriate candidates for product testing, by requiring, as appropriate, corrective action procedures to address the presence of a pathogen or indicator organism in a RTE food detected as a result of product testing. It should be noted that the term “product testing” includes ingredient testing, in-process testing, and finished product testing. The FDA is also proposing that product testing procedures and sampling schemes, as well as sample identification practices, would need to be written, would be required to specify the procedures for identifying samples and the procedures for sampling. In addition, facility corrective action procedures would be required to address the presence of an environmental pathogen or appropriate indicator organism in a RTE product detected through product testing. In addition to the specific proposed regulatory language, FDA is reopening the comment period with respect to the agency’s previous request for comment on when and how product testing programs are appropriate.

• **Environmental Monitoring:** Again, as many stakeholders requested upon review of the original proposal, the FDA uses the supplemental proposals to present specific regulatory language for environmental monitoring requirements. Consistent with their approach on product testing, FDA proposes the same general framework for environmental monitoring, by stating that environmental monitoring should be conducted as a verification activity “as appropriate to the facility, the food and the nature of the preventive control.” Specifically, the supplemental proposal concludes that environmental monitoring would be necessary if “contamination of a ready-to-eat food with an environmental pathogen is a significant hazard.” Again, each facility would be required to have written procedures for environmental monitoring, but it would be up to the facility to determine where, when and how much sampling to undertake.
The FDA proposes that consideration of environmental monitoring be part of the operations hazard analysis and include an evaluation of environmental pathogens whenever a ready to eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen. This evaluation and the subsequent written plan would need to identify the sampling locations for routine environmental monitoring and the timing and frequency, which would need to be adequate to determine whether preventive controls are effective. Importantly, facility corrective action procedures would need to address the presence of an environmental pathogen or an appropriate indicator organism detected through environmental monitoring. Like with product testing, in addition to specific proposed regulatory language, FDA is reopening the comment period with respect to the agency’s previous request for comment on when and how environmental monitoring programs are appropriate.

D. Potential requirements for a supplier program

In this supplemental proposal, FDA puts forward specific regulatory language for supplier verification programs. These requirements generally align with the foreign supplier verification program (FSVP) proposed regulations. FDA proposes to limit the scope for supplier verification to those circumstances where the supplier is responsible for control of a potential biological, chemical or physical hazard. The FDA is not requiring the manufacturer or the manufacturer’s customer to take responsibility for controlling potential hazards in the specific raw product or ingredient.

One element of the original Foreign Supplier Verification Program proposal that garnered a number of comments back to FDA was verification audits and the frequency of performing these audits on suppliers. In the supplemental preventive controls proposal, FDA indicates that when there is a reasonable probability that exposure to a hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA), the regulations would require an initial onsite audit, and annually thereafter, unless the facility documents its determination that other verification activities and/or less frequent audits provide adequate assurance that the hazards are controlled. In this supplemental proposal, FDA provides facilities with the flexibility to determine the appropriate verification activities for foreign supplier monitoring based on several risk factors including: (1) the severity of the hazard; (2) where the preventive controls for those hazards are applied; (3) the supplier’s food safety practices; (4) the supplier’s compliance with FDA food safety regulations; (5) the supplier’s food safety performance track record; and (6) any other factors, such as storage and transportation. Further, facilities can conduct alternative verification activities for materials received from qualified facilities or a farm not subject to requirements under the produce safety rule. Audits would need to be conducted by a qualified individual who has technical expertise obtained by a combination of training and experience. Inspections by FDA or an officially recognized or equivalent food safety authority may substitute for an audit. Of course,
companies would need to take action to address supplier non-conformances and document such actions. Further, FDA uses the supplemental proposal to change directions a bit by foregoing earlier proposals that required the operator to make audit reports accessible to the agency by changing their position so that the operator would only be required to provide the conclusions of the audit and corrective actions taken in response to significant deficiencies. FDA also demonstrates the linkage of the preventive controls and FSVP supplemental proposals by proposing regulatory language in the FSVP supplemental proposed rule stating that when importers or their customers are in compliance with the supplier program requirements in the preventive controls regulations, the importers would be deemed in compliance with most FSVP requirements (in cases involving customer compliance with preventive controls supplier program requirements, the importer would need to obtain written assurance of compliance annually).

Lastly, FDA is seeking comment on how supplier verification activities should address gaps in the system where materials pass through more than one facility that would not be required to verify control of hazards (e.g., various distributors which ship to retailers); and more specific to our industry where raw agricultural commodities will not be handled by any facilities that would be required to have preventive controls (and, hence, supplier verification responsibilities) before reaching consumers. FDA is reopening the comment period with respect to its previous request for comment on when and how supplier programs are appropriate. The agency also is requesting comment on whether it should include requirements to address conflicts of interest for individuals conducting supplier verification activities and the scope of such requirements.

E. Potential requirements for a hazard analysis to address economically motivated adulteration

FDA has formally proposed that Economically Motivated Adulteration (EMA) be included within preventive controls rules as part of the hazard analysis (“hazards that may be intentionally introduced for purposes of economic gain”). FDA proposes to require the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain. FDA explains that the focus would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value. FDA believes that it is possible to determine whether purposeful adulteration of food is reasonably likely to occur by focusing on circumstances where there has been a pattern of such adulteration in the past, suggesting there could be the potential for intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product. FDA cites a recent report from the Congressional Research Service as a source of information on past economically motivated adulteration incidents.
F. Definition of business size and provisions for withdrawal of an exemption for a qualified facility and reinstatement of a “qualified exemption”

FDA is proposing in this supplement to simplify the definition of a very small business as one that has less than $1 million in total annual sales of human food, adjusted for inflation. The definition has significant ramifications as business size affects the compliance date for those facilities once the final rule is published, the exemption for qualified facilities, and the exemptions for on-farm low-risk packing and holding activity/food combinations and on-farm low-risk processing activity combinations. In reality, the proposed definitions of $1 million in annual sales would simplify a facility’s determination of whether it is a qualified facility and essentially make “very small business” and “qualified facility” synonymous. Under the statute, a facility is a qualified facility if it is either a “very small business” or it had average food sales of less than $500,000 during the preceding 3-year period, and it primarily sells food directly to “qualified end-users” (i.e., consumers of the food or restaurants or retail food establishments located within the same state or 275 miles or the facility and purchasing the food for sale directly to consumers). Because the dollar threshold for qualifying as a “very small business” encompasses the second set of criteria, the facility would only need to calculate its total sales of human (and/or animal) food rather than determine how much food was sold to qualified end-users and whether food was only distributed within a specified radius.

FDA may withdraw a “qualified exemption” (Tester-Hagen Amendment exemption) for two reasons:

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to the farm in question; or
- If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm.

The proposed revisions contained in this supplement would establish procedures to guide the FDA in withdrawing an exemption for a facility for food safety reasons as specified in the proposed regulation. The FDA may consider one or more other actions to protect public health prior to withdrawal, such as issuance of a warning letter, recall, administrative detention, or seizure and injunction. FDA believes that withdrawal of a “qualified exemption” will be a rarely used enforcement tool and other less severe enforcement tools will be used before withdrawal of a “qualified exemption” is considered. The FDA must notify the farm of the circumstances that jeopardize the exemption, provide an opportunity for the farm to respond, and consider actions taken by the farm to address the issues raised by the agency.

The proposed revisions would establish procedures to guide the FDA to reinstate a withdrawn exemption for a farm for food safety reasons as specified in the proposed regulation:
• The FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition [CFSAN]) will be responsible for determining if a farm had adequately resolved problems with the conduct or conditions that were material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak.

• A farm may request FDA to reinstate a qualified exemption that has been withdrawn under the procedures of subpart R of the produce safety rule. The procedure involves the farm submitting a request, in writing and presenting, in writing, data and information to demonstrate that the farm entity has adequately resolved the problems with the conduct or conditions that were material to the safety of the food produced and harvested at that farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

• FDA will proactively reinstate a farm qualified exemption and notify the farm entity in writing, if FDA determines after finishing an active investigation of a foodborne illness outbreak, that the outbreak was not directly linked to that farm.

###