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MEMORANDUM

via Email

TO: Clients and Other Interested Parties **September 21, 2015**

RE: Overview of FDA's Final Rule to Implement FSMA's Hazard Analysis and Risk-Based Preventive Controls for Human Food

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On September 10, 2015, the Food and Drug Administration (FDA) issued an advance copy of its final rule on Current Good Manufacturing Practices (CGMPs) and Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Human Food primarily to implement Section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which was created by Section 103 of the FDA Food Safety Modernization Act (FSMA).[1] FDA issued a proposed rule to implement the human HARPC provisions in January 2013, followed by a supplement to the proposal in September 2014.[2] Although the final rule clarifies and refines many concepts and provisions, the final regulations generally are consistent with the proposal and the supplement.

The final rule achieves three primary goals:

1. Promulgating requirements for food facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls (HARPC);

2. Modernizing and recodifying existing Current Good Manufacturing Practices (CGMPs); and

3. Clarifying the definition of a "farm," which is central to the determination of whether certain entities must register as food facilities (thus generally becoming subject to the HARPC requirements).

The final rule is effective November 16, 2015.[3] Companies generally have 1 year from the date of publication to comply with the final rule (including both the revised CGMPs and the new HARPC

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[1] The final rule was published in the Federal Register on September 17, 2015. *See* Final Rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908 (Sept. 17, 2015), available at: http://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf.

[2] Proposed Rule: 78 Fed. Reg. 3646 (Jan. 16, 2013); Supplement: 79 Fed. Reg. 58524 (Sept. 29, 2014).

[3] Two exceptions to this effective date are: (1) that the CGMP regulations located in 21 C.F.R. Part 110 will be removed from the regulations on September 17, 2018; and (2) that the definition of a "qualified auditor" as

requirements), i.e., September 19, 2016. Small businesses (< 500 full-time equivalent employees regardless of annual sales) must comply within 2 years, i.e., September 18, 2017. Very small businesses (averaging less than $1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale) must comply within 3 years, i.e., September 17, 2018.[4]

I. Key Differences Between Proposed Rule and Final Rule

Throughout the final rule – and as discussed in detail in the preamble to the rule – FDA has added flexibility and clarity to various HARPC provisions in response to stakeholder comments. Nevertheless, the core components of the HARPC framework and the modernized CGMPs remain substantially similar to those expressed in the proposal and the supplement. Although it is not an exhaustive description of the differences between the proposal and the final rule, we note certain key changes/clarifications below:

- **Establishment of Term, "Preventive Controls Qualified Individual":** FDA has established a new term – "preventive controls qualified individual" – to describe with greater specificity the category of individuals qualified to administer HARPC programs. The definition of "qualified individual" has been revised to refer generally to persons with the requisite combination of education, training, and/or experience to perform their assigned food processing duties.

- **Economic Adulteration:** A facility's hazard analysis must involve the consideration of hazards that may be intentionally introduced for purposes of economic gain.

- **Flexibility in HARPC Framework:** FDA has increased flexibility surrounding specific preventive control management components, corrections, and verification activities.

- **Product Testing and Environmental Monitoring:** As anticipated, product testing and environmental monitoring are included as potential verification activities, but are only required as appropriate to the food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system. FDA specifically notes that in many cases, neither of these components will be appropriate, e.g., in facilities that pack or hold raw agricultural commodities (RACs) that are rarely consumed raw, such as potatoes.

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it relates to an audit agent of a certified body that is accredited in accordance with FDA's regulations will take effect at a later date, to be announced in the Federal Register once FDA finalizes its third-party certification rule.

[4] Additional details regarding staggered compliance dates for qualified facilities, businesses subject to the Pasteurized Milk Ordinance (PMO), and facilities participating in the supply-chain program are available in a chart on page 56128 of the Federal Register Notice.

- **Delegation of Hazard Control Within Supply Chain:** In recognition of the reality of modern distribution chains, FDA does not require a manufacturing/processing facility to implement a preventive control in certain circumstances when the hazard requiring a preventive control will be controlled by another entity in the chain. For example, if a facility's customer (or another entity in the chain) will control the hazard, then that facility can rely on its customer to provide annual written assurance that the identified hazard will be controlled by a subsequent entity.

- **Supplier Verification Activities Across Supply Chain:** Recognizing that a receiving facility and a supplier may be separated by several entities in a supply chain, FDA has revised the supplier program provisions to permit entities such as distributors, brokers, and aggregators to determine, conduct, and document appropriate supplier verification activities as a service to the receiving facility, provided that the receiving facility ultimately takes responsibility for final review and assessment, as well as supplier approval.

- **Definition of "Holding" Clarified to Preserve Storage Exemption:** As anticipated, FDA has revised the definition of "holding" to encompass activities performed incidental to storage of food (e.g., activities performed to facilitate the safe or effective storage of that food, and activities performed as a practical necessity for the distribution of that food). Thus, the HARPC exemption applicable to facilities engaged solely in the storage of RACs (other than fruits or vegetables) intended for further distribution or processing is available to facilities such as grain elevators, which perform tasks such as fumigation and cleaning incidental to the storage of grain.

- **Previously Nonbinding CGMP Requirements Now Binding:** Previously nonbinding provisions – such as those related to education and training – now are binding legal requirements. Management is required to ensure that employees are sufficiently qualified to perform their duties. Employees must have the requisite combination of education, training, and/or experience necessary to engage in food processing, and must receive training in food hygiene and food safety principles.

- **Definition of "Farm" Expanded:** The rule clarifies the "farm" definition to take into account current farming practices and to recognize differences between the operations of a "primary production farm" and a "secondary activities farm."

II. Summary of Requirements in the Final Rule

Although a detailed description of all requirements in the final rule is beyond the scope of this summary memo, below we provide a synopsis of key requirements and definitions intended to implement the rule. In turn, we address the provisions establishing: (1) the HARPC framework; (2) CGMPs; and (3) the "farm" definition.

A. HARPC Framework (Subpart C Part 117)

As anticipated, the final rule imposes HARPC requirements for facilities that manufacture, process, pack, or hold human food for consumption in the United States, i.e., facilities required to register under Section 415 of the FD&C Act. Certain facilities are exempt from HARPC compliance or are subject to modified HARPC requirements, as follows:

Facility Type	21 C.F.R. Reference	Applicability of HARPC Requirements
"Qualified facilities"[5] - Very small business - Average annual sales <$500,000 and at least 50% of sales directly to consumers or to local retailers or restaurants (within the same state or within 275 miles of facility)	§ 117.5(a)	Modified HARPC requirements (described in 21 C.F.R. § 117.201) A qualified facility must: - Notify FDA about its status; and - Either: o Notify FDA that it is addressing hazards through preventive controls and monitoring; or o Notify FDA that it complies with applicable non-federal food safety regulations and notify consumers of the name and complete address of the facility where the food was manufactured or processed - Notification takes the form of an "attestation" which must be submitted to FDA every 2 years
Activities subject to seafood, juice, and low-acid canned food (LACF) hazard analysis and critical control points (HACCP) requirements	§ 117.5(b), (c), (d)	Exempt, except that for LACF facilities, the exemption only applies with respect to microbiological hazards
Dietary supplement facilities in compliance with 21 C.F.R. Part 111	§ 117.5(e)	Exempt
Facilities subject to produce safety standards under Section 419 of the FD&C Act	§ 117.5(f)	Exempt

[5] FDA has the authority to withdraw a qualified facility exemption in the event of an active investigation of a foodborne illness outbreak directly linked to the qualified facility or if the Agency determines that it is necessary to protect the public health, and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food handled at such facility. (21 C.F.R. § 117.251). Procedures governing the withdrawal of a qualified facility exemption are specified in 21 C.F.R. § 117.254 *et seq.*

Low risk activity/food combinations performed by farm mixed-type facilities that are small or very small businesses	§ 117.5(g), (h)	Exempt
Alcoholic beverages at a facility required to obtain a permit from, register with, or obtain approval from the Secretary of the Treasury as a condition of doing business in the United States	§ 117.5(i)	Exempt
Facilities engaged solely in the storage of RACs (other than fruits or vegetables) intended for further distribution or processing	§ 117.5(j)	Exempt
Facilities engaged in the storage of packaged food that is not exposed to the environment	§ 117.7	Modified HARPC requirements related to the storage of unexposed packaged food that must be refrigerated for safety

For covered facilities, the final rule requires the owner, operator, or agent in charge of the facility (shortened to "the facility" in this memo) to prepare and implement a written food safety plan. 21 C.F.R. § 117.126. A food safety plan must be prepared, implemented, and reanalyzed by a "preventive controls qualified individual," which means someone who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. 21 C.F.R. § 117.180. A food safety plan must include the following elements, each of which is associated with recordkeeping obligations:

1. Hazard Analysis (21 C.F.R. § 117.130)

Facilities must identify known or reasonably foreseeable hazards that may be present in the food handled at that facility (including biological, chemical, and physical hazards), whether such hazards are naturally occurring, unintentionally introduced, or intentionally introduced for purposes of economic gain. Hazards must be analyzed to assess 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 hazard evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat (RTE) food is exposed to the environment prior to packaging, and the packaged food does not receive a treatment or otherwise include a control measure that would significantly minimize the pathogen. The hazard evaluation also must take into consideration the effect of factors such formulation and processing of the food, facility equipment, ingredients, and the intended use of the products. The goal of the hazard analysis is to determine whether there are any hazards that require the development of preventive controls.

2. Preventive Controls (21 C.F.R. § 117.135)

Facilities must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and that food manufactured, processed, packed, or held by the facility will not be adulterated or misbranded. Preventive controls are facility- and food-specific, and may include process controls, food allergen controls, sanitation controls, supply-chain controls, the recall plan, and other controls, e.g.,

- A facility that handles raw materials that could be contaminated with pathogens may identify *Salmonella* as a biological hazard requiring a preventive control; the appropriate control may be a process control such as heat processing, e.g., pasteurization.

- A facility that uses metal cutters and slicers in its processing operations may identify metal fragment contamination as a physical hazard requiring a preventive control; the appropriate control may be conducting periodic equipment checks to assess and address wear and tear.

A facility is not required to implement a preventive control under the following circumstances (21 C.F.R. § 117.136):

1. Where the food could not be consumed without application of an appropriate control (e.g., RACs such as cocoa beans, coffee beans, and grains);

2. Where the facility relies on a customer subject to HARPC requirements to ensure that the identified hazard will be significantly minimized or prevented (and the facility discloses that it does not process the food to control the hazard and annually obtains written assurance from the customer that they are controlling the hazard);

3. Where the facility relies on a customer who is not subject to HARPC requirements (e.g., a qualified facility or a retail establishment), but who nevertheless provides assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements (subject to the disclosure and annual written assurance requirements noted above);

4. Where the facility relies on a customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer (subject to the disclosure and annual written assurance requirements noted above, with additional assurances to establish that the subsequent entity is controlling the hazard); or

5. Where the facility has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product distributed by that facility and where the facility documents the implementation of that system.

Of potential benefit to ingredient suppliers and distributors, the provisions above permit the delegation of preventive control responsibilities to downstream customers. For example, under 21 C.F.R. § 117.136(a)(2), a manufacturer/processor of a bulk ingredient that potentially could be contaminated with *Salmonella* would not have to implement a preventive control to address this hazard if the facility: (1) discloses to its customer in documents accompanying the food (e.g., bills of lading, food labels) that the food is "not processed to control *Salmonella*," and (2) annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance)[6] that will significantly minimize or prevent *Salmonella* contamination.

3. Recall Plan (21 C.F.R. § 117.139)

Facilities must establish a written recall plan for any food with a hazard requiring a preventive control. The plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions (as appropriate):

1. Directly notifying the direct consignees of the food being recalled, including how to return or dispose of the affected food;

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

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

4. Appropriately disposing of recalled food, e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

4. Monitoring (21 C.F.R. § 117.145)

The facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. For instance, a facility implementing a pasteurization process control to address *Salmonella* may monitor the control's effectiveness by checking time/temperature records to ensure that the process met parameters essential for a "kill step." A facility implementing equipment check controls to prevent metal fragment contamination may monitor the control's effectiveness by using an appropriately sensitive metal detector on the production line.

5. Corrective Actions (21 C.F.R. § 117.150)

The facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. Corrective action procedures must be established to address, as appropriate, the presence of a pathogen in an RTE product or an environmental

[6] Under 21 C.F.R. § 117.137, a facility that provides such written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance.

pathogen/indicator organism detected as a result of product testing or environmental monitoring performed under the HARPC framework, respectively.

6. Verification/Validation (21 C.F.R. § 117.155, 117.160)

The facility must – as appropriate to the nature of preventive controls and their role in the facility's food safety system – validate the adequacy of the preventive controls identified and implemented in accordance with the requirements above and must verify that monitoring and corrective action procedures are appropriately implemented. No validation is required for food allergen controls, sanitation controls, the recall plan, the supply-chain program, or other preventive controls if the preventive controls qualified person prepares a written justification for why validation is inapplicable. Product testing and environmental monitoring are listed as possible verification activities, but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control.

7. Supply-Chain Program (21 C.F.R. § 117.405)

FDA has defined the term, "supply-chain-applied control" to mean a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. The final rule requires a receiving facility to establish and implement a risk-based supply-chain program for raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. The supply-chain program must include:

1. The use of approved suppliers;[7]
2. Determining appropriate supplier verification activities;
3. Conducting supplier verification activities;
4. Documenting supplier verification activities; and
5. Where applicable, verifying a supply-chain-applied control performed by an entity other than the receiving facility's supplier and documenting that verification or obtaining/reviewing/assessing documentation of an appropriate verification activity performed by another entity.

Appropriate supplier verification activities for raw materials and other ingredients are:

[7] Receiving facilities may receive materials from unapproved suppliers on a temporary basis when necessary and appropriate. 21 C.F.R. § 117.420(b)(2).

1. Onsite audits;

2. Sampling and testing of the raw material or other ingredient;

3. Review of the supplier's relevant food safety records; and

4. Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

The goal of the supply-chain program is to provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. Separate compliance dates have been established for supply-chain program provisions to accommodate compliance dates for suppliers of different sizes and subject to different FSMA rules.[8]

8. Reanalysis (21 C.F.R. § 117.170)

The final rule requires reanalysis of the food safety plan at least once every three years, if not sooner due to production changes, changes in the hazard profile, and/or issues observed during implementation of the current plan (e.g., unanticipated food safety problems, ineffective preventive controls).

B. CGMPs (Subpart B Part 117)

The final rule revises and recodifies the CGMP regulations currently in Part 110 in Part 117 (21 C.F.R. § 117.10 *et seq.*). Although most of the CGMP requirements will be familiar to the food industry, significant differences include:

- **Deletion of Nonbinding Provisions:** FDA has removed previously nonbinding provisions from the CGMP requirements, as these are more appropriate for guidance.

- **Conversion of Previously Nonbinding Provisions to Binding Requirements:** Previously nonbinding provisions – such as those related to education and training – now are binding.

- **Addition of Provisions Regarding Allergen Cross-Contact:** FDA's longstanding position that CGMPs address allergen cross-contact now is expressly included in the text of the regulations.

All facilities that manufacture, process, pack, or hold food for consumption in the United States are subject to the CGMP requirements. Thus, even if a facility is HARPC-exempt, it may still need to be CGMP-compliant.

[8] See 80 Fed. Reg. at 56128 for details. We note that the compliance dates for the supply-chain program have caused some confusion and FDA will likely be addressing this issue at a later date.

C. Farm Definition (21 C.F.R. § 1.227)

In the final rule, FDA clarifies the definition of a "farm," which is central to determining whether certain facilities must register as food facilities, and, thus are subject to the HARPC requirements. FDA's revised definition is intended to reflect current farming practices, to differentiate between distinct types of farm operations, and to allow for consistent regulatory treatment of similar operations. Under the revised "farm" definition, FDA recognizes two types of operations:

- **Primary Production Farm:** An operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.

- **Secondary Activities Farm:** An operation not located on the Primary Production Farm that is devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm.

Under the revised definition, farmers involved in certain formerly off-farm packing activities now fit under the definition of "farm," as the packing is still part of the farming operation.

Farms – whether Primary Production or Secondary Activities operations – that conduct activities related to produce covered by the produce safety standards will be required to comply with the final produce safety rule.

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We will continue to monitor and report on FDA's activities to implement the HARPC requirements and other FSMA related activities.