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FDA RELEASES PROPOSED RULE FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS AND CURRENT GOOD MANUFACTURING PRACTICES FOR HUMAN FOOD

On January 4, 2013, FDA released the long-awaited proposed rule implementing section 103 of the Food Safety Modernization Act ("FSMA") and revising FDA's food current good manufacturing practice ("CGMP") regulations. In sum, the proposed rule implements the hazard analysis and preventive controls section of FSMA, now codified as section 418 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), by creating a new 21 C.F.R. Part 117. The proposed regulations would require manufacturers to implement "food safety plans" that include a hazard analysis, preventive controls, monitoring procedures, corrective actions, verification activities, and recall plans. The proposed rule also marks a continuation of FDA's efforts to update and modernize its food CGMP regulations by proposing to revise these regulations and re-designate them as a new Subpart of Part 117. The proposed rule was released on the two-year anniversary of the enactment of FSMA, and will be published in the Federal Register on January 16, 2013.

This client alert provides a brief background on FSMA, summarizes highlights of the proposed rule, and discusses some key issues that industry should monitor and consider for comments. We also release today our client alert summarizing the highlights of FDA's proposed rule on produce safety, also released on January 4, 2013.

Stakeholders have until May 16, 2013 to comment on the proposed rule.

BACKGROUND ON FSMA

FSMA marked a shift in FDA's approach to food safety from controlling outbreaks as they occur toward a more preventive model that places the primary responsibility on manufacturers to identify and control hazards.[1] The fundamental approach to hazard analysis and preventive controls was pioneered by food industry leaders as well as by FDA's Hazard Analysis and Critical Control Point ("HACCP") regulations for juice and seafood. Section 103 of FSMA requires food facilities generally to develop and implement hazard analysis and preventative control plans, which the statute made effective for most facilities on July 4, 2012. Before the effective date, however, FDA announced on its FSMA "FAQ" page and in letters to industry that it would not enforce these provisions until the agency issued its final rule,[2] which will be based on this new proposed rule and comments from stakeholders.

In addition to the proposed rule on hazard analysis and preventive controls, FDA released its proposed rule on produce safety on January 4, 2013,[3] and will soon release three more proposed

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[1] Click here for our client alert from the time of enactment of FSMA describing its key provisions.
[2] Click here for our client alert describing the delays in the enforcement of the hazard analysis and preventive controls requirements for FSMA and the consequences for food companies. FDA also announced in late 2012 that biennial facility-registration renewal under FSMA was delayed.
[3] Covington & Burling LLP also releases today our client alert on FDA's produce safety proposal.

rules on foreign supplier verification, third-party audit certification, and preventive controls for animal feed and pet food.

HIGHLIGHTS OF THE PROPOSED RULE

Hazard Analysis and Preventive Controls

Much of the proposed rule is directed towards implementing section 418 of the FDCA, which establishes requirements for facilities to conduct a hazard analysis and institute preventive controls. FDA states in the preamble to the proposed rule that it used the HACCP concept as a framework for interpreting and implementing section 418. As a result, the rules largely resemble FDA's juice and seafood HACCP regulations (21 C.F.R. Parts 120 and 123) in many respects, with some key differences described in section III.

1. Food Safety Plans

Under FDA's proposed rule, the various requirements related to conducting a hazard analysis and instituting preventive controls will be captured in a "food safety plan." Proposed 21 C.F.R. § 117.126 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared on its behalf, and implement a written food safety plan. The plan would be required to include:

- the written hazard analysis as required by proposed § 117.130(a)(2);
- the written preventive controls as required by proposed § 117.135(b);
- the written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by proposed § 117.140(a);
- the written corrective action procedures as required by proposed § 117.145(a)(1);
- the written verification procedures as required by proposed § 117.150(e); and
- the written recall plan as required by § 117.137(a).

An important requirement pertaining to the plan, and the elements of the plan, is that it be prepared by a "qualified individual." In addition, a qualified individual must be involved in the validation of preventive controls, reviewing records for implementation and effectiveness, and performing reanalysis of the plan. FDA states in proposed § 117.155 that a qualified individual must have "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 the FDA or be otherwise qualified through job experience to develop and apply a food safety system." The qualified individual may, but need not be, an employee of the facility.

2. Hazard Analysis, Preventive Controls, and Recall Plans

Proposed § 117.130 deals with the hazard analysis required by section 418 of the FDCA. Under this proposed regulation, facilities must 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."

The term "hazard" would be defined to mean "any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control." The term "hazard that is reasonably likely to occur" would mean a hazard for which a "prudent person . . . would establish controls because experience, illness data, scientific reports, or other information

provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls."

This hazard analysis would need to be written. Further, the evaluation of hazards would need to include an assessment of the severity of the illness or injury if the hazard were to occur and consider certain specific factors, such as the formulation of the food (*e.g.*, pH), raw materials, and transportation practices.

The proposed regulation provides examples of hazards that need to be considered. For example, proposed § 117.130(b)(1) describes parasites, environmental pathogens, and other microorganisms of public health significance as examples of biological hazards. The preamble includes a discussion of specific hazards that may fall into these categories.

Proposed § 117.135 would require that these hazards be controlled through the use of preventive controls, "including at critical control points, if any." These controls would need to be written and describe "parameters" associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, dehydrating, and refrigerating foods. FDA comments in the preamble that the concept of a "parameter" is similar to a critical control point ("CCP") but also broader, because it would apply to preventive controls that are not associated with CCPs.

The proposed rule lists a number of preventive controls that must be implemented, "as appropriate:"

- process controls, which are procedures, practices, and processes performed on a food during manufacturing/processing to significantly minimize or prevent hazards that are reasonably likely to occur;
- food allergen controls, which are procedures, processes, and practices employed for ensuring protection of food from cross-contact, including during storage and use. These controls also include processes for labeling of food, to ensure that the allergens are declared;
- sanitation controls, where necessary, to significantly minimize or prevent hazards that are reasonably likely to occur (*e.g.*, when *Salmonella* is reasonably likely to occur in a ready-to-eat food due to employee handling); and
- any other controls necessary to minimize or prevent hazards identified in the hazard analysis.

Additionally, under proposed § 117.137, facilities would be required to establish a written recall plan for food in which there is a hazard that is reasonably likely to occur. The regulation would require that the plan include procedures that describe steps to be taken for notifying direct consignees and the public, conducting effectiveness checks, and disposing of recalled food. FDA comments in the preamble that the agency's recall guidelines set forth in 21 C.F.R. Part 7 could provide guidance for some of these activities.

3. Monitoring, Corrective Actions, and Verification

Monitoring

Consistent with section 418 of the FDCA, proposed § 117.140 would require facilities to establish written procedures to monitor preventive controls, including the frequency of monitoring. Proposed § 117.3 would define "monitor" to mean "to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification." Facilities would need to monitor controls with sufficient frequency to provide assurance that they are consistently performed, and would need to record all monitoring activities.

Corrective Action

Proposed § 117.45 would require that the facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. These procedures would include actions to identify and correct a problem with implementation of a preventive control, to ensure that food is evaluated for safety, and to prevent affected food from entering commerce. If unexpected corrective actions are needed, the facility would be required to reanalyze the food plan to evaluate the need for modification.

Verification

Proposed § 117.150 establishes verification requirements. Facilities would be required to validate that the preventive controls identified and implemented in accordance with § 117.135 to control hazards are adequate to do so. As described above, these activities would need to be overseen by a qualified individual. Validation would need to occur prior to the implementation of a food safety plan or, when necessary, during the first six weeks of production. Validation also would need to occur when reanalysis of a food plan reveals the need to do so.

According to the proposed rule, the validation of preventive controls includes collecting and "evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur." The preamble provides a discussion of various potential sources of scientific and technical information, such as FDA's Food Code, and methods for validating controls, such as predictive models. Validation would not be required for food allergen controls, sanitation controls, and the recall plan.

Under proposed § 117.150, verification would also include calibration of instruments and records review by a qualified individual. Verification procedures would need to be written. Importantly, reanalysis of the food safety plan by a qualified individual would be required at least every three years, whenever significant changes are made to activities that would produce new hazards or increase the likelihood of current hazards, upon new information about hazards, when preventive controls are not properly implemented, and when preventive controls are found to be ineffective or not properly implemented. In addition, FDA may require a reanalysis to respond to new hazards or developments in scientific understanding.

4. Request for Comments on Controls and Procedures Not Proposed: Testing, Supplier Verification, and Submission of Facility Profile

As described below in more detail, FDA notes in the preamble that it does not propose to require certain preventive controls that are either mentioned in section 418 of the FDCA or otherwise could be useful in preventing or mitigating hazards. In particular, FDA does not propose to require product testing as a verification procedure, environmental monitoring as a preventive control or verification procedure, or supplier verification and approval. FDA also notes that the rule does not include a provision regarding review of complaints, and it does not require submission of a "facility profile to FDA."

5. Exemptions and Modified Requirements

"Qualified Facilities"

Several provisions of the proposed rule relate to modified requirements for "qualified facilities," which generally include "very small businesses" and certain other small businesses that sell

primarily to certain "qualified end-users" (generally speaking, local purchasers). The proposed rule also sets forth a process for FDA to revoke a qualified facility exemption and an appeals process for challenging such decisions. Relatedly, proposed § 117.5 sets forth exemptions from the hazard analysis and preventive controls requirements for certain on-farm packing and holding of low-risk food activities by certain small and very small businesses.

Facilities Already Subject to HACCP or Other Regulatory Requirements

The proposed rule also would exempt from the hazard analysis and preventive controls requirements certain activities that already are subject to similar requirements, including activities subject to:

- seafood HACCP requirements;
- juice HACCP requirements;
- low-acid canned food requirements;
- CGMP requirements for dietary supplements; and
- activities subject to produce safety requirements under section 419 of the FDCA.

Likewise, the hazard analysis and preventive controls requirements would not apply to facilities "solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing," and certain alcohol producing facilities operating under a Treasury Department permit.

Facilities Solely Engaged in the Storage of Packaged Foods

In response to a petition filed by leading industry trade associations asking FDA to invoke an exemption authorized by section 418(m) of the FDCA, FDA also proposes to establish an exemption from the hazard analysis and preventive controls requirements for facilities that are solely engaged in the storage of packaged food that is not exposed to the environment. Facilities that store food requiring time/temperature control for safety would be subject only to modified requirements in proposed § 117.206. That proposed regulation would set forth certain requirements for temperature controls when necessary to significantly minimize microbiological hazards in refrigerated (including frozen) food.

Recordkeeping

The proposed rule includes additional recordkeeping and reporting requirements that implement the hazard analysis and preventive controls provisions of FSMA.[4] In particular, proposed § 117.175 requires that facilities maintain not only copies of the food safety plan itself but also records that demonstrate the implementation of the plan (*e.g.*, records of the monitoring of preventive controls or reports of specific corrective actions).

In the proposed rule, FDA seeks to apply new general recordkeeping requirements to written records. These general requirements include the length of time that documents must be stored as well as the form of their storage. FDA proposes to allow all records, except for the food safety plan, to be moved into offsite storage after six months as long as such records can be retrieved within 24 hours.

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[4] In addition, FSMA amended section 414 of the FDCA, so that FDA now has authority not only to inspect records for articles of food it reasonably believes are adulterated and present a risk of serious adverse health consequences but also to inspect records for articles likely to be affected in a similar manner. FSMA, § 101 (amending FDCA, § 414(a)). Click here for our client alert describing the recordkeeping provisions of FSMA.

Proposed § 117.305(a) would require records to be kept as original records, true copies such as scans, or electronic records. The agency tentatively concludes that electronic records must satisfy 21 C.F.R. Part 11, which sets forth general criteria for electronic records to be considered equivalent to paper records. FDA has relaxed the requirements of Part 11 in the Bioterrorism Act records rule and other contexts where existing record systems may be costly to replace or modify. The preamble to the proposed rule solicits comments on any circumstances where the requirements of Part 11 should not be applied to electronic records that could otherwise satisfy the proposed rule and FSMA.

Proposed § 117.305 also contains specific details of what will be required in the records under Part 117, including actual values and observations obtained during monitoring, legibility, and indelibility, and accurate information about date, time, and location. Finally, under proposed § 117.320, all records under Part 117 must be made promptly available upon oral or written request from FDA. As discussed below, FDA is not proposing to require submission of food safety plans to the agency.

Revisions to the CGMP Regulations

FSMA did not mandate FDA's proposed changes to food CGMP regulations. Rather, FDA took the opportunity to modernize the food CGMPs and create a cohesive rule that covers multiple aspects of food safety in new 21 C.F.R. Part 117. FDA is proposing to re-designate the Subparts of current Part 110 and to include in Subpart B of Part 117 the CGMP provisions already established in Part 110.

Activities subject to the proposed revised food CGMPs include manufacturing, processing, packing, and holding food. Dietary supplement manufacturers must comply with the food CGMPs in proposed subpart B of part 117, in addition to the dietary supplement CGMPs in Part 111, unless the regulations conflict, in which case the dietary supplement manufacturer would comply with Part 111. Exempt from the proposed food CGMPs are activities within the proposed definition of "farm" and facilities such as grain elevators that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. In most cases, however, the proposed CGMPs still apply to facilities that would be exempt from the hazard analysis and risk-based preventive control requirements or that would be subject to modified requirements.

The proposed food CGMPs do not substantially alter the existing CGMPs, and companies following the current recommendations in Part 110 likely will not be required to make drastic alterations to their operations to comply with the proposed Part 117 Subpart B. The most noteworthy changes to the existing CGMPs include:

- including measures to address allergen issues, such as: (1) the new definition of "cross-contact," which means the unintentional incorporation of a food allergen into food, where "food allergen" is a "major food allergen" as defined in section 201(qq) of the FDCA; and (2) revising the current provisions that require protection against contamination to require protection against cross-contact of food by allergens (and include provisions directed to cleanliness, plant construction and design, general maintenance, sanitation of food-contact surfaces, equipment and utensils, raw materials and ingredients, manufacturing operations, and warehousing and distribution);
- revising provisions directed to preventing contamination of food and food-contact substances to include preventing contamination of food-packaging materials;
- revising the current definition of microorganisms to include protozoa and microscopic parasites;
- adding radiological hazards to the list of contaminants as an additional category, thereby impacting the list of contaminants that may be encountered in warehousing and distribution;
- replacing "shall" with "must" and using consistent terms throughout the proposed CGMPs; and

- deleting several non-mandatory provisions, most of which FDA states would be more appropriate in a guidance document. The bulk of the deleted provisions are from current section 110.80 and include measures related to safety of raw materials and ingredients, manufacturing operations to control microorganisms, time and temperature controls, examples of measures to protect against contamination, listed mechanisms for complying with water activity and pH levels, and the recommendation that food-manufacturing areas not be used to manufacture animal feed or inedible products.

FDA is requesting comments on its proposed CGMPs. In addition, FDA is requesting comments on whether the final rule should: (1) mandate training for employees and supervisors, including a requirement for records that document training; (2) require, rather than recommend, certain provisions, such as cleaning non-food contact surfaces as frequently as necessary to protect against cross-contact and contamination; (3) include CGMP requirements for environmental monitoring for *L. monocytogenes* and *Salmonella*, and if so, what such requirements should be; and (4) include any additional CGMP provisions or revisions.

KEY ISSUES FOR INDUSTRY

Requirement of Review by a Qualified Individual

As described above, a "qualified individual" must prepare the food safety plan, validate preventive controls, review records for implementation and effectiveness, and perform reanalysis of the plan. This person need not be an employee of the facility, and different qualified individuals may perform the various tasks.

FDA notes in the preamble that the concept of a qualified individual is consistent with existing regulations and the National Advisory Committee on Microbiological Criteria for Foods ("NACMCF") HACCP standards. FDA also notes that the HACCP regulations for juice and seafood both require that trained individuals be responsible for various HACCP activities. FDA comments that it worked with an alliance of government, industry, and academic experts to create a standardized curriculum for the seafood and juice HACCP requirements, and it has similar plans for the requirements of Part 117.

Although the concept of a qualified individual may be consistent with other HACCP regimes, including those previously implemented by FDA, it is absent (at least in express terms) from the statutory language of FSMA. Many firms that currently use HACCP approaches to ensuring food safety may use qualified individuals for these activities, but they should consider whether the proposed rule would impose a realistic burden on such personnel. For example, a manufacturer with many small facilities may need to employ additional personnel to ensure that verification activities at each facility are overseen by a qualified individual.

Allergen Controls

The proposed rule addresses allergen controls in both the proposed CGMP regulations and the proposed hazard analysis and preventive controls provisions. As stated above, proposed section 117.3 includes a new definition of cross-contact and the proposed CGMPs revise a host of provisions, so that the current provisions that require protection against contamination would also require protection against cross-contact of food by allergens. As a result, the proposed cross-contact requirements appear in almost every step of operations potentially requiring modifications to, for example, hygienic practices, operating practices or facility design, cleaning and sanitizing procedures, the handling of raw materials and ingredients, and warehousing and distribution.

In addition, as described above, the hazard analysis and preventive controls provisions would require facilities to implement allergen controls, "as appropriate." Specifically, the facility would need to include practices and processes for ensuring protection from cross-contact, including during storage and use, and labeling finished food to ensure that it declares required allergens.

The preamble explains that examples of procedures for controlling allergens include providing physical barriers; minimizing formation of dust, aerosols, or splashes; segregating certain production activities in time or space; emphasizing proper handling; and controlling movement of tools and personnel that may carry allergens. FDA also gives examples of labeling processes intended to ensure the declaration of required allergens.

One issue that may warrant comment is the need for greater clarity on the circumstances under which allergen controls need to be implemented. For example, certain facilities may engage in activities where the risk of cross-contamination is theoretically possible but remote. The responsibilities for such a facility are unclear under the proposed rule because FDA does not elaborate on the meaning of "as appropriate." It is possible, however, that FDA intends to address this issue through guidance documents specific to certain types of foods or facilities.

Recall Plans

The proposed rule includes a requirement for a recall plan as a specific preventive control for food subject to a "hazard that is reasonably likely to occur." Recall plans are mentioned in section 418(o) of the FDCA as an example of a preventive control. Notably, in contrast to the other preventive controls mentioned in section 418(o), the recall plan requirement is emphasized in the proposed rule as a distinct regulation.

The requirement for a recall plan is somewhat unique in that it is not required by FDA's juice and seafood HACCP regulations, and it is recommended, but not required, by the NACMCF HACCP standard. Likewise, the United States Department of Agriculture HACCP regulations do not require a recall plan.

Of importance, FDA requests specific comments on several issues concerning recall plans. FDA requests comments on whether the proposed procedures are appropriate for all types of facilities, or whether they should be modified for certain facilities. Manufacturers that have multiple facilities may consider commenting on how the recall plan requirement could be implemented across a network of facilities. For example, certain facilities may not need a procedure for contacting consignees or the public because this task would be handled by the corporate headquarters.

FDA also requests comments on whether these procedures should include notifying FDA, recognizing that in some cases, reporting a recall could be accomplished through making a report in the Reportable Food Registry, while in other circumstances facilities could notify the local FDA district office. In addition, FDA notes that "mock recalls" can be helpful activities for verifying the effectiveness of a recall plan. Accordingly, FDA requests comments on whether to require that a facility conduct mock recalls.

Key Omissions: Environmental and Product Testing, Supplier Verification, Complaint Review, and Submission of Facility Profiles

As described above, FDA notes in the preamble to the proposed rule that the agency is not proposing several types of verification activities and controls. FDA notes that these various controls and verification measures "are an important part of a modern food safety system," though their usefulness may depend on the type of facility and food involved.

Of note, FDA does not propose the use of finished product testing, even though it is mentioned in section 418(f) of the FDCA as a potential verification activity. FDA does, however, discuss its usefulness at length. For example, FDA notes that "[f]inished product testing is more important and useful when there is a reasonable probability that exposure to an identified hazard will result in serious adverse health consequences or death to humans or animals." FDA then gives example of circumstances where finished product testing might be appropriate, such as for raw vegetables intended as ready-to-eat foods that may contain *Salmonella* spp. or *L. monocytogenes*, or when ingredients are added after kill steps. Likewise, FDA does not propose the use of environmental testing—which also is mentioned in section 418 as a potential verification activity and preventive control—but discusses various circumstances in which such testing would be useful. FDA discusses the expenses of these activities, which for product testing could range from $14,000 to $813,000 per facility, suggesting that economic impact may have been a factor in their omission from the proposed rule. FDA requests comments on whether these types of testing should be included in Part 117.

FDA also includes a lengthy appendix to the proposed rule discussing scientifically valid sampling and testing, verification testing of raw materials, verification of sanitation controls, the role of environmental testing (including commentary on the use of indicator organisms such as generic *E. coli* and *Listeria* spp.), the role of finished product testing, and metrics for microbiological risk management. FDA requests comments on its analysis. Even though these activities are not part of the proposed rule, industry—particularly any manufacturer that uses environmental testing or finished product testing—should review the appendix and consider commenting. It is possible that FDA may change course at some point, either in the final rule or later, and incorporate testing activities into the rules. In addition, FDA's thinking likely will be influential on voluntary standards, and it is possible that it could influence state tort law regarding standards of care.

FDA also notes that a supplier verification and approval program can be useful in some circumstances, depending on the hazards involved and the ability of the facility or supplier to control them. FDA requests comments on whether supplier verification should be required and, if so, to what level of specificity. FDA lists a number of specific verification activities (*e.g.*, written list of approved suppliers as well as audits) to consider. FDA notes, with respect to imported food, that the agency will be releasing a proposed rule on the foreign supplier verification requirements of section 805 of the FDCA in the "near future."

FDA also requests comments on the utility of requiring review of consumer complaints, noting that this activity is required by its juice HACCP regulations but not by other HACCP regimes. In addition, FDA requests comments on the "submission of a facility profile to FDA." FDA notes that "there are significant obstacles to realizing the benefits from submission of food safety plans," but the submission of a more limited set of facility profile information may be useful to target inspections to facilities that handle certain types of food or have inadequate controls. The proposal is somewhat similar to FDA's May 2012 proposal to accept voluntary submission of facility profile information,[5] though the more recent proposal is for mandatory (not voluntary) submission of this information.

Compliance Date

FDA proposes to allow one year after the date of publication of a final rule for most facilities to come into compliance. Small businesses (those with less than 500 employees) and very small businesses would have two and three years, respectively, to come into compliance. The agency proposed three alterative definitions of "very small business"—$250,000; $500,000; or $1,000,000 of total annual sales of food, adjusted for inflation.

[5] 77 Fed. Reg. 27,779 (May 11, 2012).

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Covington & Burling LLP will continue to monitor FDA's implementation of FSMA—including FDA's release of additional proposed rules—and advise clients on developments.

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