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FDA Releases Long-Awaited Draft Guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Food

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Food, Beverage, and Dietary Supplements

Earlier this week, FDA released five chapters of a multi-chapter draft guidance on hazard analysis and risk-based preventive controls for human food.[1] The long-awaited draft guidance is intended to help industry comply with certain requirements of the agency's final rule for preventive controls for human food (PC rule) under the Food Safety Modernization Act (FSMA). The PC rule generally requires all FDA-registered domestic and foreign food facilities to establish and implement a food safety system, documented in a written food safety plan that is prepared by a preventive controls qualified individual (PCQI) and includes an analysis of hazards and implementation of risk-based preventive controls (PCs).[2]

The draft guidance is one of the most detailed and instructive guidance documents that FDA has released for the food industry, and is a must-read for all PCQIs and other persons involved in preparing for and overseeing compliance with the PC rule. It helps provide clarity by defining additional terms not defined in the PC rule, identifies a number of common PCs, and includes numerous examples and fairly concrete (though still non-binding) recommendations for industry. This alert highlights key aspects of the draft guidance and discusses how it may be of value to industry stakeholders.

Purpose and Key Aspects of the Draft Guidance

The draft guidance is specifically directed at industry members who are subject to the full requirements of the PC rule. It does not help facilities determine whether they are exempt or subject to modified PC requirements, nor does it provide guidance regarding implementing those modified requirements.

The primary objective of the draft guidance is to help covered facilities create and implement a food safety plan. To this end, the first five chapters, which FDA released this week, cover the following topics:

[1] The draft guidance is available here. FDA subsequently released two draft guidances relating to animal feed. Covington's client alert on those draft guidances will follow soon.

[2] See our client alert "FDA Publishes Final Rule on CGMPs, Hazard Analysis, and Preventive Controls for Human Food."

- The food safety plan;
- Conducting a hazard analysis;
- Potential hazards associated with the manufacturing, processing, packing, and holding of human food;
- Identifying and implementing PCs; and
- Application of PCs and PC management components.

Although the draft guidance is not intended to substitute for the judgment of the PCQI, it provides detailed information that the PCQI likely will find to be particularly useful in helping him or her develop the facility's food safety plan. Below we provide highlights of each of the five chapters published this week. We recommend that all covered facilities review the draft guidance in detail.

Chapter 1: The Food Safety Plan

In this chapter, FDA explains what a food safety plan is and how it differs from a Hazard Analysis and Critical Control Point (HACCP) plan. As FDA noted in the PC rule, a facility that has a HACCP plan (or other food safety plan) in place before the PC rule becomes effective "can build off its existing program and can rely on existing records, supplemented as necessary to include all of the required information and satisfy the requirements of this rule." This chapter should be particularly helpful for facilities who already have a HACCP plan and would like to adapt that plan to satisfy the PC rule requirements for a food safety plan.

Chapter 2: Conducting a Hazard Analysis

This chapter guides covered facilities through the steps involved in conducting a hazard analysis. As an initial matter, the draft guidance defines the term "hazard analysis," which is not defined in the PC rule. Specifically, "hazard analysis" means "the process of collecting and evaluating information on hazards and the conditions leading to their presence to determine which hazards are significant for food safety and therefore should be addressed in a HACCP plan or food safety plan."[3]

Although not required by the PC rule, FDA recommends that covered facilities conduct certain preliminary steps, and set up a Hazard Analysis Worksheet, as a useful framework for organizing and documenting their hazard analysis. Those preliminary steps are:

- Assemble a Food Safety Team of individuals with expertise in the day-to-day operations of the facility to conduct the hazard analysis under the oversight of a PCQI;
- Describe the product, its distribution, intended use, and consumer or end user;
- Develop a process flow diagram (i.e., a clear, simple description of the steps involved in the processing of the food product and its associated ingredients as they "flow" from receipt to distribution) and verify it on site; and

[3] See page 18 of the draft guidance. This definition was developed by the Food Safety Preventive Controls Alliance.

- Develop a detailed process description to supplement the process flow diagram. Include information such as the maximum length of time a food is exposed to ambient temperature during processing, whether a food is handled manually, and whether rework is incorporated into product.

The draft guidance provides a number of other useful tools to use in conducting a hazard analysis, including the following:

- A template for a Hazard Analysis Worksheet, with an explanation of how to use the worksheet; and
- A list of relevant information to consider in generating a list of biological, chemical, and physical hazards.

Chapter 3: Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food

Here, FDA addresses ingredient-related hazards, process-related hazards, and hazards that may be introduced from the food-production environment (facility-related hazards). Although the draft guidance provides an extensive amount of information that should be useful for facilities as they consider the biological, chemical, and physical hazards that should be addressed in a hazard analysis, and key examples of each type of hazard and potential sources, it does not provide an exhaustive list of hazards or details about each hazard.

In addition, this chapter provides insight into how FDA expects facilities to identify and control known or reasonably foreseeable hazards that may be intentionally introduced for purposes of economic gain. In particular, FDA recommends that facilities focus on circumstances where there has been a pattern of such adulteration in the past. For example, FDA identified the use of melamine to increase the apparent protein content of milk as a past instance of economically-motivated adulteration. Given this history, FDA recommends that facilities include the potential for melamine adulteration in their hazard analysis when using milk products from countries where melamine adulteration has occurred; however, FDA does not expect facilities to consider melamine to be a significant hazard when using domestic milk products, or milk products from countries without a history of melamine adulteration. Generally, if you determine through your hazard analysis that a hazard that may be intentionally introduced for purposes of economic gain is a hazard requiring a PC, FDA recommends that you address that hazard through your supply-chain program.

Chapter 4: Preventive Controls

This chapter identifies common PCs that facilities could use to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards requiring a PC, including process controls, sanitation controls, food allergen controls, supply-chain controls, and recall plans. It also provides guidance regarding monitoring those PCs.

While the PC rule generally requires facilities to establish and implement PCs to control each hazard identified as requiring a PC, the rule provides two exceptions to this requirement. Specifically, under 21 C.F.R. 117.136, a manufacturer/processor is not required to implement a PC under either of the following two circumstances:

- The manufacturer/processor determines and documents that the type of food could not be eaten without processing that would control the hazards requiring a PC.

- The manufacturer/processor demonstrates and documents that the identified hazard will be controlled by another entity in its distribution chain, provided that the manufacturer/processor takes certain steps, including (1) disclosing to its customers that the food is "not processed to control [identified hazard]"; and (2) annually obtaining written assurances from its customers regarding appropriate procedures they will take to control the identified hazards.

Neither this nor any other of the first five chapters of the draft guidance touches on these exceptions. Earlier this week, FDA issued a final rule extending compliance dates for certain provisions of FSMA rules, including a two-year extension for the written assurance requirement of 21 C.F.R. 117.136 and related provisions.[4] The agency did not delay the compliance date for the disclosure statement provision, however, and intends to further address this provision in guidance.

Chapter 5: Application of PCs and PC Management Components

This chapter provides examples of the application of PCs to significantly minimize or prevent the occurrence of a number of biological, chemical, and physical hazards. In addition, it provides an overview of PC management components (i.e., monitoring, corrective actions and corrections, and verification activities).

Additional Issues Clarified in the Draft Guidance

The draft guidance clarifies a number of issues covered in the PC rule, including the following:

- *Process controls*. Process controls are one type of PC that may be applied to a hazard requiring a PC. Under the PC rule, process controls must include (1) parameters associated with the control of the hazard; and (2) minimum or maximum values to which any biological, chemical, or physical parameter must be controlled.[5] The draft guidance clarifies that process controls do not include those procedures, practices, and processes that are *not* applied to the food itself (e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards). In addition, the draft guidance provides the following examples of processing parameters that can have a minimum or maximum value (or combination of values): time, temperature, flow rate, line speed, product bed depth, weight, product thickness or size, viscosity, moisture level, water activity, salt concentration, pH and others, depending upon the process.
- *The relationship between sanitation controls and current good manufacturing practices (CGMPs)*. Sanitation controls, another type of PC, may include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Accordingly, some of the facility's sanitation procedures, practices, and processes will be sanitation controls, while others will be CGMPs. FDA expects facilities to determine which hazards require a sanitation control, rather than CGMPs, through a hazard analysis. Specifically, FDA

[4] See our client alert "FDA Extends Compliance Dates for Certain Provision of FSMA Rules."

[5] 21 C.F.R. 117.135(c)(1).

recommends that facilities first assess the sanitation procedures, practices, and processes they will have in place to comply with the CGMP requirements, then assess what additional sanitation controls will be needed.

- *The difference between corrections and corrective actions*. The PC rule defines the terms "corrections" and "corrective actions." A correction is an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure. By contrast, a corrective action is an action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce). In the draft guidance, FDA provides the following example to illustrate the difference between corrections and corrective actions:

  > If you observe food residue on "clean" equipment prior to production, corrections would involve re-cleaning and sanitizing the equipment before it is used. Because you observed the food residue prior to production of food, and you corrected the problem in a timely manner, no food is affected and no actions are needed with respect to food. You are not required to record the correction because this isolated incident does not directly impact product safety, and you made the corrections in a timely manner (i.e., before the production starts).
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  > On the other hand, if you make an RTE [ready-to-eat] creamed vegetable soup using a continuous heat exchanger and hot-fill process, and after packaging the soup your review of temperature records of the processed soup at the discharge end of the hold tube shows that the soup did not reach the temperature you identified as a critical limit, corrective actions would involve destroying the product, reheating it or sending it to animal food as appropriate, investigating the cause of the problem, and taking the actions needed to reduce the likelihood that the problem will recur based on the root cause of the problem.

Forthcoming Guidance Documents

FDA intends to release the remaining nine chapters of the draft guidance on a rolling basis through the end of 2018. Those chapters will cover, among other things, the supply-chain program requirements of the PC rule, as well as guidelines for establishing a recall plan.

Comment Period

Although FDA accepts public comments on guidance documents at any time, you should submit comments on the draft guidance by February 21, 2017 to ensure that the agency considers those comments before it issues the final version of the guidance.

Covington continues to monitor closely FDA's implementation of FSMA and will keep its clients apprised of significant developments.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

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