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FDA Releases Draft Guidance on "Disclosure Statement" Provisions of Four FSMA Rules

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Food, Beverage, and Dietary Supplements

Last week, FDA released a draft guidance[1] clarifying requirements for the "disclosure statement" provisions of its four major Food Safety Modernization Act (FSMA) rules.[2] Entities subject to these provisions must disclose, in documents accompanying the food, that certain hazards have not been controlled. The draft guidance provides insight into the circumstances in which FDA would expect covered entities to utilize the "disclosure statement" provisions, explains how the covered entity should describe the identified hazard, and discusses what type of documents may be used for the disclosure statement. Additionally, FDA reminds industry stakeholders that the entity receiving such a disclosure statement is responsible for taking appropriate steps to ensure that the identified hazards are controlled before the food reaches the consumer.

Scope of the Draft Guidance

The draft guidance provides recommendations regarding the following four FSMA "disclosure statement" provisions:

- **The Human PC Rule (21 C.F.R. 117.136(a)(2)-(4))**: If a manufacturer/processor identifies a hazard requiring a preventive control (PC), does not control the identified hazard, and relies on an entity downstream in its distribution chain to address the hazard, the manufacturer/processor is not required to implement a PC for the identified hazard if the manufacturer/processor takes certain steps, including disclosing to its customers that the food is "not processed to control [identified hazard]."
- **The Animal PC Rule (21 C.F.R. 507.36(a)(2)-(4))**: The disclosure statement provisions of the Animal PC Rule mirror those of the Human PC Rule.

[1] The draft guidance is available here.
[2] These four rules include the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Final Rule (the "Human PC Rule," codified in FDA's regulations at Part 117), the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals Final Rule (the "Animal PC Rule," codified in FDA's regulations at Part 507), the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals Final Rule (the "FSVP Rule," codified in FDA's regulations at Part 1, Subpart L), and the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Final Rule (the "Produce Safety Rule").

- **The FSVP Rule (21 C.F.R. 1.507(a)(2)(i), (a)(3)(i), and (a)(4)(i))**: If an importer imports a food for which the hazards are controlled after importation, the importer must disclose to customers that the food is "not processed to control [identified hazard]."
- **The Produce Safety Rule (21 C.F.R. 112.2(b)):** Produce that otherwise would be covered by this rule is eligible for an exemption if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance and the covered farm satisfies other requirements, including disclosing that the food "is not processed to adequately reduce the presence of microorganisms of public health significance."

FDA's Recommendations Regarding the Disclosure Statement

The draft guidance provides recommendations regarding the circumstances in which it is appropriate for a covered entity to utilize the disclosure statement provisions, as well as how and in what types of documents the entity should describe the identified hazard. Although the draft guidance separately discusses each of the four FSMA rules, there is significant overlap in FDA's recommendations, and thus we provide one summary of the agency's recommendations.

When a Disclosure Statement Is Appropriate

The draft guidance states that while the disclosure statement provisions apply to all types of hazards, FDA believes that in practice, the disclosure statement will be used mostly for biological hazards. This is because FDA expects that if a chemical or physical hazard is identified as requiring a PC, the first manufacturing/processing facility in the supply/distribution chain would most likely control that hazard.

How to Describe the Identified Hazard

According to the draft guidance, the specificity the entity should use to describe the "identified hazard" will depend on the type of hazard at issue. Under this approach, FDA would consider the following to be in compliance with the applicable FSMA requirements:

- For biological hazards, the entity may describe each hazard using a general term (e.g. "microbial pathogens," "microorganisms of public health significance") rather than a specific term (e.g., "*Salmonella*" or "*Listeria monocytogenes*").
- For chemical and physical hazards, the entity should describe the hazard using a specific term (e.g., "mycotoxins," "aflatoxin," "stones") that adequately communicates key safety information regarding the hazard that needs to be controlled.

Types of Documents that May Contain a Disclosure Statement

The applicable FSMA rules require the covered entity to disclose the hazards in "documents accompanying the food, in accordance with the practice of the trade." The draft guidance provides the following guidelines for satisfying this requirement:

- FDA recommends that entities place a disclosure statement on documents or papers associated with the shipment that a food safety manager for the customer is likely to read, including labels, labeling, bill of lading, and shipment-specific certificates of analysis.

- FDA does not recommend use of documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions, because such documents generally are not specific to a particular shipment and may not be available to the customer's food safety manager.

Additionally, FDA states that covered entities may use labeling that includes the disclosure statement and directs the recipient to a website for additional information about the specific hazard. They may not, however, reference a website in lieu of a disclosure statement.

Comment Period

While the draft guidance provides clarification as to FDA's current thinking about how best to satisfy the disclosure statement provisions, the agency may not have anticipated all circumstances and commercial arrangements. Industry stakeholders should consider whether outstanding questions remain and could benefit from further FDA clarification. Stakeholders should also consider whether they have additional information to share with the agency that might help inform its current thinking, including with respect to the burden of the disclosure statement provisions and potential alternatives.[3]

Although FDA accepts public comments on guidance documents at any time, you should submit comments on the draft guidance by May 1, 2017 to ensure that the agency considers those comments before it begins work on 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.

[3] In August, FDA delayed the compliance dates for the written assurance provisions in the Human and Animal PC Rules that are companions to the disclosure statement provisions, to address concerns about the practicality of compliance with those provisions and to give FDA time to consider the regulatory text. *See* FDA Extends Compliance Dates for Certain Provisions of FSMA Rules, COVINGTON ALERT (Aug. 23, 2016).

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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