LIEBERMAN PLLC

1010 Wisconsin Avenue NW, Suite 250
Washington, DC 20007
+1.202.830.0300
+1.202.830.0904
info@liebermanpllc.com

Regulatory Alert: FDA Releases Draft FSMA Guidance on Communicating Hazards Requiring a Control Downstream in Supply Chain

November 28, 2016

In October 2016, the U.S. Food and Drug Administration (FDA) released draft guidance to industry entitled "Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act (FSMA)."

The draft guidance may be found here.

The Foreign Supplier Verification Program Rule, Preventive Controls Rules for Human and Animal Food and Produce Safety Rules all contain provisions requiring written disclosures for certain hazards that are controlled downstream in the supply chain. More specifically, written disclosure statements are required in the following circumstances:

1. Foreign Supplier Verification Program Rule: For foods that cannot be consumed without hazards being controlled (and such hazards are not controlled before importation) or for which hazards are controlled after importation.
2. Preventive Controls for Human and Animal Food Rules: When a manufacturer/processor of food identifies a hazard requiring a preventive control, does not control the identified hazard and relies on an entity in its distribution chain to address the hazard.
3. Produce Safety Rule: Produce grown under an exemption from the requirements of the rule for fruits and vegetables that receive commercial processing downstream that adequately reduces the presence of microbiological hazards.

Please note that these recommendations are only for use in documents accompanying the food. Hazard analyses and other compliance requirements under these rules require hazards to be described with more specificity.

How should hazards be described in documents accompanying the food?

Preventive Controls for Human and Animal Food Rules

For biological hazards a general term such as "microbial pathogens" or "microorganisms of public health significant" is adequate. It is not necessary to identify the specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*).

FDA notes that "regardless of whether the establishment that receives food accompanied by such a disclosure statement is subject to the CGMP requirements, the human food preventive

controls requirements, or both the CGMP and the human and animal food preventive controls requirements in parts 117 of 507 respectively, that establishment is responsible for taking appropriate steps to ensure biological hazards applicable to that food are controlled before the food reaches the consumer."

For chemical and physical hazards, FDA expects that hazard to be identified with specificity (e.g. mycotoxins, aflatoxin, stones). Referring to physical or chemical hazards using a general term only does not provide a customer with sufficient information to address the hazard according to FDA.

Produce Safety Rule

It is not necessary to specify the particular pathogen of concern, rather "not processed to adequately reduce the presence of microbial pathogens" or similar phrases, is acceptable.

Foreign Supplier Verification Program

FDA states that they believe that, in practice, the FSVP disclosure statement will be required mostly for biological hazards because in the case of most chemical or physical hazards, a chemical or physical hazard that an importer identifies as requiring a control would most likely be controlled by the first manufacturing/processing facility in the supply chain.

For biological hazards using a general term such as "microbial pathogens" or "microorganisms of public health significance" rather than a specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*) is compliant.

For chemical and physical hazards, FDA expects that hazard to be identified with specificity (e.g. mycotoxins, aflatoxin, stones).

On which documents should hazards be communicated?

The hazard disclosure statement may be provided on documents that accompany the food, such as labels, labeling, bills of lading, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that a food safety manager for the customer is likely to read.

It is not sufficient to reference a website in a document of the trade without including the disclosure statement itself, in the document of the trade. It is however permissible to use labeling that includes a disclosure statement such as "not processed to control microbial hazards" and then directs the recipient to a website for additional information about those microbial pathogens.

FDA does not recommend documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions be used to communicate the information required in the disclosure statement. Such documents generally are not specific to a particular shipment, and some may not be available to the customer's food safety manager.

Please contact Erik Lieberman at erl@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information