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food safety challenges for small and medium size importers

MSK Client Alert

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On February 17, 2011, around the time the Food Safety Modernization Act (FSMA) became law, Michael R. Taylor, Food and Drug Administration (FDA) Deputy Commissioner for Foods, spoke before the Global Food Safety Conference in London, England stating: "Importers will, for the first time, have a clearly defined responsibility and accountability for the safety of the food they [import]." At about the same time, the Centers for Disease Control and Prevention [CDC] stated 1 in 6 Americans suffers a food borne illness yearly. In its July 13, 2010 edition, *USA Today* publisheda story stating: "Close to one in 25 outbreaks of foodborne [sic] illness in restaurants and delis can be traced to contaminated, freshly-made salsa or guacamole, the [CDC] is reporting. Of the 136 salsa and guacamole-associated outbreaks reported between 1998 and 2008, 36 were linked to guacamole, 95 to salsa and the rest to both. All were from fresh-made salsa or guacamole from restaurants or delis." "None of the outbreaks were caused by commercially prepared salsas, products you might buy in a grocery store," says Robert Tauxe, deputy director of CDC's division of foodborne [sic] waterborne and environmental diseases." See http://www.usatoday.com/news/health/2010-07-13-Salsa14_ST_N.htm.

Since then, concern about food safety has only heightened against a backdrop of serious food safety lapses in countries like China and its milk scandal. One basis for objection by food importers to the complex new regulations is all shipments are reported to FDA at time of importation, but the same is not true of U.S. domestic food production, a frustration for importers as the vast majority of food related illnesses have been associated by the CDC with domestic production. On November 3, 2011, CNN ran a story about the 10 biggest foodborne illnesses of the decade, see http://www.cnn.com/2011/09/30/health/high-profile-food-borne-illnesses-gallery/index.html, while the 10 cases cited were serious, 8 related to solely U.S. processing, while the 2 imported incidents involved Mexican peppers and cantaloupes.

The concept of risk management is not new, even to FDA. For years, Hazard Analysis and Critical Control Points (HACCP) plans have been required for

attorneys

Susan Kohn Ross

practice areas

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imports of seafood, juice and low acid canned food, but are voluntary for dairy product. HACCP operates on the principle each member in the supply chain must identify potential hazards and minimize or eliminate them during production or handling, but if that fails, manage them when they arise. This concept has been expanded by the FSMA to all imported food. The definition of food is broad and encompasses articles used for food or drink for man or animals; chewing gum; and inputs, ingredients and components for such articles, including dietary supplements, but not pesticides. FDA is able to inspect barely 1% of these food imports, so the focus is on prevention mechanisms and that is where the burden is greatest on smaller companies due to higher risk and compliance costs, in an already tough economic environment. Cost alone can no longer drive the deal.

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An importer is here defined as the U.S. owner or consignee at time of entry, or, if there is none, the U.S. agent or representative of the foreign owner or consignee. Under the proposed rules, importers must now ensure their foreign suppliers comply with FDA safety rules or equivalent local regulations. The clearest expectations come from the newly proposed foreign supplier verification (FSVP) rules wherein the importer is expected to focus on foreseeable food safety risks identified through a hazard assessment process, not every possible risk. The regulatory requirements differ depending on the type of food product or dietary supplements; category of importer; nature of hazard; and who controls it.

The proposed FSVP rules require importers do much more homework and keep records of such actions as:

- Review the compliance status of the imported product and foreign supplier(s), including warning letters, import alerts and required certifications.
- Analyze the hazards associated with each food and evaluate the severity of the illness or injury, if such hazard occurs, with more robust efforts mandated as the hazard risk increases.
- Importers must maintain a written list of foreign suppliers; establish written verification procedures; and verify that reasonably likely to occur hazards are adequately controlled.
    - If the importer or its customer/buyer controls the hazard, the importer must document such controls, including obtaining buyers' certification if they control the hazard.
    - If the foreign supplier controls the hazard or its compliance is verified as being controlled by its raw material/ingredient supplier:
        - Option 1 – Importer must conduct on-site auditing of the foreign supplier or rely an inspection by FDA or the approved food safety authority in the country for the reasonable probability exposure will result in serious adverse health consequences or death, or hazards in certain raw agricultural commodities. For others, importers may choose: onsite auditing, periodic or lot-by-lot sampling and testing, periodic review of the supplier's food safety records, or other appropriate measures.

- Option 2 – Importers may choose from the various verification options for all types of hazards, so long as the chosen verification activities are sufficient to ensure the hazards presented are adequately controlled.
- Whichever option is chosen, the importer must implement and revalidate it every few years or sooner as circumstances warrant.

These initial steps are costly on their own, but then importers are expected to review complaints, investigate adulteration or misbranding, and take corrective actions in noncompliance cases, including supplier termination, plus reassess the suppliers' activities if new information arises about potential hazards, or otherwise every three (3) years.

Importers must also now make sure all such efforts are documented and resolve all red flags adequately. The records must be maintained for at least two (2) years from date of last revision or replacement, and sometimes longer.

There are also specific provisions for dietary supplements and their components; for very small importers or very small foreign supplier importations (defined as $500,000 in annual worldwide food sales); and imports from foreign suppliers in countries were FDA has recognized the food safety system.

Given the huge responsibility now being put on small and medium sized companies to insure the safety of their imported food, it is obvious the risk of doing business has just gone up considerably, but the cost, too. Even if the supplier is in a county where FDA approves the food safety system, and even if the local government provides the inspectors, it is reasonable to expect there will be a cost for the resulting report and that cost is likely whether the inspector is from the government or is a third party auditor. Third party auditors are the subject of a separate proposal.

What this means to smaller companies is representatives can no longer simply go to a trade show and rely on what they are being told by a potential seller. They can also no longer place an order electronically and wait for its delivery. Even if the importer is satisfied the supplier controls the risk and is the party which must manage it, compliance with the FSMA mandates the importer visit the processing facility or receive a report from an auditor in order to have taken all reasonable steps. Obviously, the size of a given order may influence the amount of due diligence an importer exercises, but, in the end, if FDA finds a problem with the shipment, you need to be prepared with the proper documentation, and maybe private lab testing, to get your shipment released. Having done too little or nothing to vet the supplier can also lead to class action lawsuits and more headaches. Given the costly burden put on small- and medium-sized companies by these new proposals, make sure you file your comments with FDA by the November 26, 2013 deadline.

An additional area of concern is the potential for phony documentation. The audit process is not transparent, so unless the auditors and/or FDA create a way for importers to validate these reports, one has to ask – how can companies, especially small- and medium-sized ones, really protect themselves from the unscrupulous supplier who misrepresents the condition of his supply chain with phony audit reports? At the very least, FDA should provide a means for an importer to report the parties and food product and have the agency provide a simple yes

los angeles
t 310.312.2000
f 310.312.3100

new york
t 212.509.3900
f 212.509.7239

washington, dc
t 202.355.7900
f 202.355.7899

or no to these two questions – was the company audited and, if so, did it pass (was it found compliant)? FDA may resist out of concern of disclosing trade secrets, but, it can simply require that any party submitting an audit report agree certain details may be released publicly, or, put another way, trade secrets are waived as to those specific data elements.

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