FSMA ALERT

5/31/13

FDA Issues Final Rule Regarding Prior Notice

The Food and Drug Administration (FDA) has published the final rule that amends the prior notice requirements of the Food, Drug and Cosmetics Act (FD&CA)[1]. Effective May 30, 2013, all prior notice submissions to FDA accompanying imported food intended for human or animal consumption must report the name of any country to which the article has been refused entry.

Prior notice requirements were established in 2002 pursuant to the Bioterrorism Act and were intended to safeguard the food supply. Requirements included the receipt of certain information about imported foods prior to arrival in the U.S. and established a system of refusal of admission when prior notice was not provided to the FDA. Section 304 of the Food Safety Modernization Act (FSMA) amended section 891(m) of the FD&CA to require that additional information be provided in a prior notice of imported food submitted to FDA. This additional information was comprised of notifying FDA if the food article had been previously refused entry in another country. The final rule adopts, with no changes, the Interim Final Rule (IFR) that had become effective on July 3, 2011.

In its review of the comments to the IFR, FDA clarifies that the meaning of a "refused entry" reported in the prior notice disclosure will be limited to refusals based on "food safety reasons" such as intentional or unintentional contamination. FDA also states that it intends to further explain the meaning of refused entry in its guidance on the prior entry notices. Additionally, FDA states that it will not require importers to submit the reason for a refusal in another country.

The FDA has stated that it will base its admission decisions on the information submitted by importers and on the risk to public health that the imported food may cause if allowed into the U.S. Where FDA finds a violation of the prior notice requirement, the agency will take into account the totality of the circumstances in determining whether and how to enforce the violation.

While the final rule clarifies numerous aspects of the new prior notice requirement, importers, brokers and other companies involved in the U.S. food supply chain will have to await updated guidance for further specifics regarding prior notice.

Extension of FSMA Deadlines to Promulgate Final Regulations by the FDA

The Food and Drug Administration and the Center for Food Safety (CFS) have been granted an extension for coming up with a schedule for issuing proposed rules, as required by the Food Safety Modernization Act.

In May 2012, CFS and the Center for Environmental Health (CEH) sued the FDA for failing to promulgate final regulations by mandatory deadlines contained in the FSMA. On April 22, 2013, Judge Hamilton of the United States District Court (N.D. California) ruled that FDA had to come up with a timeline for issuing the delayed proposed rules by May 20, 2013. As the parties were unable to agree on a timeline, on May 17 Judge Hamilton granted the parties' Joint Stipulation for Extension of Time. Accordingly, CFS and FDA now have until June 10, 2013, to agree on a timeline for releasing the pending rules.

[1] Amendment of section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&CA) (21 U.S.C. 381 (m))

In January of this year, FDA released rules regarding preventive controls for human food and standards for produce safety. FDA has missed FSMA deadlines for publishing the following proposed rules: the foreign supplier verification program, voluntary qualified importer program, accreditation of third party auditors and sanitary transportation practices.

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