

ALERTS

Food, Drug & Device Law Alert - FDA Expected To Issue Revised Proposed Rules On Produce Safety And Preventive Controls For Food Manufacturing

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Michael Taylor, the head of FDA's Center for Food Safety and Nutrition (CFSAN), recently announced that by early summer the FDA intends to issue revised versions of two of its pending food safety rules, the ones addressing produce safety and preventive controls for food manufacturing (or cGMPs). Mr. Taylor also stated that the FDA intends to submit the revised portions of the rules for public comment before making final revisions and adopting the rule. The FDA is currently subject to a court-ordered deadline to complete these rules and others by the end of June 2015.

As noted in Alerts from January of this year, on the two year anniversary of the Food Safety Modernization Act (and six months after a statutory deadline), the FDA released proposed rules for enhancing produce safety and for implementing Hazard Analysis and Risk-Based Preventive Controls more broadly in food manufacturing.

In general, the rule on preventive controls requires (1) a written hazard analysis identifying and evaluating known or reasonably foreseeable for each type of food manufactured, process, packed or held in the facility and (2) written and implemented preventive controls, including process, food allergen, and sanitation controls, to assure that any hazards that are reasonably likely to occur are prevented or at least significantly minimized so that food at the facility will not be adulterated.

The produce safety rule proposes minimum standards for the safe growing, harvesting, packing and holding of produce on farms in several areas, including (1) worker training and hygiene, (2) agricultural water, (3) biological soil amendments, (4) domesticated and wild animals, (5) equipment, tools, and buildings, and (6) sprouts.

According to Mr. Taylor's announcement, the anticipated revisions fall in the "sections covering water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities (such as a farm that has a food-processing operation), and procedures used to withdraw the qualified exemption to these requirements for certain farms." He added that, as FDA continues to review comments it has received to date, it may decide to revise other sections as well.

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A copy of Mr. Taylor's announcement can be [found here](#).

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