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## **Food and Drug Administration (FDA) Issues Final Produce Safety Rule**

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### **Overview**

In early 2011, the President signed into law the Food Safety Modernization Act (FSMA) of 2010 (codified at 21 U.S.C. §301, et seq.). The FMSA gives the FDA expansive power to regulate the food supply, including the ability to establish standards for the harvesting of produce and preventative control for food production businesses. Beginning in 2018, the new rules will significantly impact many growers and handlers of fresh produce.

### **Litigation Over Regulatory Process**

The FMSA also gives the FDA greater authority to restrict imports and conduct inspections of domestic and foreign food facilities. To implement the requirements of the FMSA, the FDA has to prepare in excess of 50 rules, guidance documents, reports and studies in short order. Indeed, the timeframe was so short FDA complained that they didn't have enough time to do the job appropriately. That led to lawsuits being filed by activist groups to compel the FDA to issue several rules that were past-due. A federal court agreed with the activists in the spring of 2013 (*see Center for Food Safety v. Hamburg, 954 F. Supp. 2d 965 (N.D. Cal. 2013)*) and, as a result, the FDA issued four proposed rules with comment periods that ended in November of 2013. One of the most contentious issues involved the rule FDA was supposed to develop involving intentional adulteration of food. FDA said it needed two more years to develop an appropriate rule, but the Court ordered them to develop it immediately. The hope, at that time, was that the Congress would step in and modify the deadlines imposed on the FDA so that reasonable rules could be developed rather than being simply rushed through the regulatory process for the sake of meeting an arbitrary deadline.

### **Final Rule**

In late 2015, the FDA issued its Final Produce Safety Rule that has application to growers and fresh produce handlers (those that pack and store fresh produce). The rule is designed to reduce the instances of foodborne illnesses. Effective, January 16, 2016, the rule generally covers the

use of manure or compost as fertilizer, allowing (at least for the present time) a 90 to 120-day waiting period between the application of untreated manure on land and the time of harvest. That timeframe is in accordance with USDA National Organic Program Standards. Relatedly, the rule requires that raw manure and untreated biological soil amendments of animal origin must be applied without contacting produce and post-application contact must be minimized. Also, the rule addresses water quality and establishes testing for water that is used on the farm such as for irrigation or handwashing purposes. Under the rule, there must be no detectable generic E coli in water that has the potential to contact produce. The rule establishes a timeframe for noncompliant growers to come into compliance with the water requirements.

The rule also addresses scenarios that could involve contamination of food products by animals, both domestic and wild, and establishes standards for equipment, tools and hygiene. As for potential contamination by wild animals, the rule requires farmers to monitor growing areas for potential contamination by animals and not harvest produce that has likely been contaminated. In addition, the rule establishes requirements for worker training, health and hygiene, and particular rules for farms that grow sprouts.

### **Exemption for Low Sales Levels**

Under the rule, farms that sell an average of \$25,000 or less of produce over the prior three years are exempt. Similarly, exempt are farms (of any size) whose production is limited exclusively to food products that are cooked or processed before human consumption. For producers whose overall food sales average less than \$500,000 annually over the prior three years where the majority of the sales are directly to consumers or local restaurants or retail establishments, a limited exemption from the rule can apply. However, these producers must maintain certain required documentation (effective Jan. 16, 2016) and disclose on the product label at the time the product is purchased the name and location of the farm where the food product originated. In addition, the rule also allows commercial buyers to require that the farms from which they purchase produce follow the rule on their own accord.

### **Effective Date**

Generally, the new rules aren't effective to growers and handlers until 2018. Smaller operations have to come into compliance by late 2020. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Fed. Reg. 2015-28159 (Nov 27, 2015).*