

# FDA RELEASES INITIAL FSMA FINAL RULES

Today the U.S. Food and Drug Administration released the first two final rules that implement the Food Safety Modernization Act ("FSMA"). The Preventive Controls for Human Food Rule sets new safety requirements for facilities that process package and store food for human consumption. Similarly, the Preventive Controls for Animal Food Rule establishes safety requirements for facilities that manufacture animal feed.

Compliance deadlines for FSMA rules are tied to the rules' official publication dates. Generally, the key dates and deadlines for each rule track the following schedule:

## **(1) Preventive Controls for Human Food**

The final rule will be formally published on September 17, 2015, and revises existing current good manufacturing practice (CGMP) regulations, as well as requires that covered food and beverage facilities develop and put in place a written "Food Safety Plan."

### ***Compliance deadlines:***

- Businesses with 500+ employees: one year after publication
- Businesses less than 500 employees: two years after publication
- Businesses with less than \$1 million in annual sales: three years after publication

## **(2) Preventive Controls for Animal Food**

The final rule will be formally published on September 17, 2015, and establishes safety requirements for facilities that manufacture, process, pack, or hold animal feeds. Similar to the final rule for Preventative Controls for Animal Food, it establishes current good manufacturing practice regulations, as well as requires that covered facilities develop and put in place a written "Food Safety Plan." Compliance deadlines will be staggered between CGMP requirements and preventive control requirements associated with the "Food Safety Plan."

### ***Compliance deadlines:***

- Businesses with 500+ employees: one to two years after publication
- Business with less than 500 employees: two to three years after publication
- Businesses with less than \$2.5 million in annual sales: three to four

## **PEOPLE**

Laura A. Bentele

## **SERVICES AND INDUSTRIES**

Agribusiness and Food

Litigation

years after publication

From now until May 2016, a total of seven rules will be issued by the FDA to implement the FSMA. The next five rules will be published according to the following timeline:

**(3) Foreign Supplier Verification Program (FSVP)**

The final rule will be issued on Oct. 31, 2015, and makes importers liable for ensuring that foreign food suppliers meet the same standards required of domestic producers.

**(4) Produce Safety Rule**

The final rule will be issued on Oct. 31, 2015, and establishes new standards for growing, harvesting, packing and holding produce on domestic and foreign farms.

**(5) Third Party Certification of Auditors for Foreign Suppliers**

The final rule will be issued on Oct. 31, 2015, and establishes a system for the accreditation of third-party auditors to inspect foreign food producers.

**(6) Sanitary Transportation Rule**

The final rule will be issued on March 31, 2016, and establishes new sanitary standards and practices for transporting food.

**(7) Intentional Adulteration Rule**

The final rule will be issued on May 31, 2016, and requires facilities to develop a food defense plan to prevent actions intended to cause public harm.

Armstrong Teasdale's Agriculture Food and Health Group will be providing follow-up alerts regarding each of the above rules as they are released.