

Update to the Food Safety Modernization Act

Richard S. Sellers¹

American Feed Industry Association

The President signed the Food Safety Modernization Act (FSMA) into law on January 4, 2011. The 115-page law provides a host of new authorities for the U.S. Food and Drug Administration (FDA) not seen since the creation of the FDA in the federal Food, Drug and Cosmetic Act of 1938.

The centerpiece of the new law is Section 418: Hazard Analysis and Risk-Based Preventive Controls, which requires domestic food and feed facilities that manufacture, process, pack, or hold food or feed products to perform a hazard analysis at each facility for hazards that are “reasonably foreseen,” prepare adequate controls to “significantly minimize or prevent the occurrence” of each, monitor performance, and routinely maintain records. Facilities must maintain such records for at least 2 years.

FDA proposed 2 rounds of regulations for feed, food, produce and imported products to implement this new law. Facilities making products for export to the U.S. are required to comply with the same provision. Facilities that import products must assure that the foreign facilities have developed hazard analyses and written risk-based preventive controls. This can be accomplished by direct inspection of the foreign facilities or the use of FDA-accredited third party entities that can certify compliance with the new law.

FSMA provides FDA with authorities to revoke facility registrations, thereby halting operations at these plants. FSMA also grants FDA mandatory recall and administrative detention authorities under specific conditions or causes.

Implementation of the Safe Food Transportation Act of 1990 is required by FSMA, and FDA must promulgate rules within 18 months enactment of FSMA.

Congress is unlikely to fully fund the requirements of this new law (a budget request of \$300 million), including hiring 4,000 new field staff; 600 or more foreign facility inspections annually and the development of performance standards for affected industry, which are the tolerances/guidance levels for contaminants, among many other requirements.

The cost of preventive control regulations for the feed industry is estimated to exceed \$700 million and may cause delay in FSMA rulemaking. The food and feed industry estimates that training and compliance inspections will take 10 years to fully implement the provisions of FSMA. Focus on the final rules is expected to be on Current Good Management Practices (CGMP), which were not in FSMA.

For more information visit: www.fda.gov/food/foodsafety/FMSA.

¹Contact at: 2101 Wilson Blvd., Suite 916, Arlington, VA 22201, (703) 524-0810, Email: rsellers@afia.org.

