

in the news

Food and Agriculture



November 2013

Food Safety Modernization Act Hits the Animal Food Industry

For More Information:

For more information on this area,
please contact:

Kathleen A. Hardee

816.395.0644

khardee@polsinelli.com

On October 29, 2013 (the “Publication Date”), the Food and Drug Administration (“FDA”) published in the Federal Register its latest set of proposed regulations implementing the Food Safety Modernization Act (“FSMA”)¹. The current proposed regulations will apply to the animal food industry, including food for livestock, pets, raw materials and ingredients therewith. Animal food companies must act quickly to provide comment to the FDA if they hope to have input into the final rules with which they will be required to comply. Additionally, the proposed requirements of these rules may require significant in-house changes to how animal food companies do business.

As with the previous proposed regulations under the FSMA, the FDA is once again decidedly focused on preventative efforts. The FSMA was signed into law on January 4, 2011, and it is the most comprehensive effort to reform U.S. food-safety and security laws in more than seventy years. Brought on by an increase in outbreaks of food-borne illnesses, the FSMA puts the federal government in a proactive stance rather than its typical reactive one. The federal government’s focus has now shifted from responding to food contamination crises to affirmatively taking proactive action to prevent them.

¹ <https://www.federalregister.gov/articles/2013/10/29/2013-25126/current-good-manufacturing-practice-and-hazard-analysis-and-risk-based-preventive-controls-for-food>



The FSMA itself is simply a detailed outline of goals. The rules and guidance, which impact what those in the animal food industry will be required to do to satisfy those goals, has been left to the FDA. The FDA has methodically tackled these goals one at a time, conferring with the scientific community and the companies being impacted. The new rules under consideration include:

1. Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food. (Published: 1/16/2013).
2. Produce Safety: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption. (Published: 1/16/2013).
3. Foreign Supplier Verification Program for Importers of Food for Humans and Animals. (Published: 7/26/2013).
4. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications. (Published: 7/26/2013).
5. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. (Published: 10/29/2013).

The new regulations addressing the animal food industry includes primarily on two requirements:

- a. Current Good Manufacturing Practices (CGMPs)— if implemented as drafted, the proposed rule would for the first time establish CGMPs designed specifically for the manufacturing, processing, packaging and holding of animal food.
- b. Food Safety Plan – Every company subject to the FSMA will be required to create and implement a written Food Safety Plan. These safety plans are said to be flexible in that they should be designed to address the risks for a particular company and its products. The safety plan must include a Hazard Analysis and include Risk-Based Preventative Controls.

The Hazard Analysis section of the required Food Safety Plan would impose a duty to analyze any known or reasonably foreseeable hazard for animal food that is manufactured, processed, packaged or held by the company. The analysis must also address risk to both animals consuming the food and to humans handling it.

Based upon the hazards and risks identified, the Food Safety Plan must then create and implement preventative controls. The preventative controls must include a monitoring component, corrective action processes, verifications that the plan is working, and significant recordkeeping requirements. Where there are hazards that may be deemed “reasonably foreseeable,” there must also be a plan for quickly recalling the animal food.

The general public has 120 days after the Publication Date (until 2/26/2014) to submit comments to the FDA. There will also be at least three public meetings to explain the proposed rule and receive additional comments from the public. Following this comment period, the FDA will review the comments it has received from the general public and will ultimately issue a final rule. Upon issuance of the final rule by the FDA, every covered company will have to begin complying with the final issued rule based upon staggered start dates which are designed to give smaller companies additional time to be prepared. ■





Dennis J. Dobbels
Practice Area Chair
Kansas City
816.360.4312
ddobbels@polsinelli.com

Michael A. Williamson
Practice Area Vice-Chair
Kansas City
816.360.4168
mwilliamson@polsinelli.com

Kathleen A. Hardy
Practice Area Vice-Chair
Kansas City
816.395.0644
khardee@polsinelli.com

James R. Asmussen
Chicago
312.873.3697
jasmussen@polsinelli.com

Jonathan G. Brinson
Phoenix
602.650.2305
jbrinson@polsinelli.com

Lauren A. Crawford
Phoenix
602.650.2354
lcrawford@polsinelli.com

James H. Davidson
Washington, D.C.
202.783.3300
j davidson@polsinelli.com

Jeffrey E. Fine
St. Louis
314.552.6824
jfine@polsinelli.com

Troy B. Froderman
Phoenix
602.650.2300
tfroderman@polsinelli.com

Robert S. Goldstein
Denver
720.931.1164
rgoldstein@polsinelli.com

Nicole M. Hamilton
Phoenix
602.650.2315
nhamilton@polsinelli.com

Quentin L. Jennings
Kansas City
816.360.4108
qjennings@polsinelli.com

Paul G. Klug
St. Louis
314.552.6832
pklug@polsinelli.com

Mark. B. Weinheimer
Edwardsville
618.692.2602
mweinheimer@polsinelli.com

Jennifer L. Worstell
Chicago
312.873.3619
jworstell@polsinelli.com

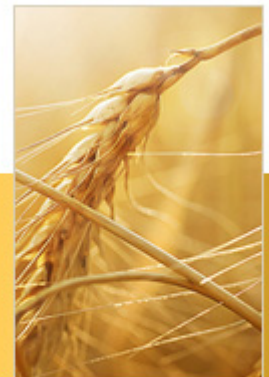
About Polsinelli's Food and Agriculture Group

The food and agricultural industries face both opportunities and challenges. Opportunities from developing intellectual property for new products and processes that create new markets and trademark brands to the expansion of market share through joint ventures; challenges from litigation, regulation and intellectual property theft/misappropriation. Our attorneys help clients develop their opportunities and confront their challenges in a thoughtful and efficient way. A fully integrated, interdisciplinary team combines business acumen with regulatory, litigation and scientific experience to help protect our clients' interests.

We understand the complete picture, from helping our clients' R&D team develop and protect innovative products and processing techniques, to creating and protecting brand recognition and ensuring labeling requirements are met. We also provide risk assessment and litigation support if recall or litigation concerns arise after a product is in the market. We provide a unique perspective that takes into consideration our clients' business plan as well as their legal risks and opportunities in the short and long-term.

We have extensive experience in the following areas:

- Food Products, Additives, and Nutraceuticals
- Food Production and Distribution
- Food Wholesalers
- Animal Feed, Treats, and Supplements
- Natural and Organic Foods





About Polsinelli

real challenges. real answers.SM

Serving corporations, institutions, entrepreneurs, and individuals, our attorneys build enduring relationships by providing legal counsel informed by business insight to help clients achieve their objectives. This commitment to understanding our clients' businesses has helped us become the fastest growing law firm in the U.S. for the past five years, according to the leading legal business and law firm publication, The American Lawyer. Our more than 680 attorneys in 17 cities work with clients nationally to address the challenges of their roles in health care, financial services, real estate, life sciences and technology, energy and business litigation.

The firm can be found online at www.polsinelli.com. Polsinelli PC. In California, Polsinelli LLP.

About this Publication

If you know of anyone who you believe would like to receive our e-mail updates, or if you would like to be removed from our e-distribution list, please contact Kim Auther via e-mail at KAuther@polsinelli.com.

Polsinelli provides this material for informational purposes only. The material provided herein is general and is not intended to be legal advice. Nothing herein should be relied upon or used without consulting a lawyer to consider your specific circumstances, possible changes to applicable laws, rules and regulations and other legal issues. Receipt of this material does not establish an attorney-client relationship.

Polsinelli is very proud of the results we obtain for our clients, but you should know that past results do not guarantee future results; that every case is different and must be judged on its own merits; and that the choice of a lawyer is an important decision and should not be based solely upon advertisements.

Polsinelli PC. In California, Polsinelli LLP.

