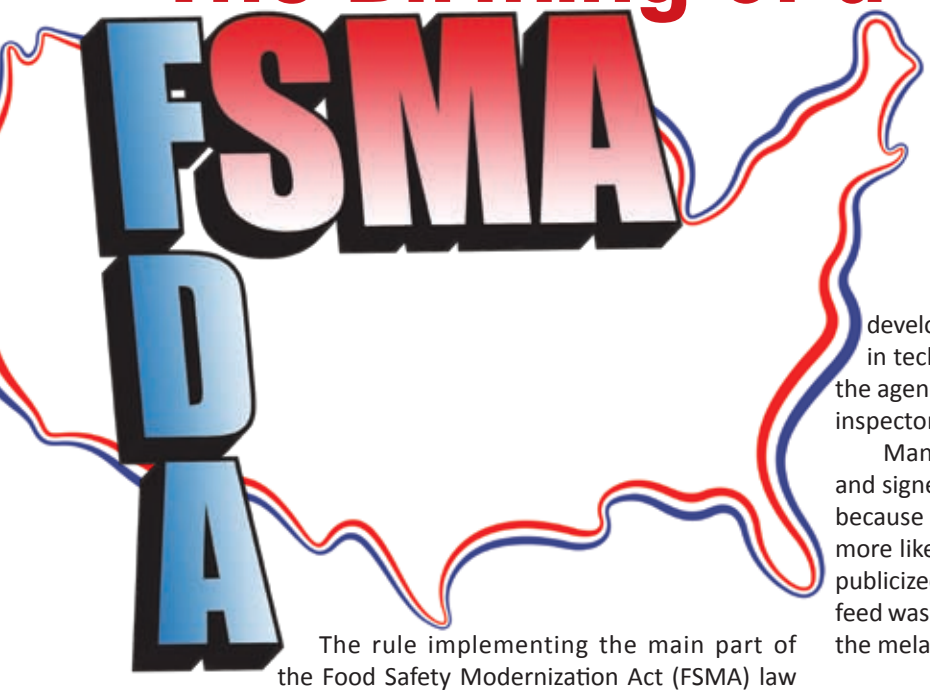
The Birthing of a Giant Rule



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The rule implementing the main part of the Food Safety Modernization Act (FSMA) law affecting renderers, titled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals," is now final and compliance dates for some operations will begin in September 2016. The National Renderers Association (NRA) will analyze this rule in detail and provide information to its members to ensure compliance while it also works with the Food and Drug Administration (FDA) on developing guidance and learns more about how details will be interpreted by the agency.

In the weeks following the deadline for this article, NRA will be working with animal feed and pet food allies to determine how FDA intends to move forward on each FSMA requirement. NRA will discuss concerns and questions with FDA and communicate back to its members. The NRA Feed Regulation Committee has been engaged throughout the development of the association's positions and responses to FDA proposals. NRA plans to present a detailed report on this final rule at the committee meeting during its convention on October 21, 2015.

Note that FDA's regulation refers to "animal food," which indicates it applies to pet food as well as livestock feed. The rendering industry has traditionally used the term "feed" when referring to diets for livestock and poultry, but will use the term animal food throughout this article since it is about FDA's regulation. NRA will not attempt to change the traditional usage of the word feed in most other venues.

Background

The new law includes the most significant changes to food safety laws in over 70 years. FSMA authorizes FDA to promulgate new rules for preventive controls, develop performance standards, and create new administrative detention rules. FSMA also provides FDA authority for mandatory recall of adulterated products and the hiring of more than 4,000 new inspectors. NRA commends the agency for engaging industry in a transparent and collaborative process throughout the development of this rule. NRA has been intimately involved in technical responses to FDA proposals and also assisted the agency in developing training programs and guidance for inspectors and industry.

Many believe that FSMA, passed by Congress in 2010 and signed into law on January 4, 2011, was pushed through because of the "great melamine pet food recall of 2007." It is more likely that FSMA was written because of several highly publicized human food contaminations and recalls, but animal feed was certainly included in the human food law because of the melamine contamination.

Impact on Rendering

The rendering industry is bound to have an easier transition to this new era of FSMA regulation than other feed industry sectors because of responsible responses to past challenges. *Salmonella* education and testing programs dating back over 30 years and high compliance to bovine spongiform encephalopathy feed regulations put in place over 10 years ago give renderers a solid foundation to smoothly comply with this new regulation. Many of the thousands of feed mills and ingredient manufacturers now covered by the new rule have never experienced an FDA inspection and will have to learn many procedures renderers have already implemented. To our colleagues in some of these other animal feed sectors, welcome to our world!

Early Analysis of the Final Rule

Early analysis of the final rule shows no big surprises. The good news is that FDA listened to most of the industry's important comments. The animal feed manufacturing industry asked for a phased compliance schedule, allowing for an extra year to develop preventive controls. This was granted, although the extra year is not much of a benefit to renderers who are already in the habit of implementing good manufacturing practices (GMPs) and process controls (namely cooking) as part of the *North American Rendering Industry Code of Practice*. In the final rule, NRA received a key positive response to its comments on the proposed rule – environmental and product testing will not be required carte blanche, but only when appropriate (such as for pet food).

NRA was also successful in getting a provision removed that would have required pathogen testing in raw materials, something that obviously made no sense in rendering since raw materials are destined for thorough cooking. NRA joined many other industries to oppose requirements for facilities to send records and food safety plans to FDA. We were successful here since FDA will now only review records when

on-site in the course of an authorized inspection and will have the right to copy records as necessary and appropriate as in an animal food recall investigation. FDA had proposed that electronic records must be kept in accordance with 21 *Code of Federal Regulations* Part 11, but NRA and others had commented that this requirement would be burdensome and costly while unnecessary to achieve FSMA goals. FDA changed the final regulation to require only that "facilities should take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper," rather than requiring adherence to Part 11.

FDA received more than 2,400 comments on the proposed FSMA rule and the final rule shows the rendering industry fared well in the agency's responses to comments. Some commenters called for more rigid restrictions on raw materials, more required environmental and product testing, less flexibility in compliance, and many other impractical requirements that would have hindered commerce. It is a testament to NRA's cooperative relationship with FDA and the credibility of its technical comments to them that these anti-business interests did not have more impact on the final regulations.

Rather than prematurely comment on all the details that were included in the final rule before each section is carefully analyzed, this article will provide some historical perspective and examine the "big picture" impacts of the regulation.

Historical Perspective

It is a natural American political response to a crisis – such as hundreds of dogs and cats dying unexpectedly from the melamine contamination – to pass a law to prevent it from happening again. The fear of the unknown led to pressure to legislate and regulate. The FSMA law and associated regulations are well-intentioned, developed in collaboration with industry, and will be reasonable for renderers to comply with. They will also foster an overall manufacturing environment that will prevent most hazards. Yet, there is no way to know or predict all hazards. Industry will prevent, mitigate, and reverse all known and foreseeable hazards as required by FSMA, but the public is likely to be disappointed when something unknowable or unforeseen happens in animal food so more legislative action can be expected in the future if a new hazard arises from an unexpected source.

In the real world, ahead of Congress and public pressure, industry and regulators have been collaborating a long time on the very concepts now required by the new FSMA law. In 2003, FDA introduced the Animal Feed Safety System (AFSS) to address the safety of all animal food at all stages of production and use, filling in gaps of regulation and encouraging industry to be proactive. NRA was involved back then assisting FDA to develop proposed rules for process controls for animal food ingredients that would be practical for industry and effective for food safety goals. This process was underway when FSMA came along, but AFSS provided the foundation for the new regulation. In addition, the Association of American Feed Control Officials (AAFCO) adopted model GMPs for feed and feed ingredients in 2009 after a long incubation period (NRA helped develop these GMPs that had already been implemented in many states). NRA was also involved in a European-based effort, the British Standards Institute's Publicly Available Specification (PAS) 222 – *Certification for Animal Feed Manufacturing*, that was and remains consistent with the rendering *Code of Practice* and FSMA.

The *Code of Practice* was formally adopted by NRA in 2004 and the first rendering plants were certified in 2005. All of the related background work with FDA, AAFCO, PAS 222, and the American Feed Industry Association's Safe Feed/Safe Food audit program have informed and improved the *Code of Practice* over the past 11 years. Since January 2015, rendering plants can certify in both the Safe Feed/Safe Food and rendering *Code of Practice* with a single third-party audit aimed principally at the necessary components to comply with FSMA. The rendering industry has reasons for optimism:

- Renderers have a long-standing commitment to address animal feed safety.
- Renderers have worked closely with regulators and other industries for many years.
- Renderers are well prepared to comply with new FSMA regulations.
- Participation in the rendering *Code of Practice* will ensure compliance and provide the structure to meet the new FSMA rule requirements.

The Birth of FSMA Regulation Timeline

- Melamine in pet food (2007), *Salmonella* in peanut butter (2009)
- Consumer awareness and concern ebbs and flows
- Pressure to legislate on politicians and bureaucrats from activists and the public
- Legislation passed (2010), NRA comments to FDA
- FDA proposes its animal food safety rule (2013), NRA comments to FDA
- FDA re-proposes its animal food safety rule (2014), NRA comments to FDA
- FDA finalizes its animal food safety rule (2015), NRA and other industries assist FDA in practical interpretation and inspector training

FSMA's Big Questions for Renderers

- Do you have an animal food safety plan for your operation?
- Are your employees trained to do their job and do they understand the importance of hygiene for animal food safety?
- What are the animal food safety hazards in your plant?
- Which of these hazards require a preventive control?
- What is your process to control these "significant" hazards?
- How do you know this process is effective (validation)?
- Do you make corrections in your process when needed?
- How do you know your process was properly completed (verification)?
- Where is your documentation for all of this (records)?
- Do you implement current GMPs throughout your plant?
- Do you have a recall plan in case something goes wrong?

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- Do your suppliers and customers understand which hazards (if any) they are responsible for?

Compliance Dates

Rendering operations with more than 500 full-time equivalent employees must have current GMPs in place by September 17, 2016, and preventive controls in place by September 17, 2017. For renderers with fewer than 500 full-time equivalent employees, current GMPs must be in place by September 17, 2017, and preventive controls will have to be in place by September 17, 2018. Renderers qualifying as "very small businesses," averaging less than $2.5 million in revenue per year, will have one additional year – current GMPs in place by September 17, 2018, and preventive controls in place by September 17, 2019. However, the paperwork to prove the small business exemption and the requirements still in effect for these exempt firms seem more complicated than simply complying with the FSMA rule. Something to remember about compliance dates is that if a plant supplies a large animal feed manufacturer or a large pet food manufacturer, these customers will have the earlier compliance dates and will likely require their suppliers to meet the same standards even if it is not yet required by law. This is yet another reason all renderers are encouraged to participate in the rendering *Code of Practice* by September 2016 if not already doing so.

What is NRA Doing to Help?

Most of what FSMA requires FDA inspectors to examine in the future are factors that must be analyzed, observed, and measured in a plant. While the rendering *Code of Practice* will guide renderers through most of this, one very important piece – data to validate the rendering cooking process – will be provided by the Fats and Proteins Research Foundation. The foundation has funded several studies to collect data proving that cooking is effective at mitigating risks from microbiological hazards, providing very specific data on time and temperature required to kill pathogens in raw materials such as animal tissues, poultry offal, and rendered fats. These studies will lead to published scientific journal articles that can be referenced to show FDA that rendering cookers are an appropriate preventive control for microbiological hazards. Scientific publishing takes time, so NRA plans to publish a white paper summarizing and presenting this validation data for members to use so each plant does not have to do its own validation research.

Fundamental to a preventive system is FDA changing from the traditional inspection model where it tries to find something wrong to one focused on whether firms are implementing systems that effectively prevent food contamination. This is a fundamentally different approach to food safety inspection and compliance that is encouraging for industry, but also raises some skepticism about how quickly FDA can change its culture. However, the agency intends to give this change in culture a serious effort. FDA plans to deploy specialized investigators, backed up by technical experts, to assess the soundness and performance of a facility's food safety system. Such a knowledgeable team should help minimize different interpretations between industry and inspectors. FDA emphasizes training for industry as essential for this transition whereas industry emphasizes training for inspectors. In spite of different opinions over who needs the most training emphasis, NRA is working together with FDA to produce a standardized training curriculum available to both industry and inspectors.

More information can be obtained on FDA's FSMA website at www.fda.gov/Food/GuidanceRegulation/FSMA/. **R**