

Training in Preparation for FSMA Compliance

On September 17, 2015, the Food Safety Modernization Act (FSMA) final rule, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, was published in the *Federal Register*. The National Renderers Association (NRA) continues to work with the Food and Drug Administration (FDA) on interpretation and implementation of this rule. Of the seven sets of new FSMA rules, this one is most important to renderers. Below are some important facts renderers need to know.

FSMA was signed into law on January 4, 2011, and provides FDA with sweeping new authorities and requirements. It authorizes FDA to promulgate new rules for preventive controls, develop performance standards, and create new administrative detention rules. It also provides FDA authority for mandatory recall of adulterated products and the hiring of more than 4,000 new field staff, among other provisions. However, Congress is reticent to provide sufficient funding to fully implement the law due to a tight federal budget. All renderers will need to comply and FDA scrutiny on rendering that began with bovine spongiform encephalopathy 15 years ago will continue even if agency funding is not as much as requested.

FSMA Compliance Dates

To accommodate the feed manufacturing industry that is already familiar with good manufacturing practices but not preventive controls, FDA is phasing in the rule stepwise giving an extra year to implement preventive controls. However, this compliance schedule does not make sense for renderers because their main operation, cooking, is a preventive control and is already in place. With the industry's obligations to produce safe animal food ingredients along with customer expectations, renderers should make every effort to comply with both good manufacturing practices and preventive controls requirements by September 18, 2017, for most renderers (with fewer than 500 employees) and by September 18, 2016, for large firms (with more than 500 employees) (see

table 1). Renderers may want to comply as early as possible as a good business decision to serve customers, such as some pet food companies, with early compliance dates.

NRA believes the best way for renderers to prepare for FSMA compliance is to certify facilities in the *North American Rendering Industry Code of Practice* and/or the American Feed Industry Association's Safe Feed/Safe Food program. Both can be done now with the same audit. The *Code of Practice* now includes all main points covered by FSMA after a January 2015 update. Prior to that, it contained about 80 percent of what FSMA requires, with emphasis on records and documentation as the main missing element.

FSMA requires that each operation have a "preventive controls qualified individual" (PCQI) in place for compliance. The PCQI is defined as "a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by [FDA], or is otherwise qualified through job experience to develop and apply a food safety system." According to the regulation, a PCQI would need to be in place once a facility is in compliance with 21 *Code of Federal Regulations* (CFR) Part 507, Subpart C as detailed in table 1, with the earliest date being for large firms (more than 500 employees across the company) on September 18, 2016. However, the PCQI is responsible for preparation of the facility's animal food safety plan so it is very likely a facility will need to have a PCQI in place before the facility's legal compliance date in order to properly prepare the animal food safety plan.

Title 21 CFR Part 507.53(c)(1) states the PCQI does not need to be an employee of the facility and could be a team of individuals. Each firm will need to review the requirements for the PCQI and determine if they can be met by PCQI(s) not located at the facility. Section 507.53 details the requirements applicable to the PCQI and in part states "one or more preventive controls qualified individuals must..." therefore implying that it can be more than one individual.

| Business size | Compliance date for Subpart B and related requirements (Current Good Manufacturing Practices) | Compliance date for Subpart C and 21 CFR 507.7 (Preventive Controls) |
|---|--|---|
| Business other than small and very small | September 19, 2016 | September 18, 2017 |
| Small business (a business, including any subsidiaries and affiliates, employing fewer than 500 full-time equivalent employees) | September 18, 2017 | September 17, 2018 |
| Very small business (a business, including any subsidiaries and affiliates, averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale [e.g., held for a fee or supplied to a farm without sale]). | September 17, 2018 | September 17, 2019, except for records to support its status as a very small business (January 1, 2017) |

A person can be a PCQI by training or experience. The preamble to the final rule states, "It is the responsibility of the owner, operator, or agent in charge of the facility to determine whether any individual who prepares (or oversees the preparation of) the food safety plan has appropriate qualifications to do so, whether by on-the-job experience or by training." Having the PCQI go through a standardized curriculum now being developed by the Food Safety Preventive Controls Alliance (FSPCA) is one method to determine if the PCQI is qualified. NRA is among the industry representatives assisting FSPCA to prepare this curriculum that will be used to train FDA inspectors. FSPCA is scheduled to finalize the training curriculum for animal food before June 2016. NRA will use the same curriculum in its *Code of Practice* and FSMA training for association members this June. A similar educational program for the *Code of Practice* will be offered online by NRA through Kansas State University starting later this summer.

NRA believes most plants already have a PCQI among current employees that are quality and/or regulatory team members due to their experience and training, particularly if plants have previously been certified in the *Code of Practice* or other hazard analysis and critical control point-like programs. However, NRA recommends that one or more employees take the PCQI training even though it is not essential to initially have all PCQIs trained. The individuals could be identified immediately and begin preparing the hazard analysis and animal food safety plan. As part of the curriculum, NRA will be preparing materials to assist association members and their PCQIs in these efforts.

In addition to the PCQI, the regulation defines "qualified individuals," which means virtually all employees in the plant will need minimum awareness that they impact animal food safety. The final rule defines a qualified individual as "a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties.

A qualified individual may be, but is not required to be, an employee of the establishment." Title 21 CFR 507.4 details the applicability and qualifications of all individuals engaged in manufacturing, processing, packing, or holding animal food. NRA is also working on a video for training "qualified individuals" on important food safety and hygiene measures.

Training Opportunities

It is recommended that NRA members have at least one person attend the association's *Code of Practice* and FSMA training in Denver, Colorado, in June and then have multiple employees take the remote online training through Kansas State to complete the food safety team with people familiar with the regulations and compliance expectations. Many consultants, organizations, and even universities will also offer PCQI training for the animal food and human food rules. Any program using the FSPCA "animal" curriculum will be suitable and worthwhile, but NRA will offer the only FSPCA curriculum given by instructors well-versed in rendering and using rendering teaching examples. **R**