Food Safety and Modernization Act: How Will It Affect the Feed Industry?

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Introduction

The Food Safety and Modernization Act (FSMA) was signed into law in January 2011. This law brings a sea change in the Food and Drug Administration's approach to food safety. The bill was introduced and passed by Congress due to the fact that in the US about 48,000,000, or 1 in 6, US citizens suffer from food poisoning annually. Many of these victims are hospitalized and about 3,000 die yearly. Many of these cases will be prevented by a new approach to food safety.

The feed industry is regulated by the Food and Drug Administration (FDA). Often people are under the mistaken notion that the US Department of Agriculture has this responsibility, when in fact USDA has no duties related to feed production in the US.

The regulatory oversight of the feed industry is given to FDA in the Food Drug and Cosmetic Act of 1938 as amended. It states the following:

"..(f) The term "food" means
(1) Articles used for food or drink for man or other animals…"

This simple statement gives FDA the legal authority to write and enforce regulations and rules that determine how the feed industry operates.

FSMA brings sweeping changes to food and feed regulation, which has not been updated for over 70 years. If you are interested, the full text of the law can be found at:

http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm

Depending on its style, the law is about 80 pages of fine print, which takes a while to go through. This includes many deadline dates for various portions to be put into effect. This process requires FDA to write regulations for each of the points in the law. FDA has fallen behind and has failed to meet many of these dates. FDA has released the Rules for Human Foods. These regulations are about 680 pages long. Since this release, FDA has also released the Animal Feed Rules, which as you might imagine are also quite lengthy they are in the area of 450 pages. As initially released the Animal Feed Rules were virtually the same as those for Human Food. This presents quite a problem, due to the fact that feed mills are vastly different from say a sausage

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making plant. The Human Food Rules contain a lot of rules in regard to sanitizing food contact surfaces that are impossible to perform in a feed mill and do not make any sense.

Following release of the Animal Feed Rules, FDA opened a comment period. The American Feed Industry Association (AFIA) as well as the National Grain and Feed Association (NGFA) submitted detailed and lengthy comments. There were also other industry groups that commented, but these two probably had the largest impact. After reviewing the comments, FDA realized that they pretty much had to go back to the drawing board in regard to Animal Feed Rules. FDA did a lot of editing and incorporated many of the suggestions made by industry, thankfully! They then re-released the rules and opened another comment period. AFIA and NGFA again submitted comments. FDA is under a court order, as a result of a lawsuit buy a consumer group to release the Final Rules by August, 2015. At this point we are not sure what they will look like. Nonetheless, they will no doubt be more practical then the first release. The second comment period was closed on December 15, 2014.

Teeth of FSMA

FSMA changes the FDA food safety process from a reactive to a preventative mode. In the past, FDA could only take action after an event had occurred. Now their efforts will be focused on science-based prevention. It should also be mentioned that in the past FDA could not demand a recall, they could only request it, now they can.

Current Good Manufacturing Practices (cGMP)

A major portion of the rules will be based on Current Good Manufacturing Practices (cGMP). cGMP cover a lot of ground. One of the largest is related to employee training. An example of this may include personal hygiene. Are employees provided with a clean sink to wash their hand in prior to entering the feed plant? Have they been trained in the appropriate method to wash hands? Is this training documented? This may sound silly, but many pet food companies and poultry integrators are bringing in Public Health nurses and other personnel to provide this training. When this, or any other training is given, a written record reporting who was there, the date, who did the training must be created. Every person trained, must sign the roster, creating a record of the fact that they did receive the training. The owner/operator of the facility will be expected to be able to produce these records during an FDA inspection. This is just one example of cGMP, but the record keeping requirements are the same for all training. This specific example may or may not be part of the final rule, however it was part of the first release. There are other issues to keep in mind in regard to personal hygiene. Do you have a written policy on clothing and cleanliness? Many feed mill employees are also part time farmers. Do you allow your employees to enter your feed plant with manure on their shoes? Do you require that your employees have a dedicated pair of shoes that they put on when they arrive at work? Do you have a written policy on illness and infections? Have you trained your employees on this policy? Have you documented it? If a person seems to have the flu,

do you allow them to work? Keep in mind that these calls are up to the owner/operator to make and document. FDA enforcement people have said over and over, “If it is not documented, it did not happen”.

As part of cGMP, each plant will no doubt be required to have a written housekeeping plan. Who cleans what and when is it done? What tools are they provided with? The days of using air hoses to blow dust around are probably over even though this may be the only practical method to remove dust from overhead beams etc. Many pet food plants and some broiler integrators have installed central vacuum systems to remove dust. Each time an area is cleaned, the cleaning must be documented. The person doing the cleaning must sign and initial a sheet with the date showing what cleaning was done. Has each person with cleaning responsibility been trained on how to clean those areas of responsibility? Has the training been documented? Has that employee signed off on the training?

This is just a brief overview of cGMP. There are many rules and most likely the vast majority of feed plants are already operating under these rules. Licensed medicated feed plants have had cGMPs for year. Now, all feed plants will be subjected to cGMPs. In my experience in the feed industry for many years, cGMPs are an essential part of making safe and effective feeds.

Hazard Analysis

The major portion of FSMA is based on hazard analysis. There are folks running around telling feed people that they must have a HACCP plan. This is not true. You have to come close though. For those not familiar with HACCP take a look at this website; we do not have time or space to go through it here.

https://en.wikipedia.org/wiki/Hazard_analysis_and_critical_control_points

The most recent proposed rules require the following:

- A written food safety plan;
- Hazard analysis;
- Preventive controls for hazards that are reasonably likely to occur;
- Monitoring;
- Corrective actions;
- Verification; and associated records

The written food safety plan will contain the hazard analysis. In this case the owner/operator will be expected to appoint trained personnel to perform the hazard analysis. Basically, this means that this team will start at the plant gate and review every process throughout the plant until the loaded truck leaves the gate. This will take time and effort. All these activities must be documented. All reasonably foreseeable.

“Hazard means any biological, chemical, physical (including radiological), or physical agent that is reasonably likely to cause illness or injury in animals or humans in the absence of its control.” This quote if from the re-written proposed rule.

http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM417131.pdf

That simple sentence covers a lot of ground. The owner/operator will be expected to identify all potential hazards associated with the feed manufacturing and delivery process. The law itself is not prescriptive. The operator is expected to make all the decisions regarding potential hazards. Of course FDA inspectors may not necessarily agree, however, if documentation and justification is complete, the facility will be on solid ground.

Biological hazards will no doubt include things like rodents an insects. Each plant will need to have a documented pest control program. The rodent bait stations will most likely need to be mapped. A written program will need to be in place that identifies how often the bait stations are checked, what specific chemical is used to control pests, and where it is stored if on site. A similar program will have to be in place for insect control. FDA will probably expect windows and doors to be screened to prevent the entrance of pests. They will expect the building perimeter to be clean and weed free. Most likely these issues will be covered by cGMP.

Preventative Controls

§ 507.36 Preventive controls for hazards that are reasonably likely to occur.

For hazards identified in the hazard analysis as reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur, will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

It is interesting that FDA mentions critical control points. These are points in a HACCP plan that allow influence on the process to be exerted. While a HACCP plan is not required by FSMA, HACCP is not a new concept to FDA. They have had mandated HACCP requirements for seafood and juice for years. The only reason HACCP is not required, according to an FDA official is that the people who wrote the law were not aware of it.

Preventative controls simply are what will be done to prevent bad things from happening. We have identified the hazards, now we must define and document the process to prevent these hazards from occurring. An example of an identified hazard in may feed plants is the unloading pit. What will you do to prevent feed contamination from the pit? Is the pit always kept covered when not in use? Perhaps the unloading

shed has doors that are kept closed when not being used and the overhead is closed off to prevent birds from roosting.

Monitoring

This is pretty simple. Basically, a method including documentation must be prepared that answers the question: Is what I think is happening really happening?

Maybe a plan a developed that the covering on the receiving pit is checked every 4 hours. Then a document is created, with an initial, documenting that this monitoring function is happening on schedule. This function may include about anything that the operator identified as a hazard that can be prevented. Another example might be measuring and recording the temperature of the mash in the conditioner to be sure it matches a specification you have set as a preventative control.

Corrective Actions

§ 507.42 Corrective actions.
(a) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. The corrective active procedures must describe the steps to be taken to ensure:

(1) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;

(2) All affected animal food is evaluated for safety; and

(3) All affected animal food is prevented from entering into commerce if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

In this case, the operator must have a documented plan in place that describes what actions will be taken, should a preventative control fail. For example, should something fall into the receiving pit while unloading, what will be done to prevent feed being manufactured at that time, that may be adulterated according to the FDA definition of adulteration, from leaving the plant. Here is how FDA defines adulterated:

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[1]
(2)

(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a (a) of this title; or

(C) if it is or if it bears or contains
(i) any food additive that is unsafe within the meaning of section 348 of this title; or
(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

Again, this is a very broad definition and it covers lots of issues. So the goal of this program of hazard analysis and preventative controls is to prevent adulteration of feed.

Verification and Records

Finally, the operator must verify that all these efforts are working. Basically this mean that the system must be tested at scheduled and documented intervals. Ways must be found and described as to how the system will be challenged to see if it is working. Again it needs to be pointed out that the law and the rules are not prescriptive. The responsibility to come up with these programs and plans lies with the owner/operator. FDA reserves the right to disagree if they feel an important component has been left out or is address in a non-appropriate fashion.

Conclusion

FSMA brings major changes to how the feed industry will do business going forward. The final Animal Feed Rules will be published in August 2015. FDA released the proposed rules once and the comments were so detailed, and the suggested changes so important, that they basically rewrote the rules and released them again. Following that comment period which ended in December 2014, FDA is performing edits again. They have said they will not open these rules for any further comments. What the final rules look like remains to be seen.

While firms will not be required to have a full blown HACCP plan they will need everything else. Hazard analysis, preventative control, cGMPs and records will be key.

When FDA shows up at your door, you will have 24 hours to produce the requested records. Thus it is critical that these records be organized and that more than one person knows where they are and how to access them. Some of the rules suggest that companies will be responsible for nutrient excesses or deficiencies. This could have a large impact on consultants who own the formulations. If a company is making a feed that a consultant requests and it is deficient in say selenium, it is possible that that consultant will be liable for producing an “adulterated” feed.

Employee training and the appropriate documentation will be critical. If something results in an adulterated feed and FDA can show that the person involved was not trained that company is going to have a problem.

Document everything. Keep the documents organized so that they can be accessed while the FDA inspector is on site.

This is a shallow treatment of FSMA and its impact on the feed industry. If your company has not started implementing FSMA requirements as we know them today, you had better get going. FDA has the legal authority to enforce FSMA already, even though the final rules are not released. It will be incumbent on the industry to stay calm in the face of an FDA inspection by an inspector who may not be well trained. FDA has indicated that it is working hard to train inspectors but they are not sure they have the financial resources to get it done quickly enough. An excellent cGMP program will answer many of the needs of FSMA by elimination of hazards. My advice is be prepared and have great records and a detailed written food safety plan.

National Grain and Feed has a great document available for purchase that will help you get started.

The HACCP Approach To Feed Quality Assurance…What it Entails.
National Grain and Feed Association
1250 Eye Street, N.W., Suite 1003, Washington DC, 20005
Phone: (202) 289-5388

While a HACCP plan is not required, this document will provide lots of help in meeting FSMA requirements without establishing critical control points. In fact critical control points are about the only thing left out of FSMA rules.

Another program is offered by AFIA. They call it SAFE FEED/SAFE FOOD. FDA has indicated that firms that are SF/SF-certified will most likely meet all their FSMA requirements. Information on this program can be found here: http://safefeedsafefood.org/main/home.cfm

This is probably the simplest way to meet FSMA demands.

In addition there are consultants in the industry who will help you get your programs in order.

One last point in regard to enforcement. In that past, FDA has pretty much gone after consent decrees as its enforcement procedure. The FDA Secretary has ordered that FDA now go after direct criminal proceedings against the CEO or whoever is in charge. This can result in jail terms, in fact they have already gotten convictions of several corporate officers as a result of FSMA. This process has a way of getting the guys in charge very interested in FSMA compliance. Arrest and jail time is not precedent setting. Cases like this have gone to the US Supreme Court who have ruled the CEO deserved to go to jail.

SESSION NOTES